

Background: NAFTA Settlement Agreement with Quebec

A number of interpretations of the NAFTA Settlement Agreement between Canada and Dow AgroSciences have been circulated in the public domain. In most instances, non-governmental organizations have reached conclusions which do not benefit from a full understanding of the federal regulatory process, the consideration of 2,4-D by Quebec during the 2002/03 period and the findings of provincial officials at that time.

The foundation of the NAFTA Settlement Agreement is the agreement by the Government of Quebec that 2,4-D does not present a human health risk. Section 3 a) of the settlement agreement states:

"... the Government of Quebec agrees that products containing 2,4-D do not pose an unacceptable risk to human health or the environment, provided that the instructions on their label are followed, as concluded by Health Canada's Pest Management Regulatory Agency ("PMRA") in its May 16, 2008, decision on the re-evaluation of 2,4-D."

The agreement with Health Canada's regulatory decision – which considered the human carcinogenicity potential of 2,4-D in five separate reviews – by the Government of Quebec is of paramount importance. Furthermore, Quebec acknowledged in the 2002/03 period that the IARC classification of chlorophenoxy herbicides did not support a conclusion that 2,4-D presented a human carcinogenicity risk.

Application of the Precautionary Principle:

Canada has a very strict set of laws controlling the availability and use of pesticides. The *Pest Control Products Act* (PCPA) establishes a robust federal regulatory regime designed to scientifically assess the safety, value and merit of pesticides prior to their availability on the market. Section 2(2) of the *Pest Control Products Act* establishes the threshold for acceptable risk as:

"For the purposes of this Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from the exposure to or use of the product taking into account its conditions or proposed conditions of registration."

Section 4.1 of the *Act* goes on to provide more clarity and detail of considerations to make when conducting a risk assessment:

"For greater certainty, protection and consideration afforded to children in this Act shall also extend to future generations."

“The Minister may cancel or amend the registration of a pest control product if...(b) in the course of re-evaluation or special review, the Minister has reasonable grounds to believe that the cancellation or amendment is necessary to deal with a situation that endangers human health or safety or the environment, taking into account the precautionary principle...”

Given the above understanding, it is therefore unambiguously clear that Health Canada takes into account precautionary principles, as established in the federal *Pest Control Products Act*. The ability of municipalities to enact additional restrictions on the use of pesticides is dependent on provincial municipal related legislation. Adding additional use restrictions by a municipal government on the basis of “the precautionary principle” is not valid given the statutory requirement of Health Canada to conduct the re-evaluation of 2,4-D on the basis of precaution, as per Section 20.1(b) of the *Act*.

Consideration of the IARC Classification by Quebec:

On July 3, 2002, the Quebec Minister of the Environment released a proposed *Pesticides Management Code* (the “Code”) and the accompanying Schedule I, a list of potential prohibited active ingredients. Based on Environment Quebec’s initial interpretation of the International Agency for Research on Cancer (“IARC”) Group 2B (possible carcinogens) classification of chlorophenoxy herbicides, the herbicide 2,4-D, among others, was included on this list.

On March 5, 2003, Quebec announced that it was adopting the Code, and the accompanying Schedule I. At that time, a revised “Methodology for Establishing the List of Prohibited Active Ingredients (Schedule I)” was issued, dated March 2003.

The new March 2003 background report continued to recognize IARC as the basis for inclusion of the Active Ingredients listed in Schedule I. However, based on Quebec’s recognition of the weakness of this position, the description of its reliance on the IARC review was re-stated as follows:

“In all, the IARC identified 11 of the active ingredients on our list of 38 active ingredients registered for lawn use as possible carcinogens (Group 2B). These are chlorothalonil and chlorophenoxy herbicides which include the various chemical forms of 2,4-D, Mecoprop and MCPA. However, since the IARC list does not classify each active ingredient individually, but rather the entire chemical family of chlorophenoxy herbicides, and since epidemiological and clinical studies on each active ingredient taken individually are not sufficient to assess the carcinogenicity potential to man, it is preferable to wait for the reassessment of these active ingredients in order to classify them individually. In fact, it is currently difficult to justify scientifically the introduction of these active ingredients taken individually, on the basis of this criterion. Given the doubt that persists, they are maintained on the list pending the outcome of the reassessments in progress.”

70
 years
 of and
 RESEARCH
 DISCOVERY

In other words, the background report recognized the absence of a scientific basis for including 2,4-D in Schedule I. Instead, Quebec stated that because of the “doubt that persists”, the herbicide would be prohibited pending the outcome of the Health Canada PMRA re-evaluations in progress. This was affirmed in the March 5, 2003 news release announcing the Code:

“Due to the continuing uncertainty about their harmfulness herbicides made up of active ingredients, 2,4-D, MCPA and Mecoprop will continue to be prohibited for precautionary reasons until the availability of the products’ re-evaluation results by recognized organizations.”

Most importantly, in a Memorandum to Cabinet dated February 4, 2003, from then-Environment Minister André Boisclair, the following statement was made:

*“There have been comments to the effect that the various 2,4-D, MCPA and Mecoprop molecules cannot be retained in Schedule I because of the reference used, that of the International Agency for Research on Cancer (IARC) assessed the product family (chlorophenoxy) and not the products individually. **The prohibition cannot be scientifically defended on the basis of the criteria put forward.**” (Emphasis added.)*

All of these statements make clear that the Quebec government recognized the absence of a scientific basis for its inclusion of 2,4-D in Schedule I and that 2,4-D was not classified as a human carcinogen by IARC.

Health Canada’s Consideration of the IARC Classification:

With regard to the IARC classification, in 2005-06 the PMRA considered this matter in conducting the re-evaluation of 2,4-D and concluded:

“The International Agency for Research on Cancer is the only international regulatory organization that has not revisited the issue of 2,4-D in its entirety. More recent re-evaluations by the European Union, the United States Environmental Protection Agency, New Zealand and the World Health Organization do not classify 2,4-D as human carcinogen.”

Over the course of several years, the PMRA thoroughly and rigorously examined the toxicological and epidemiological data pertaining to 2,4-D and determined that 2,4-D does not present risks of concern. In the final PMRA decision document released in May 2008, the agency stated:

- *“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.”*
- *“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.”*


 70
 years
 of and
 RESEARCH
 DISCOVERY

- *"The use of 2,4-D and its end-use products to treat lawns and turf does not entail an unacceptable risk of harm to human health or the environment."*
- *"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 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."*

Notice of Objection:

The May 2008 decision was subsequently challenged by two individuals under Subsection 35(1). Under the PCPA, anyone who believes there is a scientific basis for the reconsideration of a PMRA decision may file a Notice of Objection within 60 days of the publication of the decision. When a Notice of Objection is filed, a team of PMRA scientists, who were not involved in the original decision, is established.

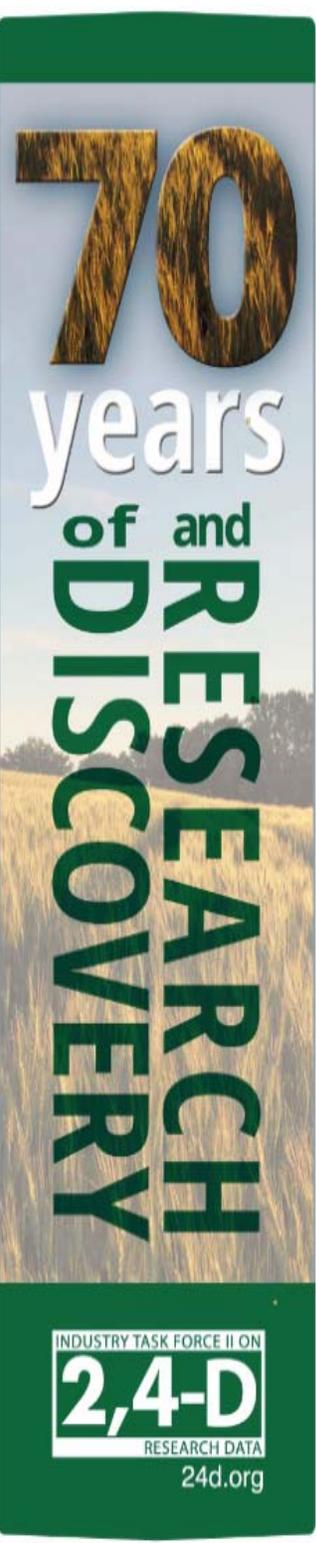
This independent team of experts examines the evidence presented in the objection and determines whether the notice raises scientifically founded doubt as to the validity of the evaluation or re-evaluation. If this team determines that scientifically founded doubt is raised, a Review Panel is convened to reassess the findings of the original evaluation or re-evaluation.

In both cases, after review, the Notices of Objection were not found to raise any scientifically founded doubt in the re-evaluation of 2,4-D. In responding to one objection Health Canada stated:

"The team did not identify any scientifically founded doubt with respect to the validity of the re-evaluation in the information you provided in your objection. As a result this notice of objection does not fulfill the criteria to establish a review panel to reconsider the decision for continued registration of 2,4-D."

It is of particular importance to note that the Canadian Cancer Society did not present any concerns to the PMRA during the Notice of Objection period nor during the public consultation periods in 2005 and 2007.

Since the NAFTA Settlement Agreement was made public on May 25, 2011, the Government of Quebec has changed references to 2,4-D on its website. Notably, all references to the association between human cancer and the use of 2,4-D have been eliminated. As well, Quebec has published the statement:



"The Government of Quebec agrees that products containing 2,4-D do not pose an unacceptable risk to human health or the environment, provided that the instructions on their label are followed, as concluded by Health Canada's Pest Management Regulatory Agency in its May 16, 2008, decision on the re-evaluation of 2,4-D."

Additionally, in Figure 1 below, the Government of Quebec states that there is no carcinogenic potential associated with 2,4-D.

Figure 1
Quebec Website Concerning the Carcinogenicity Potential of 2,4-D
Updated July 26, 2011

The screenshot shows a web browser window displaying a page from the Government of Quebec. The page title is "Gardening ... all naturally" and the subtitle is "Relative toxicity of the main active ingredients contained in Lawns and paved surfaces". A table lists various pesticides and their toxicity levels across four categories: Short-term health risk, Carcinogenic potential, Endocrine system disruptors, and Toxicity to birds. A security warning is visible in the bottom right corner of the browser window.

| Active ingredient | Short-term health risk ² | Carcinogenic potential ³ | Endocrine system disruptors ⁴ | Toxicity to birds ⁵ |
|--------------------------------|-------------------------------------|-------------------------------------|--|--------------------------------|
| INSECTICIDES/ACARICIDES | | | | |
| Borax | ☺☺ | | | |
| Carbaryl | ☺☺ | ☺ | | ☺☺ |
| Dicofol | ☺☺ | ☺ | | ☺☺ |
| Spinosad | ☺☺ | | | |
| FUNGICIDES | | | | |
| Chlorothaloni ⁶ | ☺☺ | ☺ | | ☺☺ |
| HERBICIDES | | | | |
| 2,4-D ⁸ | ☺☺ | | | ☺☺ |
| Acetic acid | ☺☺ | | | |
| Corn gluten meal | ☺☺ | | | |
| Nicotiana | ☺☺ | | | |

Any assertion that the Government of Quebec still considers 2,4-D to be a human carcinogen is not supported by the factual evidence of the case. Furthermore, there is now agreement between Health Canada PMRA and the Government of Quebec that the use of IARC to classify the human carcinogenicity potential of 2,4-D is inappropriate.

The established principles of domestic and international law recognize that measures undertaken by all levels of government in Canada to protect human health must be based on transparent scientific principles. The NAFTA Settlement Agreement is an affirmation of this obligation.

70 years of and RESEARCH DISCOVERY

INDUSTRY TASK FORCE II ON
2,4-D
RESEARCH DATA
24d.org

About the Task Force

The Industry Task Force II on 2,4-D Research Data is organized to provide funding for the on-going Good Laboratory Practice (GLP) research studies required to respond to the US EPA registration review and PMRA pesticide re-evaluation programs. The 2,4-D Task Force is comprised of those companies holding technical 2,4-D registrations: Dow AgroSciences (U.S.), Nufarm, Ltd. (Australia) and Agro-Gor Corp., a U.S. corporation jointly owned by Albaugh, LLC. (U.S.) and PBI-Gordon Corp. (U.S.).

March 17, 2016



70

years

of and

**RESEARCH
DISCOVERY**



INDUSTRY TASK FORCE II ON
2,4-D
RESEARCH DATA
24d.org