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# Questions and Answers - Final Decision on the Re-evaluation of 2,4-D

Following extensive consultation and scientific review using the most current scientific methods, the Health Canada Pest Management Regulatory Agency (PMRA) has determined that 2,4-D meets Canada's strict health and safety standards, and as such is acceptable for continued registration in Canada.

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

Health Canada is aware of public concern regarding domestic uses of pesticides on lawns and gardens (often referred to as "cosmetic" or aesthetic uses). The following questions and answers on the re-evaluation decision of 2,4-D and pesticide regulation in Canada have been developed to help clarify concerns on the safety of pesticide use.

If you have any further questions regarding the 2,4-D re-evaluation decision, or about any other pesticide issue, please contact Health Canada's <u>Pest Management Information Service</u>.

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### About the re-evaluation of 2,4-D

### Why did Health Canada re-evaluate 2,4-D specifically?

As part of our normal process, Health Canada is currently conducting a reevaluation of all pesticides registered before January 1, 1995 to ensure they meet modern health and safety standards. As scientific knowledge evolves and new information becomes available, Health Canada requires that registered pesticides be re-evaluated according to modern risk assessment approaches. (See <u>Re-evaluation Information Note</u> for further details).

Similar re-evaluation programs exist in other countries within the Organisation for Economic Co-operation and Development (OECD), such as the United States and those of the European Union.

### How did Health Canada conclude that 2,4-D can be used safely?

Health Canada has recently completed an in depth re-evaluation of all uses of 2,4-D. The re-evaluation was based on all available information which included an extensive proprietary database, published scientific information including epidemiology and toxicity studies, foreign reviews, and use pattern information collected by Health Canada. (See <u>2,4-D</u> <u>Information Note</u> for further definition of types of information assessed).

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 PMRA's assessment that 2,4-D can be used safely when used according to label directions, with some uses requiring additional protective measures.

Health Canada's re-evaluation included:

- 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 which took into consideration potential human exposure levels through ingestion/dietary, 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 subpopulations 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; and
- an assessment of value as it relates to the efficacy of the product.

To assess the safety of children and any potential 2,4-D exposure, Health Canada also took into consideration the unique physiology, behaviours and play-habits of children, such as their body weight and hand-to-mouth contact while playing on treated grass.

What additional protective measures have been determined by Health Canada as a result of the re-evaluation?

- Buffer zones are required for liquid commercial class products that are applied by tractor-pulled field sprayers (<u>e.g. (for example</u>), to golf courses or sod farms), in order to protect adjacent non-target vegetation.
- Label improvements have been made for increased protection to human health and the environment.
  - Updated label instructions/statements to protect users/applicators and minimize exposure to 2,4-D (<u>e.g. (for example</u>), additional protective equipment, reduced application rates).
  - Updated label instructions/statements to minimize release of 2,4-D into the environment as well as statements to protect sensitive aquatic and terrestrial habitats (e.g. (for example), buffer zones).
- All products containing the diethanolamine (DEA) form of 2,4-D have been phased out as there was a lack of adequate data for assessment.
- Products for aquatic uses are being phased out as the risks exceed current health and environmental standards.

#### What are label improvements?

Label improvement is an ongoing process. Pesticide labels are legal documents that users must comply with in accordance with the Pest Control Products Act. They provide information to the user on the use conditions of a product, use rates and use patterns (<u>i.e. (for example</u>), how,

when and how much of the product is applied). These directions consider the acceptable exposure levels. They also contain many standard statements such as instructions for disposal.

In 1994, a label improvement program was implemented for 2,4-D to reduce both occupational and public exposure. It improved label clarity, consistency and accuracy. The new label directions included commonsense precautions such as wearing long clothing and gloves when applying the product and washing up when application is complete.

### What are the label improvements for 2,4-D turf and lawn uses?

Label improvement recommendations resulting from the re-evaluation:

- Set all label rates to the lowest effective level, as per Health Canada's policy for all pesticides. This further minimizes exposure to the products.
- Provide instructions for both domestic and commercial products to reduce accidental contamination of water and increase the protection of non-target vegetation.

### Could the PMRA please set the record straight on the dioxins in 2,4-D. There are many reports with inconsistent messages.

In the early 1980s, the manufacturing process for 2,4-D was carefully examined in light of the emerging knowledge and concerns regarding 2,3,7,8-TCDD. Modifications were made to reduce the levels of contamination for all dioxins, including 2,3,7,8-TCDD. In 1983, Agriculture Canada's Pesticides Division Memorandum to Registrants R-1-216 established a production limit of "not detectable at 1 <u>ppb (parts per</u> <u>billion)</u>" for 2,3,7,8-TCDD in 2,4-D. Since the 1980s, more sensitive analytical methodologies have been developed and dioxins in 2,4-D can be detected at levels much lower than before. Although 2,3,7,8-TCDD or other dioxins of concern may be present at levels below the production limit, this level is so low that they would not be detected above background levels following use of 2,4-D products. As noted in Health Canada's *It's Your Health* publication on dioxins and furans (2004), the greatest sources of dioxins in the environment include the incineration of medical and municipal waste, the burning of fuel and wood, electrical power generation and tobacco smoke.

### Is 2,4-D Agent Orange?

No, 2,4-D is not Agent Orange. Agent Orange was a product made for the United States military and was never registered in Canada. Although its exact chemical composition is not known, 2,4-D was a component of Agent Orange, along with TCDD-contaminated 2,4,5-T. TCDD is a dioxin that has been shown to cause cancer, and 2,4,5-T is no longer on the market. With the refined manufacturing processes that have been required by federal regulatory bodies over the years, dioxin contamination of 2,4-D is not considered to be a concern to health or the environment.

## Physician groups say 2,4-D can cause cancer in children. How can Health Canada say it can be used safely?

No other international regulatory body considers 2,4-D to be a human carcinogen. Based on all available and relevant data, Health Canada agrees with this position.

When re-evaluating a pesticide, Health Canada has access to the available scientific information on that product including an extensive database of toxicology studies, epidemiology studies, and numerous other scientific reports. No other non-regulatory group or organisation carries out this

detailed level of review to determine if a product can be used safely when used according to label directions. Health Canada determines allowable uses, doses and other label instructions for each pesticide product.

For 2,4-D, Health Canada examined the epidemiology literature, some of which suggested weak associations to adverse health effects, while others suggested no link to the use of 2,4-D. The Agency also reviewed the extensive database of toxicology information that specifically looked for the potential to cause adverse effects such as cancer.

An Ontario Family Physicians Report published in April of 2004 recommended that the public limit their exposure to pesticides wherever possible by seeking alternative pest control methods, and, if using pesticides, by educating themselves on their safe handling, mixing, storage and application. As the report notes, children are more susceptible to pesticides due to their behaviour and unique physiological characteristics.

Health Canada conducts specific risk assessments for sensitive subpopulations including children, and takes their unique physiological characteristics and behaviour into account. The potential effects of single, multiple, or life-time exposure to a pesticide are also considered.

Health Canada found that 2,4-D does not increase the risk of cancer and can be used safely by homeowners, provided label directions are followed.

### A study in Québec found traces of pesticides in the urine of children. Was 2,4-D one of them?

Health Canada reviewed the study conducted by the Institut national de santé publique du Québec and found that the detected levels of phenoxy herbicide (2,4-D) were well below levels of concern.

It is normal to find the presence of a trace amount of a pesticide or other environmental contaminant in tissues or fluids when an individual has been exposed to it. However, exposure does not mean there will be a negative health effect, particularly if the levels are very small.

#### Does 2,4-D cause cancer in dogs if they walk on treated lawns?

Based on re-examination of the data, various scientists and workgroups have concluded that there is no relationship between 2,4-D use and canine malignant lymphoma (CML).

Although a 1991 article by the National Cancer Institute (NCI) indicated a link between dogs with CML and dog-owners that applied 2,4-D to their lawn, a 1991-1992 independent panel concluded that the NCI study design was severely flawed and, in fact, did not show an association between CML and 2,4-D use. In 1999, scientists at Michigan State University re-examined the NCI data and also concluded that there was no relationship between 2,4-D use and CML.

## Should I be concerned about exposure to 2,4-D from track-in of residues into my home?

No. A risk assessment conducted for adults and children exposed to 2,4-D as a result of playing on recently treated turf, considered the combined oral and dermal exposure and indicated no unacceptable risks. Since the levels of 2,4-D that have been measured in house dust are much lower than the concentrations on soil and turf, for which no concern was identified, the potential exposure from 2,4-D residues inside the home is not a cause for concern.

### Should I be concerned about exposure to 2,4-D from spray drift?

No. Risk assessments conducted for individuals applying 2,4-D to residential turf indicated no unacceptable risks. Available data suggest that spray drift exposure to bystanders near the application area would be at least 100 to 1,000 times less than the exposure to applicators for whom health and safety factors have already been considered.

### How long does 2,4-D stay present in the environment?

2,4-D is not considered to be persistent on turf. Studies from both industry and independent sources show that 2,4-D residues on turf decline quickly with little detection after 24 hours.

### **Consideration of Canadians' Health**

## How are the health risks from pesticide use assessed, including risks to children?

Pesticides are stringently regulated in Canada. Before a product is registered for use, it must undergo a comprehensive and rigorous scientific assessment, including the results of epidemiology and toxicity studies. If the assessment does not indicate that a product can be used safely, it is not registered for use in Canada. Pesticides undergoing re-evaluation must meet that same standards.

The human health risk assessment looks for the short- and long-term potential of a pesticide to cause adverse health effects such as cancer, birth defects and endocrine disruption. A broad range of toxicity studies are examined, which must be conducted following strict methodologies. Dose levels that cause an effect in laboratory animals as well as the dose where no effect is observed are noted. The dose where there is no effect is then compared to levels that people may be exposed to, in order to determine how far apart these numbers are - the larger the difference (<u>i.e.</u> (for <u>example</u>), the farther apart the numbers are), the better in terms of ensuring that risk is minimal.

All sources and routes (oral, dermal, inhalation) of potential exposure are assessed, including exposure from the diet and drinking water and from contact with treated areas like lawns and gardens. As well, occupational exposures, both during and after pesticide application, are considered.

Because some population groups may be more susceptible to potential effects of pesticides, the assessment ensures that the most sensitive subpopulations, like children and pregnant women, are protected. Special attention is also given to the unique exposures and physiological characteristics of children, ensuring that factors such as their unique behaviors, different diets and lower body weights are considered.

Pesticides are only registered if there is a wide enough margin of safety between what people are exposed to and the dose that causes no effects according to scientific research. Normally this margin is 100 to 1,000-fold. When a registered product is used according to label directions and when good hygiene practices are followed, exposure will usually be minimal and pose no risk.

### How does the PMRA identify the hazards and evaluate the health risk associated with 2,4-D?

In order to identify the potential hazards of a chemical, it is tested at dose levels that are many times higher than the level to which humans would be exposed, and testing is done over both short and long term durations and via different routes of exposure (e.g. (for example), dietary vs. (versis) dermal [skin] exposure). Although a given chemical may be toxic at high doses, lower doses are less toxic. Part of the risk assessment is to apply safety factors so that under conditions of normal use, there is a sufficient margin of safety (typically a 100-1,000 fold difference) between the potential exposure levels to humans and any toxic effect noted in laboratory tests. Additionally, as part of the assessment of a pesticide, the effects of a single, multiple, or life-time exposure are examined.

When a registered product is used according to label directions and when good hygiene practices are followed, exposure will usually be minimal and pose no risk.

### Where can I find more information on Health Canada's health risk assessment?

You can consult the "<u>About PMRA</u>" and the "<u>Product Application</u>" sections of the Health Canada PMRA website for a more detailed account of the health risk assessment.

The <u>Children's Health Priorities</u> within the Pest Management Regulatory Agency Science Policy Notice details the Agency's commitment to protecting children's health.

Finally, the <u>Decision Framework for Risk Assessment and Risk Management</u> in the Pest Management Regulatory Agency Science Policy Notice provides further details on the decision making process at Health Canada.

### 2,4-D decisions in other countries

How do the United States Environmental Protection Agency (US EPA) and Health Canada re-evaluations compare?

The approach and outcome of Health Canada and the US EPA assessments are similar.

In June 2005, the EPA completed its re-evaluation on turf and non-turf uses and determined that 2,4-D is acceptable for continued use. Details on their assessment can be found in the US EPA document

For more information, see the "<u>Reregistration Eligibility Decision for 2,4-D</u> (PDF Version - 956.47 K)".

### How does Health Canada's re-evaluation assessment compare with that of other countries?

Our review concurs with the findings of regulators in other OECD countries, including the European Union, New Zealand, and the Word Health Organization.

### General questions about pesticides

## What is the review status of the other commonly used lawn-care pesticides?

On September 27, 2000, Health Canada announced the priority reevaluation of the eight most commonly available lawn pesticides, as part of its Action Plan on Urban Use of Pesticides. 2,4-D was one of these. This reevaluation uses modern scientific standards to determine their continued acceptability for registration, and whether any changes need to be made to the conditions of registration of these chemicals.

#### Chlorpyrifos

Re-evaluation of lawn and turf uses of chlorpyrifos has been completed. All Domestic Class products, with the exception of containerized lowconcentration ant baits), and all Commercial Class products with claims for uses in and around residences and other areas where children may be exposed, were phased out in 2001.

#### Diazinon

Re-evaluation of dizainon for lawn and turf uses has been completed, and this product has been phased out.

#### Malathion

Through voluntary action by the registrant, both indoor and residential broadcast turf uses of malathion have been discontinued.

#### Racemic mecoprop

The racemic mixture products have been phased out. The reformulated products with the related chemical isomer mecoprop-p has been registered.

#### Dicamba

Lawn and turf uses were proposed as acceptable in February 2007, and a final decision for all uses is pending.

#### МСРА

Lawn and turf uses were proposed as acceptable in April 2006, and a final decision for all uses is pending.

#### Carbaryl

Re-evaluation of lawn and turf uses is proceeding at the same time as other uses; reviews are underway.

# Some provinces and municipalities are looking at banning pesticides. How can they do this when the federal government allows them to be on the market?

Pesticides must be registered before they can be imported, manufactured, sold or used in Canada. Health Canada is responsible for administering the *Pest Control Products Act* (PCPA) on behalf of the Minister of Health. Registration under the PCPA requires a thorough scientific evaluation to determine that new pesticides are acceptable for a specific use, and that registered pesticides remain acceptable for use, once on the market. If Canadians choose to use pesticides, they can only use a pesticide registered by the federal government for the pests and treatment areas listed on the label, and use them according to the label directions.

Provinces, territories and municipalities can impose restrictions such as pesticide bans, however they are not required to base their decision on science. (See: <u>Cosmetic Bans and the Roles of the Three Levels of</u> <u>Governments</u>)

## What should homeowners do if they're concerned about pesticide use?

Health Canada suggests that Canadians become informed about the pest they wish to control and explore all the options available to them. Prevention is key. "Pest Notes" are available that provide information on how to deal with common household pests.

If you decide you need to use a pesticide, make sure you use a registered product and that you read and follow the label directions. The label tells you how to use a product safely. Do not use a pesticide to control a pest that is not listed on the label. Always use pesticides for their intended purposes. To prevent accidental poisonings, ensure that pesticides or any other household chemicals are stored safely out of reach of children and pets, and are appropriately labeled.

## Are there any alternative pest control methods or products for use on my lawn?

Pest prevention is key. One of Health Canada's programs is to promote Integrated Pest Management (IPM) practices that include a variety of methods to effectively control pests and prevent lawn and garden infestations.

Health Canada also publishes a list of Pest Notes which provide useful tips on how to effectively control common household pests.

### More information on 2,4-D:

### What is 2,4-D?

2,4-D is a selective systemic phenoxy herbicide that mimics the plant growth regulator indole-3-acetic acid (also known as auxin). As a result of re-evaluation, 2,4-D has been determined to be acceptable for the control of broadleaf weeds, weedy trees and brush. Use is permitted on fine turf, forests and woodlots (conifer release and forest site preparation), terrestrial feed and feed crops, and industrial non-food sites (noncropland). The different forms of 2,4-D (acid, amine salts and esters) are formulated as emulsifiable concentrate/emulsion, solution, suspension, soluble or wettable granules, granules and pellets. Products containing 2,4-D can be applied by ground equipment or by air.

#### When was 2,4-D first registered?

2,4-D was first registered in 1946.

### What is the difference between commercial and domestic class pest control products?

All pest control products are classified for their intended use.

**Domestic Class** products are sold for consumer use in and around the home. The intent of domestic classification is to provide consumers with products for use as insect and rodent control within the home, weed

control in lawns and gardens, and swimming pool disinfection, that can be used safely.

**Commercial Class** products are sold for general use in the specific commercial activities listed on the label. The intent of commercial classification is to provide operators of commercial pest control operations, such as lawn care service providers, with products that can be used safely and efficaciously in their particular business.

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