Federal re-evaluation of pesticide 2,4-D

Petition: No. 129

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

Petitioner(s): Dr. Kazimiera J. Cottam

Date Received: 17 September 2004

Status: Completed

Summary: This petition concerns Health Canada's Pest Management Regulatory Agency (PMRA) and its re-evaluation of the herbicide 2,4-D. The petitioner alleges that the Agency relies only on industry data to make its regulatory decisions and does not consider peer-reviewed scientific information. The petitioner maintains that the sporadic contamination of 2,4-D with cancer-causing chlorinated dioxins is not reported in industry data. The petitioner requests that the PMRA take into account independent, peer-reviewed scientific literature in its re-evaluation of 2,4-D, and in the evaluation of all pesticides. Finally, the petitioner requests that the PMRA maintain a statistical record of cancer incidence in Canada correlated to pesticide use.

Federal Departments Responsible for Reply: Health Canada

Petition

83-21 Midland Crescent
Ottawa, Ontario K2H 8P6 Canada
Tel.: (613) 726-1596
Fax: (613) 726-3581
e-mail: kjcottam@idirect.com

September 17, 2004

Office of the Auditor General of Canada
Commissioner of the Environment and Sustainable Development
Attention: Petitions
240 Sparks Street
Ottawa, Ontario
K1A 0G6

Re: The Pest Management Regulatory Agency of Health Canada

This is a covering letter to a Petition submitted under the *Auditor General Act.* The intent here is to treat the 80 page submission* on herbicide 2,4-D, dated August 23, 2004 and addressed to the U.S. Environmental Protection Agency (EPA), as a basis of this Petition. Thus, it is essential that this extremely important and informative document, already supplied to the Commissioner of the Environment and Sustainable Development, be attached to the Petition when it is being forwarded to the Honourable Ujjal Dosanjh, Federal Minister of Health.

First of all, I must explain the pertinence of including* the detailed submission to the EPA. Health Canada's Pest Management Regulatory Agency (hereinafter referred to as PMRA) relies extensively on the regulatory decisions of the EPA, its American counterpart, and in recent years both of these regulatory agencies have been perceived to rely exclusively on the self-interested and one-sided industry data as a basic for their regulatory decisions, while ignoring independent peer-reviewed scientific papers, such as have been included with the above-mentioned submission to the EPA. Hence the EPA, and consequently also the PMRA, are both exposing themselves to justifiable criticism that they perceive their primary function as always satisfying the demands of the chemical industry at the cost of not protecting their respective citizens' health.

The spokesmen for Industry Task Force II on 2,4-D Research Data maintain that 2,4-D is free from a significant contamination by the toxic chlorinated dioxins (inadvertently created in the reactor during the manufacture of the product). 2,4-D was developed for military purposes during WWII. It was combined with 2,4,5-T, to form the highly toxic Agent Orange for the purpose of defoliating trees in Vietnam during the Vietnam War. After a terrible industrial accident near Milan, Italy, which took place in 1976, 2,4,5-T was banned. Henceforward the industry has been blaming the banned product for the contamination of Agent Orange with the cancer-causing chlorinated dioxins. However, evidence points to sporadic contamination of 2,4-D as well. See, for instance, "Environmental inspectors find traces of dioxins in over-the-counter pesticides," a pertinent article published in the Globe & Mail on November 10, 2003.

It is noteworthy that there is apparently no other government agency that is as congenial to the private sector, specifically the chemical industry, as is the PMRA, which is indeed a very rare occurrence in government relations with the private sector. The Industry Task Force II on 2,4-D Research Data, which is a powerful and ever vigilant lobby directed by a former Vietnam War veteran, seems fully satisfied with PMRA's performance. Both of these organizations speak with the same voice, as it were, and this is a grave cause for concern.

Yours sincerely,

[Original signed by K. J. Cottam]

Kazimiera J. (Jean) Cottam, PhD
Member, Health Dangers of the Urban Use of Pesticides
Working Group at the City of Ottawa
Member, Beyond Pesticides, Washington, D.C.

PETITION

The Pest Management Regulatory Agency

Attention: Mme Johanne Gélinas
Commissioner of the Environment
and Sustainable Development

September 17, 2004

According to the Report of the Commissioner of the Environment and Sustainable Development (2003), "the Pest Management Regulatory Agency (PMRA) was created in 1995 as a branch of Health Canada" and "has the primary responsibility for regulating pesticides." The Agency's mandate is dual and often incompatible: serving the chemical industry and protecting Canadians' health.

Here is a list of the basic shortcomings in the functioning of this organization:

- The industry supplies the data and product for PMRA's evaluations and evidently for this purpose selects samples with relatively low toxicity;
- The industry reimburses the PMRA for evaluating pesticides. Hence a conflict of interest;
- The process of evaluation is extremely slow and in the case of 2,4-D dates as far back as 1980; meanwhile the exposure to the product affects Canadians' health adversely;
- The PMRA does not consult impartial sources, so as to form unbiased and well-thought out opinions on the toxicity of the chemicals being approved;
- The PMRA may approve a product on the basis of incomplete information (e.g. the case of Merit 0.5 G version of imidacloprid insecticide);
- When the PMRA discontinues licensing a chemical, it does so gradually, over a period of many years (e.g. the old version of mecoprop, a toxic phenoxy herbicide). Meanwhile, the "banned" product continues to affect Canadians' health adversely;
- To my knowledge, the PMRA does not compile cancer statistics and is unaware of the actual impact on Canadians' health of pesticides the PMRA approves.

The PMRA apparently ignores the Swedish experience on 2,4-D use, characterized by reduced rates of cancer both among people and dogs. Conversely, the PMRA is unlikely to consider the experience of East-Central Europe. For example, in Warsaw under Communism there was no separate cancer ward in the children's hospital, as children's cancer was virtually unheard of, despite heavy industrial pollution. Now that Poland has adopted the lifestyle of the West, including increased use of pesticides, there is a cancer ward in the children's hospital in Warsaw.

Recommendations:

- The PMRA should take into account independent peer-reviewed scientific literature on 2,4-D in the course of this Agency's current and long overdue evaluation of this herbicide.
- There is a need for a more balanced approach to the evaluation of pesticides in general, i.e., the Agency should be examining independent peer-reviewed scientific literature on pesticides in addition to evaluating industry submissions;

- There is a need for a re-organization of the entire PMRA with a view to increased efficiency.
- The PMRA should maintain a statistical record of the incidence of cancer in Canada with a view to correlating this data with pesticide use in this country.

We are convinced that if the pesticide approval process was stricter and the Agency erred on the side of caution, the epidemic of some forms of cancer, especially among children, would be substantially reduced. The incidence of developmental problem among children and the number of people afflicted by environmental sensitivities would also be diminished. In the final analysis, a stricter pesticide approval process would likely reduce at least some of the financial pressures afflicting our Medicare and this would result in an accelerated delivery of medical services.

We await, with great interest, the Minister's response to the issues raised. We are particularly interested in his reaction to the recommendations outlined above.

Yours sincerely,

[Original signed by K. J. Cottam]

Kazimiera J. (Jean) Cottam, PhD
83-21 Midland Crescent
Ottawa, ON K2H 8P6
Tel.: 726-1596 / Fax: 726-3581
Email: kjcottam@idirect.com

*[attachment not posted]

Minister's Response: Health Canada

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February 1, 2005

Kazimiera J. Cottam, Ph.D.
83-21 Midland Crescent
Ottawa, Ontario
K2H 8P6

Dear Dr. Cottam:

Further to my acknowledgement letter of October 18, 2004, 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 and recommendations made in your petition concerning the regulation and evaluation of pesticides.

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

Yours sincerely,

[Original signed by Ujjal Dosanjh, Minister of Health]

Ujjal Dosanjh

Environment Petition No.129: 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 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 (CFIA), promote the proper use of pesticides and the safety of our food supply.

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

Comment 1: "The industry supplies the data and product for PMRA's evaluations and evidently for this purpose selects samples with relatively low toxicity"

Response:

Overview

There are quality control measures built into Canada's pesticide regulatory process, to ensure that complete and accurate scientific data packages are submitted for evaluation. Companies are expected to provide the study results, including raw data, for review by PMRA (i.e. The PMRA does not perform toxicological studies using companies' samples). In the case of new pesticides, a pesticide sample is provided for use in PMRA's compliance activities. The PMRA's assessment of the data leads to the product being granted or denied registration. The registration of a pesticide authorizes its importation, sale and use in Canada. Products are never granted registration based on value if they represent an unacceptable risk to health or the environment.

Data requirements

Companies that wish to have the right to sell a pest control product in Canada must submit detailed information and data that are evaluated by the PMRA. Companies must provide all the scientific studies necessary for determining that the product is acceptable in terms of safety, merit and value. The PMRA tells companies what the data requirements are and how the data are to be generated. The data requirements and the internationally established protocols are consistent with those used by other Organisation for Economic Co-operation and Development(OECD) countries. If the applicant does not submit the data required by the PMRA, then the submission will not be evaluated or granted registration.

Data requirements are detailed on the following PMRA website: **http://www.pmra-arla.gc.ca/english/appregis/daco-e.html**

Data Generation

The data to evaluate risks to human health and the environment are generated in accordance with the principles of OECD Good Laboratory Practice (GLP) or another equivalent standard. Under GLP, the data undergo an independent quality assurance process to ensure they are accurate and were generated as per the required protocols. In Canada, only GLP-compliant facilities, as recognized by the Standards Council of Canada, can be used to generate the core data used for pesticide registration. These facilities must be re-certified every two years.

In the United States (US), the Environmental Protection Agency (EPA) has an inspection program in place to ensure that facilities generating data are GLP-compliant. The EPA inspects these facilities when problems are identified with the data. As a majority of the data is generated in the US, the PMRA is dependent on the inspection program in the US to ensure that the GLP requirements are met. A Memorandum of Understanding is in place between the PMRA and the US EPA that provides for this approach and allows for information exchange related to results of GLP inspections.

More information on the PMRA's regulatory position on compliance with the principles of GLP can be found in Dir98-01, Good Laboratory Practice: **http://www.pmra-arla.gc.ca/english/pdf/dir/dir9801-e.pdf**.

Data Evaluation

The PMRA ensures that it evaluates studies meeting quality standards through its screening and preliminary review mechanisms. Through these mechanisms the Agency is able to independently assess each study for its scientific merit in terms of qualities like reproducibility. The PMRA is the only OECD country to conduct such a preliminary review.

The Agency's pesticide evaluators are qualified and knowledgeable about the international standards for scientific study design. When reviewing data, they constantly cross-check data from the various studies for specific effects over time, dose and animal species and look for discrepancies in and across these studies to ensure that GLP standards have been adhered to. These measures carried out at the preliminary review stage prevent flawed, fraudulent or incomplete data packages from continuing through the evaluation process.

If uncertainties are identified in the evaluation process, the PMRA may request additional data to address them. If uncertainties are not addressed, the PMRA may add additional safety factors or deny registration of the product.

Comment 2: "The industry reimburses the PMRA for evaluating pesticides. Hence a conflict of interest"

Response: In accordance with government policy, cost recovery for the regulation of pesticides was introduced in April 1997 after extensive consultation with stakeholders. Cost recovery promotes fairness by shifting a portion of the costs of the program from taxpayers at large to those specific users who benefit most directly from the program. The PMRA charges application fees in accordance with a prescribed fee schedule for the review of applications to determine whether risks to health and environment posed by a product are acceptable and that the product has value, and an annual maintenance fee per registered product for the right to sell a product in Canada. Other countries, such as the United States and the United Kingdom have also pursued cost recovery in pest control product regulation.

Fee reduction provisions are in place for both types of fees. The reduced fees have been included to facilitate access to the Canadian market of low sales volume niche products. The onus is on the applicant to supply sufficient evidence to support the request for a reduced fee. Some applications are exempt from some or all application fees including for own-use import permit applications and user requested minor use label expansions (URMULE).

Importantly, the fees for pesticide evaluation are collected regardless of whether or not the assessment leads to the product being registered.

More information about PMRA's cost recovery program can be found at: **http://www.pmra-arla.gc.ca/english/appregis/costrec-e.html**

Comment 3: "The process of evaluation is extremely slow and in the case of 2,4-D dates as far back as 1980; meanwhile the exposure to the product affects Canadians' health adversely"

Response: 2,4-D has been continuously re-evaluated and changes have been made through the years that include new manufacturing processes, label improvements to increase applicator safety and modified use patterns. Over 300 submissions involving some level of scientific review have been assessed since 1986. In 1994, a label improvement program was implemented to reduce both occupational and public exposure and to improve label clarity, consistency and accuracy. The new label directions included common-sense precautions such as wearing long clothing and gloves when applying the product and washing up when the application is complete.

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 current re-evaluation of the lawn and turf uses of 2,4 D was initiated in 2000 and is in the final stages of completion. As part of its normal process, the PMRA will publish a consultation document (referred to as a Proposed Acceptability for Continuing Registration document) for comment by stakeholders, including the scientific community and all interested parties. All comments will be considered by PMRA prior to finalizing the decision.

Comment 4: "The PMRA does not consult impartial sources, so as to form unbiased and well-thought out opinions on the toxicity of the chemicals being approved"

Response: In general, PMRA does consult the peer reviewed scientific literature when possible and appropriate. In the case of new pesticides that companies have developed there are usually no studies available in the public domain because the pesticide is new to the market. For pesticides undergoing re-evaluation, the complete body of scientific literature regarding human and animal health is examined as part of the re-assessment process as was the case for 2,4-D.

The body of information available for 2,4-D is extensive, and compares to that on which decisions are based for the approval of human prescription drugs. In contrast to many reports, which focus on a narrow subset of selected studies from the open literature, the PMRA's re-evaluation of lawn and turf uses of 2,4-D was based on a comprehensive review of all available information, including:

- An extensive proprietary database including chemistry data, efficacy data, laboratory animal studies to determine potential health effects, studies that examine potential effects on the environment, human exposure studies, as well as epidemiological studies;
- Published scientific information;
- Foreign reviews which included scientific assessments of 2,4-D from other countries; and,
- Any use pattern information collected by the PMRA.

The re-evaluation also includes a science-based risk assessment. The assessment takes into consideration, among other things, human exposure levels including exposures to sensitive sub-populations such as children, when determining acceptable levels of use.

The PMRA seeks input from external advisory committees on a case by case basis. For example, an expert advisory committee was convened in the re-evaluation of DEET, where the PMRA sought the input of a Scientific Advisory Panel, comprised of five representatives of the Canadian

Pediatric Society as well as a representative from Health Canada's Bureau of Pharmaceutical Assessment. The PMRA has also sought input during the re-evaluation of 2,4-D for lawn and turf use, details of which will be available in the consultation document. As well, the PMRA frequently participates in various independent Science Advisory Panels that are convened by the EPA.

Comment 5: "The PMRA may approve a product on the basis of incomplete information (e.g. the case of Merit 0.5 G version of imidacloprid insecticide)"

Response: Pest control products are not registered for use in Canada if the risks are considered unacceptable. In some cases, such as the product Merit 0.5G, additional, confirmatory data is requested as part of the conditions of temporary registration. In the case of Merit 0.5G this information has been received and reviewed and the product is now fully registered.

Comment 6: "When the PMRA discontinues licensing a chemical, it does so gradually, over a period of many years (e.g. the old version of mecoprop, a toxic phenoxy herbicide). Meanwhile, the "banned" product continues to affect Canadians' health adversely"

Response: The phase out periods that are established when a re-evaluated pesticide has been found to require withdrawal from the market, depend on the nature and severity of risk and consideration of the amount of product that remains in the distribution chain. The phase out schedule includes a date of last sale and a date after which the product can no longer be used.

At any time during the registration period, the registration of a product may be cancelled or suspended if the product is found to present an unacceptable risk of harm to human health or the environment, or if it no longer meets the criteria of merit or value for its intended uses. The PMRA is continuously monitoring its international partners for developments which may affect the continued acceptability of a pesticide in Canada. Any product that poses an unacceptable risk to Canadians would be acted on immediately.

In the case of mecoprop (racemic), the decision to phase-out was based on the registrants' decision to not provide the necessary data required to complete the re-evaluation. The PMRA has concluded that continued use of mecoprop (racemic) products in the short-term would not pose an unacceptable risk to users, the public or the environment.

Comment 7: "To my knowledge, the PMRA does not compile cancer statistics and is unaware of the actual impact on Canadians' health of pesticides the PMRA approves."

Response: See response to Recommendation 4.

Comment 8: "The PMRA apparently ignores the Swedish experience on 2,4-D use, characterized by reduced rates of cancer both among people and dogs. Conversely, the PMRA is unlikely to consider the experience of East-Central Europe. For example, in Warsaw under Communism there was no separate cancer ward in the children's hospital, as children's cancer was virtually unheard of, despite heavy industrial pollution. Now that Poland has adopted the lifestyle of the West, including increased use of pesticides, there is a cancer ward in the children's hospital in Warsaw."

Response: 2,4-D is no longer used in Sweden or Norway and its use is severely restricted in Denmark. Environmental effects are cited as the primary reason for these actions as 2,4-D has the potential to enter groundwater, the primary source of drinking water in these countries. However, subsequent to these actions, the European Commission, upon completion of their re-evaluation of 2,4-D on October 1, 2001, concluded that it was acceptable for continued use the European Union, of which both Sweden and Denmark are members.

As part of the re-evaluation of 2,4-D, the PMRA has compiled all available drinking water data from various regions and sources across Canada. These data indicate that the levels in drinking water do not pose unacceptable risks for the Canadian population.

It is important to recognize that of the many studies published, some report associations between adverse health effects and 2,4-D exposure, while many others report a lack of association. As most of these papers acknowledge, epidemiology studies on their own are difficult to interpret because biases and confounding factors often preclude any convincing link between specific pesticide exposures and effects. For example, influences from other chemicals and the physical environment encountered at the same time as pesticide exposures and recall bias from the individuals examined are two factors that can strongly influence the study result. Without an actual exposure calculation, it is difficult to assess whether pesticides could have been responsible for an adverse health outcome. This is why the PMRA also relies on the more scientifically exact method of quantitatively estimating risk by comparing exposures to the results of toxicity studies in laboratory animals. The proprietary studies used are conducted to internationally accepted standards and include toxicity studies done on a number of laboratory animal species for comparative purposes, as well as studies of exposure from all routes and methods of exposure. Safety factors (typically 100 to 1000 fold) are built into the assessment to account for different sensitivities between humans and experimental animals and among humans (age, gender and individual sensitivities to pesticides). In general, this is the same approach that is currently utilized by the various international pesticide regulatory authorities including the US EPA and other OECD countries.

Comment 9: "We are convinced that if the pesticide approval process was stricter and the Agency erred on the side of caution, the epidemic of some forms of cancer, especially among children, would be substantially reduced. The incidence of developmental problem among children and the number of people afflicted by environmental sensitivities would also be diminished."

Response:

Thorough Health Hazard and Risk Assessments

The PMRA conducts a thorough assessment of pesticides before their use is permitted in Canada. These assessments are carried out in order to meet the objective of protecting humans and the environment from unacceptable risks. Products evaluated by the PMRA will not be registered if a wide enough margin of safety cannot be established to render the risks to health and the environment acceptable.

When examining data, pesticide evaluators look for potential adverse effects associated with the use of the product and the doses that cause these adverse effects. The PMRA performs exposure assessments to determine how much exposure to a pesticide could occur in a typical day. These assessments take into account the different exposures that people could have to pesticides, such as those who work with the pesticides (formulators, applicators and farmers) and bystanders (people working or living near where a pesticide is used). They also take into consideration the differing exposures that adults and children would have. Exposure data considered include residues found in air and on surfaces indoors and outdoors following application in domestic, commercial and agricultural situations. Evaluators ensure there is a wide enough margin of safety between the amount of the product that people are exposed to in their daily lives, and the highest dose of the product that would cause no adverse effects in lab animals. Assessments of the effectiveness of personal protective equipment are often performed, and wearing such equipment during handling of the product can be required as a condition of registration.

Studies assessed include short-and long-term toxicity, carcinogenicity (the capacity to cause cancer), genotoxicity (the capacity to cause damage to genetic material) and teratogenicity (the

capacity to produce fetal malformations), among others. The PMRA's toxicology sections are responsible for setting acceptable daily intakes, which refers to the amount of a compound that can be consumed daily for a lifetime with no adverse effects. Acceptable daily intakes always have safety factors built in, ranging from 100 to 1000. These safety factors are designed to take into account the potential differences in response, both within the same species (e.g., adults versus children) and between species (e.g., animals versus humans).

Where a pest control product could come in contact with food, including field crops, meat products, dairy products and processed foods, the PMRA specifies the maximum residue limits for pesticides on food, both domestic and imported, to be established under the *Food and Drug Act*. Dietary risk assessments are also carried out to ensure that the potential daily intake of pesticide residues from all possible food sources is less than the acceptable daily intake that has been established for a given pesticide.

Safety of Children

The PMRA's human health risk assessments address the Canadian population in general and sensitive sub-populations such as women of child-bearing age, pregnant and nursing women, infants and children.

Infants and children have been a special consideration in our risk assessments for many years. Recent advances in scientific understanding reaffirm that children are not "little adults" and must be considered as a discrete subgroup. In all cases where the use of a pesticide could result in exposure of children, the PMRA considers the unique biological characteristics and exposure patterns of children in its risk assessments.

The PMRA takes into account the fact that children's diets are different and that their activities vary from those of adults. The Agency considers all potential pathways of children's exposure, including dietary, drinking water, and residential exposures, in its health assessments. Internationally accepted guidelines for conducting these exposure studies and deriving exposure estimates for infants and children are followed. Dietary risk assessments take into account the different eating patterns of infants, toddlers, children, adolescents and adults, and therefore include a detailed evaluation of the foods and drinks that infants and children consume in quantity, such as fruits and fruit juices, milk and soya products. The Agency will consider registration of a pesticide for food uses only when child-specific assessments are found to be acceptable. Scientists at the PMRA also factor in the differences in children's development and metabolism when toxicology tests are assessed.

More information on PMRA and children's health can be found at: **http://www.pmra-arla.gc.ca/english/pdf/spn/spn2002-01-e.pdf**

Cancer Risk Assessments

Assessment of cancer risks involves challenges that warrant special consideration. The PMRA's approach to cancer risk assessment is based on the weight of the scientific evidence obtained through the evaluation of the entire data package.

The PMRA's assessment includes an examination of scientific studies to determine if the pesticide causes adverse effects in laboratory animals. One of the effects that is looked for is whether the pesticide causes cancer in animals. The majority of pesticides registered for use in Canada do not cause cancer in laboratory animals. If there is evidence that a proposed pesticide causes cancer in laboratory animals, a special type of assessment called a quantitative risk assessment is conducted to determine if the use of the pesticide would result in an unacceptable risk of cancer in humans. All potential exposures (eg. food, water, workplace) that may occur over a lifetime are considered in the assessment.

Detailed risk assessments and very large margins of safety are built into the human health evaluations that the PMRA carries out on proposed pesticides so that Canadians will be protected from risks such as cancer. Only pesticides which do not pose an unacceptable risk of cancer in humans are registered for use in Canada.

More information on health and cancer risk assessments are describe in *"A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency"* **http://www.pmra-arla.gc.ca/english/pdf/spn/spn2000-01-e.pdf**

Recommendation 1: ***"The PMRA should take into account independent peer-reviewed scientific literature on 2,4-D in the course of this Agency's current and long overdue evaluation of this herbicide."***

Response: See response to Recommendation 2.

Recommendation 2: ***"There is a need for a more balanced approach to the evaluation of pesticides in general, i.e., the Agency should be examining independent peer-reviewed scientific literature on pesticides in addition to evaluating industry submissions"***

Response: The PMRA has highly qualified scientists who consider their role in pesticide regulation as that of the independent peer-review body. These scientists take their role in minimizing pesticide exposure and risk very seriously.

As indicated in the response to Comment 4 above, the PMRA uses independent peer-reviewed scientific literature in its re-evaluation of pesticides and did so in its assessment of 2,4-D.

Also, as part of standard practice, when new studies are released in the public literature, the PMRA examines them to determine if further regulatory action is required on the pesticides mentioned in the study.

Recommendation 3: ***"There is a need for a re-organization of the entire PMRA with a view to increased efficiency."***

Response: The PMRA that exists today and the new PCPA, are the products of a renewed approach to pesticide regulation shaped by over a decade of consultation starting with the Pesticide Registration Review and culminating with the Government Response to the report of the Standing Committee on the Environment and Sustainable Development.

Today, pesticide registration is highly efficient and mechanisms are in place to focus on continuous improvement. In comparison to fiscal year 1997/98 to 2003/04, the time to register a new pesticide has been reduced by 48 percent. This level of efficiency has been achieved in two phases. The first phase being the consolidation, in 1995, under one roof, of the pesticide regulatory activities of four government departments (Natural Resources, Agriculture and Agri-Food Canada, Environment Canada and Health Canada). This was followed by immediate action, which continues to this day, to implement measures to increase efficiency such as re-engineering screening and review processes, and international harmonization.

Two other examples of measures PMRA is taking towards improved efficiency are participation in work sharing /joint reviews with the US Environmental Protection Agency and the electronic submissions and review of pesticide applications. Approximately 50 percent of new pesticides in Canada are reviewed jointly with the US or use assessments from other countries. Joint reviews pool the resources of both Agencies. Similarly, PMRA's re-evaluation program takes advantage of the US pesticide re-registration program which has a budget eight times the size of PMRA's re-evaluation program. PMRA reviews are timed to consider completed US reviews whenever possible, which has led to approximately 83 percent of PMRA's decisions parallelling US decisions.

The PMRA is developing the world's first web-based service for conducting pesticide regulatory transactions. The PMRA Electronic Regulatory System, dubbed e-PRS, offers a new approach to information management and will enable the PMRA to continue the evolution from a paper-based system to a sophisticated electronic system using information technology. The e-PRS is a major step in an ongoing process to increase the efficiency and transparency of pesticide regulation in Canada.

More information on PMRA plans and achievements can be found in PMRA's strategic plan: **http://www.pmra-arla.gc.ca/english/aboutpmra/plansandreports-e.html** and in the section on PMRA in Health Canada's *Report on Plans and Priorities and Departmental Performance Report:* **http://www.hc-sc.gc.ca/english/care/estimates/index.htm**

Recommendation 4: ***"The PMRA should maintain a statistical record of the incidence of cancer in Canada with a view to correlating this data with pesticide use in this country."***

Response: Statistical records of cancer incidences in Canada are collected and maintained by the Centre for Chronic Disease Prevention and Control in the Public Health Agency of Canada and by Statistics Canada in conjunction with other governments and non-governmental organizations.

Chronic cancer bioassays that assess the cancer potential of a given pesticide have been a standard data requirement for many years. The PMRA does a thorough scientific evaluation of animal toxicological studies to assess the cancer potential and to ensure the product does not pose any unacceptable risks to human health or the environment.

During the re-evaluation process or when a Special Review is announced, in addition to the previously reviewed animal cancer bioassay data, the PMRA takes into account any available reports linking the pesticide to cancer.

If the PMRA's assessment does not indicate that a product can be used safely, it is not registered for use in Canada. In the case of re-evaluation, only those products that are acceptable for use based on current scientific approaches in risk assessment are able to maintain a registration.

Document Attached to Petition

Response: The document attached to the petition raises concerns about the US EPA's human health risk assessments for 2,4-D. It is not appropriate for PMRA to respond to comments that are directed towards the EPA and their preliminary assessments, which are intended to solicit public comments prior to finalizing the decision.

The PMRA is nearing completion of its re-evaluation of lawn and turf uses of 2,4-D. During this re-evaluation the types of concerns outlined in the petitioner's attached document were addressed. All members of the public and other stakeholders will have an opportunity to give input on PMRA's re-evaluation of 2,4-D upon the release of the consultation document, referred to as the Proposed Acceptability for Continuing Registration (PACR) document, planned for early 2005. The PACR document contains summaries of the assessments and recommendations on the acceptability for continuing registration of the active ingredient and its end-use products for lawn-care use. Comments received during the consultation period will be given due consideration in the ensuing final re-evaluation decision. The re-evaluation work for the agricultural uses of 2,4-D will be completed later in 2005 and a PACR document regarding agricultural uses will be made available at that time.

PACRs are posted on PMRA's web site **http://www.pmra-arla.gc.ca/english/pubs/pacr-e.html** **http://www.pmra-arla.gc.ca/english/main/openforcomment-e.html** and copies can be obtained by calling PMRA's Information Services at 1-800-267-6315.

More information on the Re-evaluation Program at the PMRA can be found on the website:
http://www.pmra-arla.gc.ca/english/pubs/reeval-e.html

Date Issued: 2004-09-17