
Pest Management Regulatory Agency

Information Note

26 April 2006

Lindane

From the 1930s to December 31, 2004, lindane was used in Canadian agriculture as a seed or soil treatment to protect crops such as canola/rapeseed, barley, corn, wheat and other small grains.

In March 1999, Health Canada's Pest Management Regulatory Agency (PMRA) announced that agricultural products containing lindane would be reviewed. As a signatory of an international agreement aiming at restricting or eliminating persistent organic pollutants (POPs) such as lindane, Canada was committed to conduct a reassessment of all uses of lindane. POPs are toxic substances that resist degradation, bioaccumulate and are transported through air, water and migratory species across international boundaries. They deposit and accumulate in terrestrial and aquatic ecosystems. Given their potential for long-range transport, POPs are of concern for Aboriginal and northern populations who show evidence of exposure to high levels of POPs through their diet.

Much of the special review was conducted in collaboration with the United States Environmental Protection Agency. The PMRA completed its assessment of occupational risk in October 2001. The use of lindane was phased out on the basis of unacceptable risk to the health of workers exposed to lindane during seed treatment and planting. All registrants of lindane seed treatment products, except Crompton Corporation, chose to voluntarily discontinue sales of their products.

As is their right under section 23 of the Pest Control Products Regulations, Crompton Corporation requested a hearing by a Board to review the PMRA decision with respect to its lindane products. The Board, consisting of three independent scientists, reviewed the scientific information on which the decision was based as well as more recent information not available at the time of the original decision. On August 18, 2005, the Board submitted a report of its findings and recommendations to the Minister of Health and Crompton Corporation. More information on the Board of Review and their report are available on the [PMRA website](#).



Engagement of Registrants

In the report, the Board noted a lack of communication and clarity on behalf of both the PMRA and Crompton Corporation during the decision-making process. In particular, the Board felt that interested parties were not given adequate opportunity to offer new or additional data or research to the PMRA that could impact the risk assessment. The Board recommended that the Minister of Health direct the PMRA to reinstate a discussion with Crompton Corporation in an effort to consider potential measures that could mitigate the PMRA's health concerns associated with the use of lindane.

The PMRA acknowledges that at the time lindane was re-evaluated, it was practice to allow for a short consultation period with the registrant at the end of the assessment. The PMRA's re-evaluation process has since been revised and now includes a longer opportunity for dialogue with registrants and other stakeholders throughout the process consistent with the recommendations of the Board.

To address the issues raised by the Board in the case of lindane, the PMRA is initiating communications with all affected former registrants of lindane products and other interested parties, as appropriate, to seek input into the risk assessments and to explore possible measures that address health-related concerns for workers.

Occupational Risk Assessment

Occupational risk is estimated by comparing potential exposure with endpoints from the most relevant toxicology studies.

The Board felt that the outcome of the workers' risk assessment for lindane was affected by consideration of outdated labels, limited exposure data and a conservative approach taken by the PMRA with respect to the assessment of the toxicity of lindane.

During the special review of lindane, the PMRA conducted a workers' risk assessment based on data available at the time. As recommended by the Board, the PMRA is initiating a follow-up review of the occupational exposure assessment of lindane. In this review, the PMRA will take into consideration, as appropriate, the new exposure study generated by Crompton Corporation as well as opinions expressed by the Board and other information presented at the hearings. In addition, the PMRA will reconsider the original toxicology data and any supporting data relevant to the combined risk due to exposure through the skin and inhalation.

In all its toxicological assessments, the PMRA applies internal guidelines related to the use of uncertainty factors to account for differences in toxicological responses between test animals and humans as well as differences within the human population. Factors are also considered in the PMRA assessments to account for data deficiencies, severity of endpoint and concern for vulnerable populations (e.g., infants, children and pregnant women). The PMRA is currently reviewing its policy regarding the use of uncertainty factors in risk assessment. This process will



include public and stakeholder consultation. Should the outcome of the consultations result in changes to the current policy, the PMRA may consider adjusting the uncertainty factors applied to lindane accordingly.

Completion of the Re-evaluation of Lindane

A pest control product can be registered only if the health and environmental risks and value are acceptable. To ensure that the risk management decision on the use of lindane products is made with a clear understanding of all the risks, the PMRA is completing the special review of lindane. This includes completing the human health risk assessment of areas not addressed in the previous evaluation (e.g., carcinogenicity) as well as finalizing the environmental risk assessment in collaboration with Environment Canada and the United States Environmental Protection Agency.

The completion of the follow-up review of lindane data is expected by the end of 2006. A summary of the assessments and the conclusions on the acceptability of lindane uses will be published for public comment at the end of the follow-up review.

Need More Information?

The following links on the PMRA website provide further information on the topics discussed in this document.

Special Review Announcement SRA99-01, *Special Review of Pest Control Products Containing Lindane*

www.pmra-arla.gc.ca/english/pdf/sra/sra9901-e.pdf

Special Review Announcement REV2002-02, *Update on the Special Review of Lindane and the Status of Lindane Registrations*

www.pmra-arla.gc.ca/english/pdf/rev/rev2002-02-e.pdf

Lindane Board of Review—general information, procedures and report

www.pmra-arla.gc.ca/english/lindane/lindane-e.html

