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Information Note: Health Canada Releases Final Re-evaluation Decision on 2,4-D

Canada 



May 16, 2008

The Health Canada Pest Management Regulatory Agency (PMRA), the federal body responsible for the regulation of pesticides in Canada, has concluded its re-evaluation of (2,4-dichlorophenoxy)acetic acid [2,4-D]. Health Canada has determined that 2,4-D meets Canada's strict health and safety standards, and as such can continue to be sold and used in Canada.

Health Canada reviewed 2,4-D as part of the re-evaluation program that determines if the pesticides currently on the market and registered before January 1, 1995, meet modern health and environmental standards.

The decision on 2,4-D is consistent with that of regulators in other Organisation for Economic Co-operation and Development countries, including the United States, New Zealand and countries of the European Union, as well as the World Health Organization.

As a result of the re-evaluation, all products containing the diethanolamine (DEA) form of 2,4-D and products for aquatic uses are being phased out because the risks exceed current health and environmental standards or there was a lack of adequate data for assessment.

Health Canada understands that the public may have concerns over the use of pesticides and would like to convey that all registered pesticides undergo a thorough science-based risk assessment and must meet strict health and environmental standards before being approved for use in Canada.

About the Re-evaluation of 2,4-D

Health Canada reviewed the extensive body of information available for 2,4-D, which included the following:

- **An extensive proprietary database.** Manufacturers of the 2,4-D ingredient provided Health Canada with a database comprised of over 100 toxicity tests in animals. In addition to mammalian toxicity studies, numerous other studies on chemistry, exposure, environmental fate, environmental toxicity and efficacy were also provided.
- **Published scientific information.** These include reports, epidemiological studies and all other relevant scientific information published in scientific journals and other publicly available documentation.
- **Foreign reviews.** Health Canada reviewed the scientific assessments of 2,4-D from the United States, the European Union, New Zealand and the World Health Organization.
- **Use pattern information collected by Health Canada.** Health Canada collected and examined all available information from a variety of sources in order to properly characterize the use pattern of 2,4-D in Canada.

The re-evaluation included a science-based risk assessment to determine if the product can be used safely. Health Canada's re-evaluation included the following:



- a health assessment that looked at the potential for 2,4-D to cause adverse health effects such as cancer, birth defects and endocrine disruption
- a human health risk assessment that took into consideration potential human exposure levels through ingestion/diet, drinking water, skin contact and inhalation in order to determine what amount of 2,4-D is acceptable for use, with particular consideration given to sensitive population groups such as children and nursing mothers
- an environmental risk assessment that considered risks to non-target plants, birds, animals, aquatic organisms, and persistence in the environment
- an assessment of value as it relates to the efficacy of the product

Part of the human health assessment is to ensure that when 2,4-D is used according to label directions, there is a large enough margin of safety between the level of exposure humans could be exposed to and any identified toxic effect during animal testing. Health Canada's assessment included the addition of extra safety factors to ensure that the most sensitive population groups, such as children and pregnant women, were also protected. Health Canada also took into consideration the unique physiology, behaviours and play habits of children, such as lower body weight and hand-to-mouth contact while playing on treated grass.

In addition to the 2,4-D-specific animal toxicity data, Health Canada considered the large body of epidemiological studies and reviews pertaining to 2,4-D and human health. The extensive body of scientific information examined included relevant data used by non-regulatory groups, such as the Ontario College of Family Physicians in its April 2004 report. While that report focussed on a subset of epidemiology studies from the public literature, Health Canada reviewed the extensive body of information available for 2,4-D to conduct a full human health risk assessment. The examination of animal toxicity data from internationally accepted guideline studies using doses well above those to which humans are typically exposed, combined with exposure data obtained from well designed studies, is currently the best methodology available for assessing risks to human health.

Health Canada also consulted an independent Science Advisory Panel comprised of government and university experts/researchers in toxicology, epidemiology and biology. The Panel agreed with Health Canada's assessment that 2,4-D can be used safely when used according to label directions, with some uses requiring additional protective measures.

2,4-D Re-evaluation Documents

Re-evaluation Decision RVD2008-11, *Re-evaluation Decision (2,4-Dichlorophenoxy)acetic Acid [2,4-D]*, describes the final stage of Health Canada's re-evaluation of 2,4-D and summarizes the decision and the reasons for it. This decision is consistent with the proposed re-evaluation decisions stated in PACR2005-01, PACR2007-06 and REV2006-11.

Proposed Acceptability for Continuing Registration document PACR2007-06, *Re-evaluation of the Agricultural, Forestry, Aquatic and Industrial Site Uses of (2,4-Dichlorophenoxy)acetic Acid [2,4-D]*, proposes continued registration of 2,4-D for agricultural, forestry and industrial site uses. It also proposes the phase-out of DEA (diethanolamine) forms of 2,4-D, revisions to product labels to better protect workers and maximum application rates and frequency.



Re-evaluation Note REV2006-11, *Lawn and Turf Uses of (2,4-Dichlorophenoxy)acetic Acid [2,4-D]: Interim Measures*, contains a summary of the comments received in response to the consultation on lawn and turf uses, and Health Canada's responses to those comments.

Proposed Acceptability for Continuing Registration document PACR2005-01, *Re-evaluation of the Lawn and Turf Uses of (2,4-Dichlorophenoxyacetic Acid [2,4-D]*, proposes that 2,4-D is acceptable for continued use on lawns and turf, soliciting comments from interested parties on this proposed regulatory decision.

Need More Information?

Visit the following links on the Health Canada PMRA website to read more:

- [Questions and Answers about 2,4-D](#)
- [Information on the Re-evaluation of Pesticides Program](#)