

Health Canada - Pest Management Regulatory Agency

Answers to questions from – Grain Growers of Canada

1. Does Health Canada assess every ingredient that goes into the pesticide or just the active ingredients?

Evaluators do assess all components – active ingredients and formulators. Toxicity studies are conducted on the technical grade active ingredient, however, there is also a specific toxicity data set on the formulated end-products.

2. Can manufacturers withhold information about what ingredients are in their products?

No. Chemistry requirements for registration of a product under the PCPA are very specific. This information is required to meet two main objectives: i) to identify and quantify the active ingredient(s) for purposes of the pest control product's certified limits; and ii) to comprehensively characterize product composition, including active ingredient(s), impurities and formulators.

3. Aren't children more susceptible to negative effects from lawn pesticides, given their developing bodies and the way their play patterns put them in higher contact with chemical residues?

Health Canada conducts specific risk assessments for sensitive sub-populations including children and pregnant women, taking their unique physiological characteristics into account. The unique physiology, behaviours and play-habits of children, such as their body weight and hand-to-mouth contact while playing on treated grass are considered when determining how much exposure they could encounter. Extra safety factors are applied when warranted to protect sensitive subgroups that include infants and children.

The PMRA applies the risk assessment methods formalized in the *Pest Control Products Act* in its reviews of new and older chemicals. These modern risk assessment methods include an aggregate assessment that takes into account overall exposure to a pesticide from all sources (including food, water and residential uses) and exposure routes (oral, dermal, inhalation).

4. How valid are animal studies for predicting the effects these products will have on human being?

The PMRA examines toxicity data from a number of different mammalian species, including mice, rats, rabbits and dogs, to assess cross-species similarities and differences as well as species sensitivity. Studies examine short- and long-term effects as well as the potential for a chemical to induce birth defects or reproductive effects and to cause

cancer. These studies are conducted at doses many times higher than what humans are exposed to in order to understand the toxicity profile for a given chemical. Typically, the most sensitive animal species is used as the indicator species for human toxicity and health risk assessment, unless there are sufficient data to indicate another species is more appropriate. The PMRA also assumes that humans are more sensitive to effects of a chemical than the most sensitive animal species.

The difference between the human exposure level and the no effect level from animal studies is referred to as the margin of exposure / safety margin. As a minimum, this value must be a hundred times below the no effect level that has been determined from animal test data. However, this value is often several hundred times to greater than a thousand times less than the no effect level. Part of the human health assessment for a pesticide is to ensure that there is a large enough safety margin between the level to which humans are exposed and any identified toxic effect during animal testing. If the level of human exposure is hundreds or thousands of times less than the no effect level observed in animal testing, then the criteria used to define “acceptable risk” has been met.

5. Why doesn't PMRA take a precautionary approach on pesticides?

Science is the basis of all Health Canada regulatory decisions for pesticides. This scientific approach has a strong reliance on a comprehensive body of scientific evidence and scientific methods that examine both hazard and exposure. The approval system for pesticides uses a precautionary approach that provides a stringent standard of protection to human health and the environment. Before a pesticide is allowed to be used or sold in Canada, it must undergo a rigorous scientific assessment process which provides reasonable certainty that no harm will occur when pesticides are used according to label directions. Risks are acceptable if, on the basis of extensive scientific data, it has been determined that there is reasonable certainty that no harm to human health, future generations or the environment will result when the pesticide is used as directed. If the level of human exposure is hundreds or thousands of times less than the no effect level observed in animal testing, the criteria used to define “acceptable risk” has been met. This standard of acceptability applies to the pre-market evaluation of pesticides proposed for registration as well as the re-evaluation of registered pesticides for continued registration. This precautionary approach provides a significantly higher level of protection from risk of harm than does the approach of acting only to address threats of “serious or irreversible damage”.

6. Has PMRA reviewed the Ontario College of Family Physician's report on pesticides and, if so, what actions did PMRA take as a result?

Scientists within the PMRA and elsewhere have carefully reviewed the Ontario College of Family Physicians report. This report examined a subset of epidemiology studies from the public literature and reported associations between pesticides and certain cancers. It is important to be aware of the concerns that have been raised in the scientific community, particularly with respect to how this literature study was conducted. The report did not

consider all of the relevant epidemiology evidence, which has led to many questions in interpretation.

Epidemiology studies are typically designed to look for associations, not causation. These studies must be examined in conjunction with well conducted toxicity studies, which are specifically designed to elicit toxic effects over a series of dose levels. 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's PMRA undertakes this kind of assessment to supplement information about associations that may be reported in epidemiology studies.

In a response to Ontario College of Family Physicians' report, the PMRA released an Information Note stating that Canadians can and should seek opportunities to minimise their exposure to and to reduce their reliance on pesticides. Responsible pest management, which is strongly promoted by the PMRA, is consistent with recommendations of the College's report. If Canadians choose to use pesticides, they should use products only for their intended and registered use. It is important to read the label on a pesticide carefully, as it contains specific information on using the product safely.

7. Why does Health Canada continue to approve chemical pesticides when there are so many safer alternative products that exist?

A pesticide (chemical or non-conventional) can only be registered or remain registered for use in Canada if any associated risks to health or the environment have been determined to be acceptable. Risks are acceptable if, on the basis of extensive scientific data, it has been determined that there is reasonable certainty that no harm to human health, future generations or the environment will result when the pesticide is used as directed.

One of Health Canada's goals is to minimize the risk that pesticides may pose to Canadians and their environment by encouraging the development and use of sustainable pest management strategies and providing easier access to new and innovative pesticides.

8. Some groups indicate that there is a "growing body of evidence suggesting a connection between pesticides and cancer". What is Health Canada doing about this?

Health Canada's Pest Management Regulatory Agency is responsible for administering the *Pest Control Products Act (PCPA)* on behalf of the Minister of Health. Before a pesticide is allowed to be used or sold in Canada, it must undergo a rigorous scientific assessment process which provides reasonable certainty that no harm, including chronic effects such as cancer, will occur when pesticides are used according to label directions. Under this pre-market approval process, results from more than 200 types of scientific studies must be submitted to determine if the pesticide would cause any negative effects to people, animals, birds, insects, plants, as well as on the soil and in the water. This

assessment takes into consideration sensitive sub-groups, such as pregnant and nursing women, infants, children and seniors.

Additionally, scientists with the PMRA review the scientific literature for studies which reference pesticides. The PMRA recognizes the importance of epidemiology studies in risk assessment. The most useful and relevant epidemiological studies are those that properly characterize exposure in the specific context of how the product is used. Thus, reliance on epidemiology studies in regulatory decision making is challenging in the absence of a direct measure of exposure. Epidemiological studies tend to make use of surrogate or indirect measures for pesticide exposure (e.g., area treated, amount used, amount purchased), which can lead to unreliable estimates of the risk.

Epidemiology studies that identify possible associations must be examined with well conducted toxicity studies that are specifically designed to elicit toxic effects over a series of dose levels. These animal toxicity data are assessed to determine if there is any biological basis for the potential associations noted in epidemiology studies. 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 a useful methodology available for assessing risks to human health. Health Canada's PMRA undertakes this kind of assessment to supplement information about associations that may be established by epidemiology studies. This approach is consistent with that of other regulatory authorities that base human health risk assessments on animal toxicity data.

9. Also according to these groups, eight active ingredients commonly used on lawns and gardens targeted for reevaluation have not been completed and point to a 2003 CESD audit. When will these be completed and how safe are Canadians in the meantime?

The eight active ingredients which were identified as those most commonly used on lawns and gardens have been addressed under the re-evaluation program (2,4-D, mecoprop, dicamba, MCPA, chlorpyrifos, malathion, diazinon, and carbaryl).

10. One advocacy group has repeatedly stated that, "*studies have found that people who work with pesticides as part of their job are at higher risk than the average person of developing non-Hodgkin lymphoma and leukemia as well as prostate, kidney, brain and lung cancers*". Has Health Canada been made aware of these studies? If so, what conclusions were drawn?

It's not possible to address this question without knowing the exact study being referred to. However, scientists with the PMRA do review the public literature when assessing the scientific database for a pest control product. This literature is monitored and findings are included in pesticide assessments when applicable.