

Approval and registration process for pesticides

Petition: No. 141

Issue(s): Human health/environmental health and pesticides

Petitioner(s): Allan S. Taylor

Date Received: 18 April 2005

Status: Completed

Summary: The petitioner is concerned about the registration and approval process for pesticides undertaken by the Pest Management Regulatory Agency within Health Canada. Specifically, the petitioner questions the assessment and approval of 2,4-D and Mecoprop.

Federal Departments Responsible for Reply: [Health Canada](#)

Petition

April 7, 2005

Greetings;

Please accept this email letter as an Environmental Petition. The questions are for Health Canada and specifically for the Pest Management Regulatory Agency (PMRA).

I have been involved in the anti-pesticide movement for years. I have always questioned PMRA's registration process because pesticides are being found around the world, even in our own Canadian Arctic, where pesticides have never been used. Research shows that most, if not all humans, carry a body burden of unwanted pesticides. Even more important the body burden has come about without prior knowledge or consent, and only after they were approved and registered by PMRA. Most disturbing of all is many pesticides, that were approved and registered by PMRA, have now been removed from the market because they have been found to be dangerous to human health and the environment. PMRA is not, and has not, been carrying out it's legislated duty to protect the environment and the public health.

The latest glaring examples are mecoprop and 2,4-D. Mecoprop could not meet new standards of safety because of a lack of data from the pesticide companies. The lack probably existed from the time of approval for registration. Yet PMRA is allowing mecoprop to stay on the market until Dec 31/09. This is an outrageous dereliction of duty to protect. When I brought this information to the attention of Saskatchewan health, environment and agricultural officials, the routine answer I received, a mantra really, was, "PMRA is responsible for registering pesticide products ... and we (the departments) rely on Health Canada's expertise ..."

The second example is the recent examination of 2,4-D. It is the recommendations from this PMRA stacked Committee, that 2,4-D is safe if used as directed, that has prompted me to launch this Environmental Petition with the questions that follow.

I would like answers to the following:

Why did PMRA completely ignore the Precautionary Principle (PP)?

The Supreme Court of Canada, in the Hudson case, referred to international law's precautionary principle, which states, "In order to achieve sustainable development, policies must be based on the PP. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation."

How then is it possible for PMRA to ignore the PP in view of the Supreme Court's ruling and the fact the Government of Canada is a signatory to the Rio Document that required Canada to adhere to the PP?

Why did PMRA appoint [name withheld] to this Committee? [name withheld] is known throughout Canada as an employee and mouthpiece for the pesticide industry. Surely there are many unbiased toxicologists in Canada, not connected to the pesticide industry, that could have been chosen. Why weren't they?

PMRA used risk assessment, a tool that is unscientific and loaded with value judgements, to make it's decision re 2,4-D. Why didn't PMRA use epidemiology, a scientific tool, based on the collection of facts, collects and tracks health data, shuns value judgements and is the back bone of public health practise?

Why did PMRA not collect random, unannounced samples from different 2,4-D production batches for testing?

Why did PMRA allow the pesticide companies to collect and submit their own 2,4-D samples? That is about as unscientific and unreliable as you can get. The regulatee must NEVER be allowed to collect and submit samples to the regulator, if we are to have any confidence in the final results. The conflict of interest is simply too great, for such critical testing of a product, to be accepted.

Why does PMRA only test samples of technical grade 2,4-D?

Why does PMRA not test the product that is actually used in the environment? PMRA knows that up to 90 percent of consumer pesticides are inert ingredients (strange name) because some "inerts" are very active. The point is the PMRA decision is NOT based on the "real world" 2,4-D product sold and used by consumers. The PMRA assessment is akin to testing bottled water samples for health and environmental risks, and finding little, telling us that the risk of harm from bottled water is acceptable, if used as directed. Then the manufacturers of the bottled water add secret inert ingredients. From then on the manufacturers tell us, ad infinitum, that the bottled water is highly regulated by government and the risk, if used as directed, is very low. PMRA's assessment is simply not credible.

How can PMRA justify approving and registering any 2,4-D pesticide product that is not the same as the final product that hits the market?

How is it possible for PMRA to justify allowing Mecoprop to stay in the market place until December 31, 2009 when PMRA now lacks significant data to approve the product?

How did mecoprop get approved in the first place if significant data was missing?

How does PMRA justify allowing this massive, uncontrolled pesticide experiment on Canadians and their environment, without prior consent or knowledge?

Why has PMRA, given their mandate to protect the environment and human health, allowed this massive, uncontrolled, pesticide experiment to continue, still without our prior consent and knowledge?

Thank you for your attention. A reply would be appreciated.

[Original signed by Allan S. Taylor]

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Minister's Response: Health Canada

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September 1, 2005

Mr. Allan S. Taylor
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Dear Mr. Taylor:

Further to my acknowledgement letter of May 18, 2005, and in accordance with the requirements of Section 22 of the *Auditor General Act*, I am pleased to provide you with Health Canada's response to the issues raised and recommendations made in your petition concerning the pesticides 2,4,-D and mecoprop (Petition no. 141).

Thank you for your interest in this matter. I trust this information will prove helpful.

Yours sincerely,

[Original signed by Ujjal Dosanjh, Minister of Health]

Ujjal Dosanjh

Environment Petition No.141: Response to Petitioner

Introduction

The Pest Management Regulatory Agency (PMRA) of Health Canada has the mandate to prevent unacceptable risks to people and the environment from the use of pest control products. Pesticides imported into, sold or used in Canada are regulated by the federal government under the *Pest Control Products Act* (PCPA) and Regulations. The PMRA is responsible for administering this legislation, registering pest control products, re-evaluating registered products and specifying maximum residue limits for pesticides in foods to be established under the *Food and Drugs Act*. The provinces and territories may regulate the sale, use, storage, transportation and disposal of registered pesticides in their jurisdictions as long as the measures they adopt are not less restrictive than those established under the PCPA or other federal legislation.

Pesticides are carefully regulated in Canada through a coordinated federal and provincial regulatory network that delivers a program of pre-market scientific assessment, enforcement, education, and information dissemination. To prevent the use of pesticides from adversely affecting Canadians' health or their environment, the PMRA assesses the human health, environmental risks and value of pest control products prior to their use in Canada. Products are not registered if the PMRA assessments identify unacceptable risks to health or the environment or the applicant fails to demonstrate the value of the product. Once a pesticide has been registered, monitoring and compliance programs, by both the PMRA and the Canadian Food Inspection Agency, promote the proper use of pesticides and the safety of our food supply.

The petitioner's comments and recommendations are indicated below in bold followed by the PMRA's response.

Question 1: Why did PMRA completely ignore the Precautionary Principle (PP)? [in recent re-evaluation decision on 2,4-D]

Question 2: How then is it possible for PMRA to ignore the PP in view of the Supreme Court's ruling and the fact the Government of Canada is a signatory to the Rio Document that required Canada to adhere to the PP?

Response: The PMRA is supportive of the Precautionary Principle. Under both the existing and new PCPA, a pesticide can not be or remain registered for use in Canada unless 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. This standard of acceptability applies to both the pre-market evaluation of pesticides proposed for registration and the re-evaluation of registered pesticides for continued registration. It provides a high level of protection from risk of harm by addressing risks in general, not restricted to threats of "serious or irreversible damage". The PMRA is now considering comments received after publishing the Proposed Acceptability for Continuing Registration document (PACR) 2005-01, before finalizing its decision on 2,4-D.

Question 3: Why did PMRA appoint [name withheld] to this committee? [name withheld] is known throughout Canada as an employee and mouthpiece for the pesticide industry. Surely there are many unbiased toxicologists in Canada, not connected to the pesticide industry, that could have been chosen. Why weren't they?

Response: PMRA's assessment was conducted by some of its 300 highly qualified scientists. External experts were asked to comment on various aspects of PMRA's review in order to provide a broader perspective on the assessment than the usual internal review process. The panel included experts in epidemiology, exposure assessment, human toxicology, and environmental toxicology. [name withheld] input was primarily focussed on PMRA's review of environmental toxicology, while other panel experts concentrated on other aspects of PMRA's review.

[name withheld] is a professor of Environmental Biology, Director of the Centre for Toxicology at the University of Guelph, and author of numerous publications in peer-reviewed, scientific journals.

Question 4: PMRA used risk assessment, a tool that is unscientific and loaded with value judgments, to make it's decision re 2,4-D. Why didn't PMRA use epidemiology, a scientific tool, based on the collection of facts, [that] collects and tracks data, shuns value judgements and is the back bone of public health practise?

Response: When determining the acceptability of a pesticide, PMRA scientists critically examine the totality of the scientific database for pesticide active ingredients and end-use products, including epidemiology studies.

Epidemiology studies have suggested both that there may or may not be associations between adverse health effects and pesticide exposure. Epidemiology studies alone are hard to interpret because of biases and confounding factors that make it very difficult to either establish or definitively rule out links between pesticide exposures and effects. For example, other chemical and physical environment effects are usually encountered at the same time as pesticide exposures, and biases in the exposures remembered by study participants may affect the result. Without an actual exposure calculation, it is difficult to assess whether pesticides could have been responsible for an adverse health outcome.

The PMRA re-evaluation of 2,4-D included an in-depth examination of a broad animal toxicity database and human exposure studies as well as epidemiology

studies. The risk assessment approach used by the PMRA is quantitative and scientific, as it compares the amount of human exposure relative to non-toxic levels in animal tests, to determine if adequate safety margins are present. Please note that epidemiology studies are primarily designed to look for associations, not causation. When associations are noted, the next step is to examine the animal toxicity data to determine if any noted associations can be verified. 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. This approach is used by regulatory authorities worldwide.

Question 5: Why does PMRA not collect random, unannounced samples from different 2,4-D batches for testing.

Question 6: Why did PMRA allow the pesticide companies to collect and submit their own 2,4-D samples?

Response: PMRA would undertake sampling of any pest control product, if there was evidence that there could be concerns and that sampling would be appropriate. That has not been the situation with respect to 2,4-D.

In Canada, as in most other countries, pesticide manufacturers are periodically required to provide results from the analysis of their products conducted by independent laboratories. Any changes in manufacturing methods, or the start-up of a new manufacturing plant triggers requirements for analysis and submission of data. In this way, the registrants bear the cost of product analysis, and regulators have the monitoring data they need. In 1982, Agriculture Canada's Pesticide Division, now PMRA, collected random samples from the marketplace of end-use products containing 2,4-D amine and 2,4-D ester for testing of dioxins, the results of which were compared with data submitted by the registrants. The tested samples did not contain 2,3,7,8-TCDD, the dioxin with known toxicological concerns, above the limit of detection. This concurred with the data submitted by the registrants.

Question 7: Why does PMRA only test samples of technical grade of 2,4-D?

Question 8: Why does PMRA not test the product that is actually used in the environment?

Response: In general, any toxic impurities, if present in an end-use product (EP), are generated in the manufacturing process of the technical grade active ingredient (TGIA). Impurities, if present, would, therefore, be at their highest levels and be most readily detectable in the technical grade product. The processes used to mix the technical product with formulants to manufacture the end-use product do not produce new toxic impurities. The regulation of formulants by the PMRA is described in regulatory directive DIR 2004-01. Therefore, toxicological and environmental studies using the technical is viewed by the PMRA and other OECD countries to adequately represent formulations in most circumstances.

When differences in toxicology are seen amongst formulations of a pesticide, additional data are requested and reviewed.

Question 9: How can PMRA justify approving and registering any 2,4-D pesticide and registering 2,4-D pesticide product that is not the same as the final product that hits the market?

Response: Specific data requirements must be fulfilled before a technical grade active ingredient and each end-use product containing that active ingredient can be registered or re-registered. The data that the PMRA requires to support the registration of a technical grade product and its corresponding end-use product (s) depend on the nature of the product, (e.g., chemicals, microbials), and how the product will be used (use-site). As a guide for determining data requirements, the use-sites are grouped into a series of use-site categories (USCs) under three main sectors: Agriculture and Forestry (14 USCs); Industry (9 USCs) and Society (10 USCs). Each USC has a list of required and conditionally required data called Data-Code (DACO) tables for both the TGAI and the EP. For more information on specific data requirements for TGAI and EPs, Data-Codes (DACOs) and Use-Site Categories (USCs), please visit the PMRA EDDENET website at: <http://www.eddenet.pmra-arla.gc.ca/3.0/3.0.asp>

Countries including Canada, the United States, and other Organisation for Economic Cooperation and Development (OECD) members have harmonized data requirements and study protocols. These protocols were specifically designed by scientists and regulators to produce scientifically valid data. The studies are conducted either by the applicants, or more often by independent third party laboratories, and they must be conducted in compliance with internationally accepted study protocols and Good Laboratory Practice. In addition, they are subject to independent audits to ensure their reliability.

Question 10: How is it possible for PMRA to justify allowing Mecoprop to stay in the market place until December 31, 2009 when PMRA now lacks significant data to approve the product?

Question 11: How did mecoprop get approved in the first place if significant data were missing?

Response: As described in Regulatory Directive (DIR) 2001-03, PMRA Re-evaluation Program, PMRA's re-evaluation assessment includes the most modern data requirements, assessment methodologies, and internationally established protocols used by other OECD countries. In the course of re-evaluation, companies are often requested to provide additional or more modern data for review. If sufficient data are not provided, products are not acceptable for continued registration.

In the case of racemic mecoprop, products were registered prior to 1995, in accordance with data requirements and standards of safety common at the time of registration. The decision to phase-out racemic mecoprop was based on the registrants' decision to not undertake studies to bring the supporting data base up to modern standards. In such cases, the phase-out periods that are established depend on the nature and severity of risk, and consideration of the amount of

product that remains in the distribution chain. As PMRA had not concluded that continued use of racemic mecoprop products in the short-term would pose a risk to users, the public, or the environment, an orderly phase-out of products was implemented. Similar decisions were made by other Organization for Economic Co-operation and Development countries during their transition from racemic mecoprop to mecoprop-p.

As indicated in Re-evaluation Decision Document (RRD) 2004-09, *Mecoprop*, the last date of sale by registrants of end-use products is 31 December 2005. The PMRA expects the last date of retail sale will be December 31, 2006. The last date of permitted use of existing product by consumers is December 31, 2009.

Question 12: How does PMRA justify allowing this massive, uncontrolled pesticide experiment on Canadians and their environment, without prior consent or knowledge?

Question 13: Why has PMRA, given their mandate to protect the environment and human health, allowed this massive, uncontrolled, pesticide experiment to continue, still without our prior consent and knowledge?

Response: Canada's pesticide regulatory system is clearly not uncontrolled. The PMRA assesses the human health and environmental risks of pest control products according to the highest international standards, and according to international protocols, prior to their use in Canada. Our premarket review of all new products in combination with our ongoing re-evaluation of all older products, ensures that human health and the environment are protected from the use of pest control products. For many years now, the PMRA has committed to public consultations on registration decisions. If the PMRA assessments identify unacceptable risks to health or the environment the registrants are denied the registration of their products. Once a pesticide has been registered, monitoring and compliance programs promote the proper use of pesticides.

At any time during the registration period, if a product is found to present an imminent risk of harm, immediate regulatory action would be taken to mitigate concerns which might include cancellation or suspension of the product. The PMRA is continuously monitoring its international partners for developments that may affect the continued acceptability of a pesticide in Canada. Any product that poses an unacceptable risk to Canadians would be acted on immediately. As PMRA had not concluded that continued use of racemic mecoprop products in the short-term would pose a risk to users, the public, or the environment, an orderly phase-out of products was implemented.

While the PMRA is responsible for administering the PCPA, registering pest control products, re-evaluating registered products and specifying maximum residue limits, the provinces and territories may also regulate the sale, use, storage, transportation and disposal of registered pesticides in their jurisdictions. They can do that as long as the measures they adopt are not less restrictive than those established under the PCPA or other federal legislation. The health of Canadians and the environment are well protected from uncontrolled use of any pest control products.

Date Issued: 2005-04-18