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Preliminary Assessment of Health Canada's Pest Management Regulatory Agency (PMRA) Recently Published Amendment to the Proposed Re-evaluation Decision Regarding Chlorothalonil

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Health Canada's Pest Management Regulatory Agency (PMRA) recently published an amendment (REV2016-06) to the proposed re-evaluation decision (PRVD2011-14) regarding chlorothalonil that was first published in 2011.

The proposed amendment is significantly different from the previously published proposed decision and, if adopted, will significantly restrict and in some instances remove certain chlorothalonil uses. As the original registrant of chlorothalonil in Canada, Syngenta Canada Inc. is committed to addressing the questions raised by the PMRA in the recently published amendment document.

There are concerns with a number of the proposed mitigation measures and the amended re-evaluation decision.

Revised Risk Assessment

One of the main areas of concern is the use of a revised occupational and residential risk assessment.

For the operator risk assessment from dermal exposure, a route-specific endpoint of 600 mg/kg based on a 21-day dermal toxicity study was previously used. In the amendment, an oral endpoint of 1.5 mg/kg with 19% dermal absorption was utilized to assess operator risk. This equates to a reduction factor of almost 100 times compared to the 2011 proposed re-evaluation decision. This change in calculation has resulted in many current chlorothalonil uses failing the revised risk assessment.

Syngenta supports the use of a dermal toxicity study to assess operator risk from dermal exposure. The amendment indicates that the existing study, which is of 21 days duration, is not of adequate duration to assess exposure. A study duration of 21 days is in fact representative of Canadian agronomic and production practices (including a single growing season each year compared to other jurisdictions, for example) and is consistent with the approach used to assess other currently registered fungicides.

If, however, an oral endpoint is to be used for operator risk assessment from dermal exposure, as is proposed, a more realistic dermal absorption of < 1% should be applied, and would result in the maintenance of many of the current uses. Regarding the assessment of dermal absorption, the literature references cited are 35-plus years old and would benefit from a review of more recent advances regarding the assessment of dermal penetration.

Reliance on Outdated Agronomic Practices

Another concern is the fact that the amended risk assessment relies on a number of agronomic practices that are either not accurate and/or no longer in use, leading to inappropriate conclusions related to the use of chlorothalonil and operator exposure. Some examples of these include:

- Cranberry – the risk assessment does not recognize that transplanting activity occurs once, at crop establishment, before chlorothalonil is applied
- Low bush blueberries – the risk assessment does not recognize that chlorothalonil is only applied in the vegetative season
- Potato – the risk assessment does not recognize that roguing is not a practice that is used anymore
- Note: there are many other crop-specific examples.

Critical Role in Sustainable Disease Management

Chlorothalonil is also widely recognized for its important contributions to sustainable pest management. As noted by the PMRA in the proposed re-evaluation decision (PRVD2011-14) that was first published in 2011: "Chlorothalonil remains a key fungicide for sustainable pest management and Integrated Pest Management on several important crops and diseases. To date there are no recorded incidences of resistance, despite a long history of use against high risk diseases, due to its multi-site mode of action. When used in rotation, chlorothalonil helps manage the development of fungicide resistance to many older, as well as newer lower risk fungicides." As one of only a few multi-site fungicides registered for use in a broad range of crops and applications, chlorothalonil plays a pivotal role in both integrated pest management and fungicide resistance management.

Competitive Disadvantage for Canadian Growers

Finally, it must also be recognized that in the event that the amended proposed re-evaluation decision were to be implemented, another significant impact would be the competitive disadvantage imposed on Canadian growers. Specifically, growers in the United States would be able to continue with certain chlorothalonil uses that would no

longer be available to Canadian growers and continue to export their products to Canada, putting Canadian growers at a clear disadvantage in the North American marketplace.

Syngenta Position

Syngenta is working hard to address the questions raised by the PMRA in the recently published amendment to the proposed re-evaluation decision regarding chlorothalonil. With a history of safe use that dates back more than 45 years, we stand behind and remain confident in the science and product safety behind Syngenta products containing chlorothalonil. Chlorothalonil protects more than 65 crops against 125 diseases and is registered around the world as a critical disease-management tool.

We are continuing our assessment and will be responding to the Amendment to the Proposed Re-evaluation Decision during the public consultation period (which is open until April 11, 2016) and encourage you to do the same. If you have any questions about the information contained in this document, you may contact Tanya Tocheva, Director, Regulatory Affairs, Syngenta Canada Inc. (519-837-5329; tanya.tocheva@syngenta.com).