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What the Environment Commissioner Really Said: The Audit of the Federal Pest Management Regulatory Agency

SPECIAL REPORT – *November 2003*

Kate Stiefelmeyer, Al Mussell and Cher Brethour



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EXECUTIVE SUMMARY

The Federal Environment Commissioner recently released a report containing sweeping criticisms of the Canadian Pest Management Regulatory Agency (PMRA). Among the findings were that PMRA had inconsistently applied evaluation criteria, that PMRA had not met its own targets, that old pesticides have not been reevaluated, and that there are general problems with PMRA's regulatory approval processes.

The popular media interpreted the report as a finding that government regulators allowed dangerous chemicals into the environment. This was countered by defensive messages from farm groups. Both interpretations miss the mark. In fact, the Environment Commissioner found that PMRA is slow to approve newer, more effective, and safer pesticide products. This puts Canadian farmers at a competitive disadvantage, and unnecessarily puts the environment at risk.

Due to PMRA inconsistency and lengthy approval decision processes, Canadian agricultural competitiveness is impaired, environmental improvements are being delayed, and opportunities for research and development in Canada are being lost. US competitors often get faster access to new products than Canadian farmers do, decreasing the competitiveness of Canadian agriculture, because new pesticide products available elsewhere (but not accessible in Canada) are applied in products imported into Canada and markets that we compete in. Manufacturers of crop protection products are apprehensive about the Canadian approval process, which has resulted in a loss of research and development opportunities in Canada.

A concern posed in the Environment Commissioner's report is that older pesticides are in use that would not be approved today, and should be reevaluated. Evidence from Ontario field crops shows that safer herbicides are being used today, suggesting that older products are not being widely used. If they are not being used, they are not an imminent threat. However, the best way to avoid the use of old pesticides is to expedite approval decisions on newer, more effective and environmentally friendly products.

The problems observed by the Environment Commissioner in registering pesticide approvals are remarkably similar to the inconsistencies in process observed at the Health Canada-Veterinary Drugs Directorate (VDD). Studies of VDD have revealed inconsistent application of standards and consistent delays and failure to meet self-imposed targets for product approval decisions.

There is a regulatory problem in Canadian agriculture, as demonstrated for PMRA by The Environment Commissioner. However, the problem is greater than just PMRA. If innovation, research, and investment are keys to invigorating Canada's economy, we must ensure that Canada has the necessary conditions to attract research and development. Without improvement in regulatory processes in pesticides/crop protection and animal health products, we clearly do not.

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In October 2003, the federal Commissioner of the Environment and Sustainable Development released her audit of the Canadian pesticide regulatory system. In it are contained sweeping criticisms of the Canadian Pest Management Regulatory Agency (PMRA) and its processes.

The Environment Commissioner's Findings

The major findings contained in the Environment Commissioner's report on pesticide regulation are the following:

- The framework for registering pesticide approvals is not applied consistently. In some cases, steps are skipped; in others, product use persists under renewed emergency use registrations.
- PMRA has not met its own targets on reaching approval decisions for new and minor use pesticide products.
- Overly conservative estimates of aggregate pesticide use (acreage applied, volume of food products consumed) are assumed, and not verified.
- There is a problem in adequately providing PMRA regulators with information. The evidence supporting this includes the lack of third party reviewed data submissions, incomplete submissions, and heavy use of temporary pesticide registrations that are renewed.
- PMRA has not done an effective job of re-evaluating older pesticides. In some cases, older pesticides do not conform to current safety codes; in others, new research showing that lower rates of application can provide effective control has not been included on previously approved pesticide labels. An effective plan to manage re-evaluations has not been developed.
- PMRA faces significant challenges over human resource issues.

However, the message picked up by the popular press from the Environment Commissioner's report seemed to stress that government had allowed unsafe pesticides into the environment, which misrepresents the major findings of the report.

The purpose of this report is to focus on the material findings in the Environment Commissioner's report, and to put them in the greater perspective of regulations and the economic aspects of regulation in Canadian agriculture.

Clearing Up the Media's Mixed Message

In her report, what the Environmental Commissioner is really saying is that PMRA is slow to register new products, so producers' access is restricted to older pesticides instead of newer,

more environmentally friendly and targeted pesticides. As a result, there are older pesticides still on the market, and many (if not most) have not received reevaluation since they were first approved. The longer it takes PMRA to make approval decisions on new products, the longer farmers must use older ones, while farmers in other countries have access to pesticides that are newer, more effective, and typically safer. This puts Canadian producers at a competitive disadvantage, and unnecessarily puts the environment at risk. Unfortunately, the media spin on this story has been that PMRA is allowing unsafe pesticides into the environment. Farm organizations have also waded into the debate, issuing defensive statements on the safety and use of agricultural chemicals. These responses miss the point of the report entirely. There is no mention in the Environment Commissioner's report that Canadian pesticide approval standards are either too lax or too restrictive *per se*, or that PMRA's standards lack scientific rigour. Rather, the problem is that PMRA has lagged in making product approval decisions, and has thus restricted Canadian access to newer, more effective, and safer pesticide products.

There are two fundamental and related issues raised in the Environment Commissioner's report:

- Access to new pesticide products is being unnecessarily restricted by the regulatory system.
- There are old pesticides on the market that need to be reevaluated.

These are discussed below.

The Role of PMRA as Regulator

There is a need to ensure that pesticide products have their claimed effect (efficacy), that they are safe when used as labeled for humans and the environment. Product liability law and marketing under distinct brands addresses this to a large extent. In particular, if a branded pesticide product doesn't work, manufacturers can (and do) face liability claims from farmers and their market share suffers, so they have every incentive to manage efficacy (along with other aspects of liability) on their own. However, there remains a need for objective, accountable third party risk assessment determined through the use of appropriate standards of evidence. This role is filled by government. In the context of pesticides, it is the responsibility of the PMRA. Thus, the issues raised by the Environment Commissioner do not relate to the role of the PMRA, but rather to its processes and the management of its mandate.

PMRA Processes and Management

As noted in the introduction, a number of the Environmental Commissioner's findings point to the unrefined processes and operations of the PMRA that have resulted in slow and inconsistent approvals for registering crop protection products. The primary problem was found to be the inconsistency in the framework for registering pesticides. Although the process for evaluating pesticides is well defined, the steps taken during the process have not been followed systematically and clear criteria for decisions to alter the process are lacking. This lack of criteria leaves the judgments to the individuals working on the specific approvals, so there is a lack of consistency in the approval processes. Since the information required to complete new product submissions is always changing, new product sponsors remain unsure of what is required to prepare a complete submission. This results in longer approval times due to incomplete submissions.

Despite longer approval times due to incomplete submissions, the PMRA has also not met its own target of 737 calendar days for reaching new pesticide approval decisions. The

Environmental Commissioner's Report noted that 33% of all submissions were overdue and that some applications have been waiting in the queue for over 5 years.

PMRA has reevaluated many older pesticides and has restricted and removed them from the list of approved products. However, the Agency has not approved the registration of new, safer more effective pesticides to take their place resulting in the use of inferior pesticide management tools by Canadian farmers.

Implications of the Inconsistent Registration Approval Process at PMRA

The results of ineffective and inefficient PMRA approval reviews ultimately fall on Canadian farmers, scientists and the public. Due to PMRA inconsistency and lengthy approval decision processes, Canadian agricultural competitiveness is affected, environmental improvements are being delayed and opportunities for research and development in Canada are being lost.

First, due to regulatory inefficiencies and long approval decision times, manufacturers of crop protection products are apprehensive about the Canadian approval process (see Appendix A). This has resulted in a loss of research and development opportunities in Canada. Many companies are discouraged from conducting research in Canada knowing that research and development elsewhere will ensure a faster, more efficient and transparent approval process. Canada's small market size alone can discourage manufacturers from seeking approval; therefore the additional effort they must exercise during an approval process in Canada due to these issues is further discouraging.

Farmers in larger markets such as the United States, Canada's largest trading partner, have access to new products sooner than Canadian farmers, since many pesticide manufacturers choose to seek approval in the US first because of the consistent and more timely approval process. A joint US EPA/PMRA approval option does exist, but is not frequently utilized because manufacturers do not want the Canadian process to delay their US registration and access to the larger US market. Therefore, US competitors often get faster access to new products than Canadian farmers do. This decreases the competitiveness of Canadian agriculture, because new pesticide products available elsewhere (but not accessible in Canada) are applied to products imported into Canada and markets that we compete in.

Horticultural and small-acreage crop producers are feeling increased pressure. Many of the products that PMRA has de-registered have been minor-use products leaving producers to rely on older technologies until newer products are registered. However, there is little incentive for companies to expend time and money registering small-acreage crop pesticides when the market for small-acreage products is small to begin with, and the size of the Canadian market further diminishes the incentive. This issue has angered commodity groups such as the Ontario Processing Vegetable Growers, the Ontario Food Processors Association and the Canadian Horticultural Council who believe the fruit and vegetable industry in Canada has made tremendous improvements in its competitiveness, but that regulatory delays are an encumbrance to further growth.

For example, a number of horticultural commodity groups have been lobbying for the approved use of a herbicide whose active ingredient, kaolin clay, forms a non-toxic barrier between the pest and the fruit. This product also helps to reduce sun damage and rot by providing a protective barrier that lets enough light through to allow continued growth and development of

the fruit. This product has been registered in the United States since 1999, and has been regulated for use in organic production through the Organic Material Review Institute (OMRI). Four years after the initial submission, PMRA recently approved the product as an insecticide for use on pears and apples. During the time when PMRA had not yet registered the product (as a pesticide in Canada), producers had to rely on older, more toxic products to protect against pests. Interestingly, the fruit and vegetables produced in other countries, where the product had already been registered, were sold on Canadian grocery store shelves well before its approval in Canada. For further information on the approval process of this product see Appendix A.

Older Pesticides and Product Registration Re-Approvals

A second major issue raised by the Environment Commissioner is that of older pesticides that need to be reevaluated. The concern is that pesticides that were registered at a time when standards were lower and would not be approved today (for example, because of advances in toxicology, and improved ability to measure and detect) remain or are being increasingly used. If this were the case, legitimate concern would exist. Conversely, if these older products were not being used today, less concern would be warranted.

To understand whether older pesticide products are still widely used, consider (as an example) herbicides applied to corn and soybeans in Ontario. As noted above, newer herbicides tend to be safer, so if older herbicides were still in wide use, one would expect the level of active ingredient of relatively toxic products applied to be stable or growing. Figures 1 and 2 illustrate the amount of active ingredient more toxic than glyphosate used per acre of corn and soybeans, respectively, in Ontario in the five-year periods between 1973 and 1998. Glyphosate is used as the benchmark active ingredient because of its widespread use over a variety of crops (particularly since the introduction of roundup ready technology), and because it has both a fairly high oral LD50¹ and dermal LD50, which means it is relatively safe. Thus, Figures 1 and 2 measure the use of herbicides more toxic than glyphosate (see Appendix B for a list of active ingredients used on Ontario corn and soybeans between 1973 and 1998).

Figures 1 and 2 show that the amount of active ingredient that is toxic relative to glyphosate applied to Ontario corn and soybeans has decreased substantially in the last two decades. This is particularly important in soybeans, because soybean acreage increased dramatically over the period. Total corn acreage was relatively stable. As described above, if older and more toxic products were stable or increasing in use, one would expect the figures to be flat over time or have precisely the opposite shape. Indeed, the figures suggest that older products are not being widely used for corn and soybeans. It is also illustrative of the potential benefit of new product registrations; presumably, had the difficulties within PMRA noted by the Environment Commissioner not occurred, the decline in use of corn and soybean herbicides with relatively toxic active ingredients would have been more accelerated.

The foregoing is an illustration of changes in product application according to relative toxicity. What about other older products that have negative environmental impacts due to long residuals in soil? Figure 3 shows that triazine herbicides (which were mostly developed in the 1960's and are known to have a residual in the soil) used in Ontario corn production have decreased

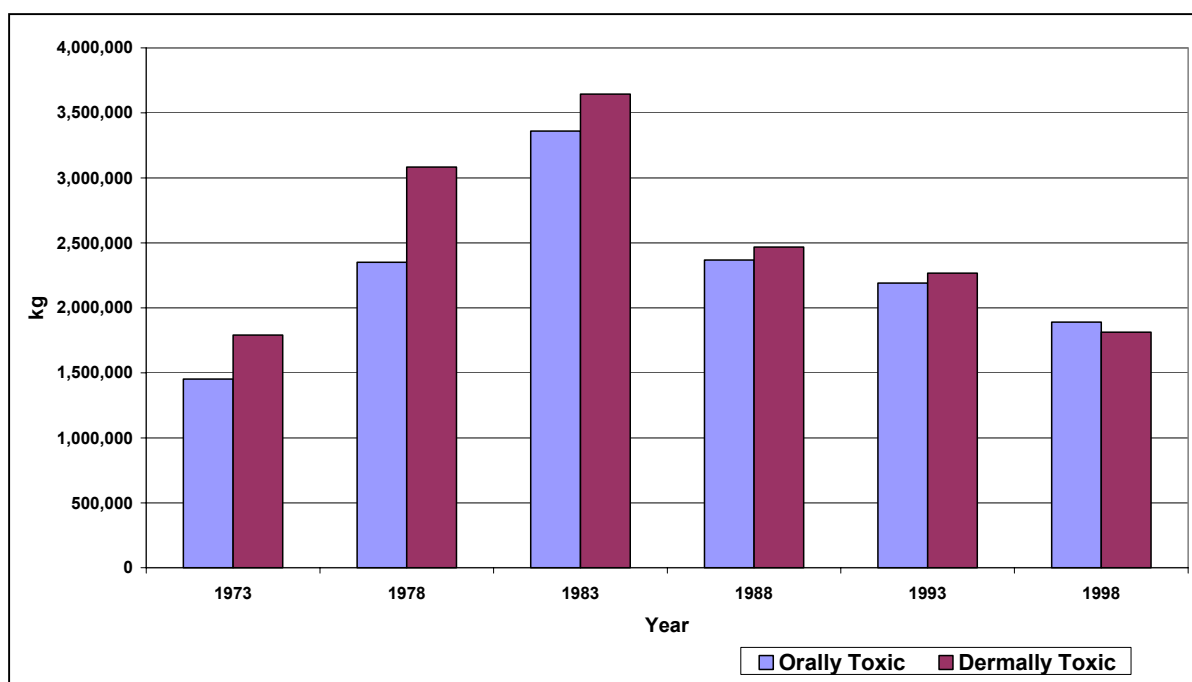
¹ LD50 or lethal dose 50% is a statistical estimate of the amount of a chemical that when administered will kill 50% of the test animals under the stated conditions (Ontario Ministry of the Environment, 1986). LD50 is the accepted measure used to represent toxicity of chemicals to humans.

dramatically. Recent use of atrazine is about one-third of what it was at its peak, and as of 1998, cyanazine had decreased to about 11% of its peak in 1983.

It is important to note that there are caveats to observe from these examples. They are drawn from a single region on only two crops. It is unclear what analogies can be made to insecticides and fungicides. However, the examples cited here relate to about half of all Ontario agricultural land, so they are significant. Further investigation can reveal the trends in the use of relatively toxic products in other crops and regions. The points to observe are:

- Older pesticides are not an imminent problem if they are not being used in practice.
- The best way to avoid the use of old pesticides is to expedite approval decisions on newer, more effective and environmentally friendly products.

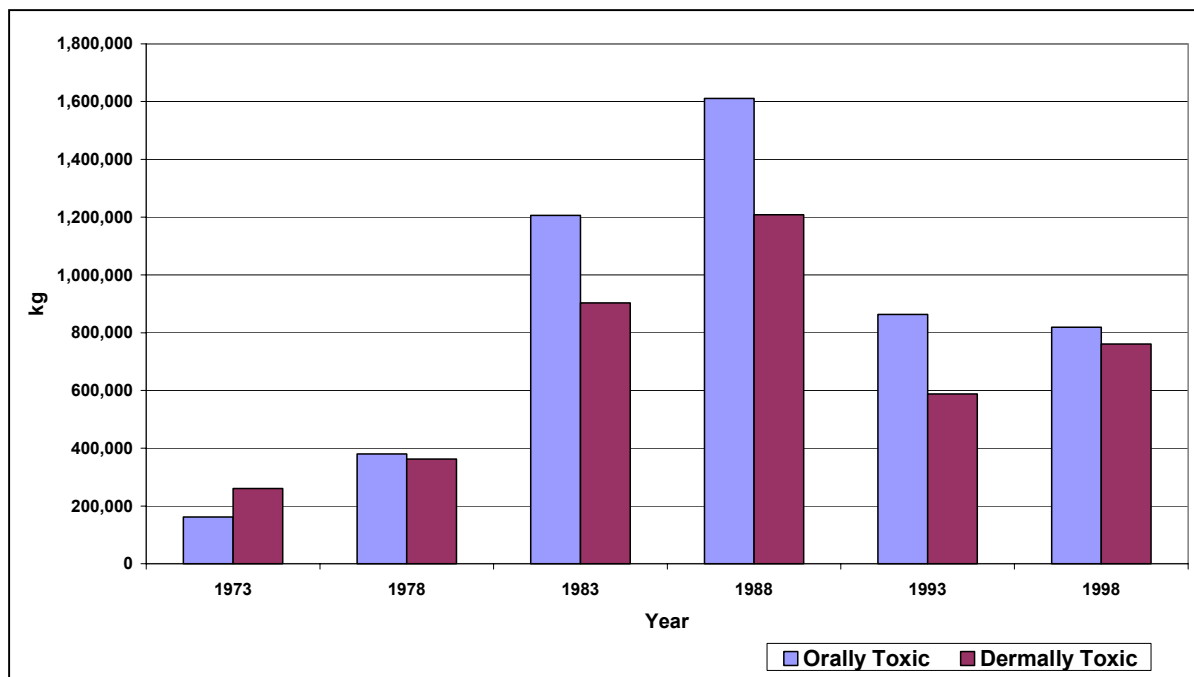
Figure 1: Applications of Active Ingredient More Toxic* Than Glyphosate, Ontario Corn



*Active ingredient with lower oral and dermal LD50 rating than Glyphosate.

Source: Survey of Pesticide Use in Ontario, Ontario Ministry of Agriculture and Food

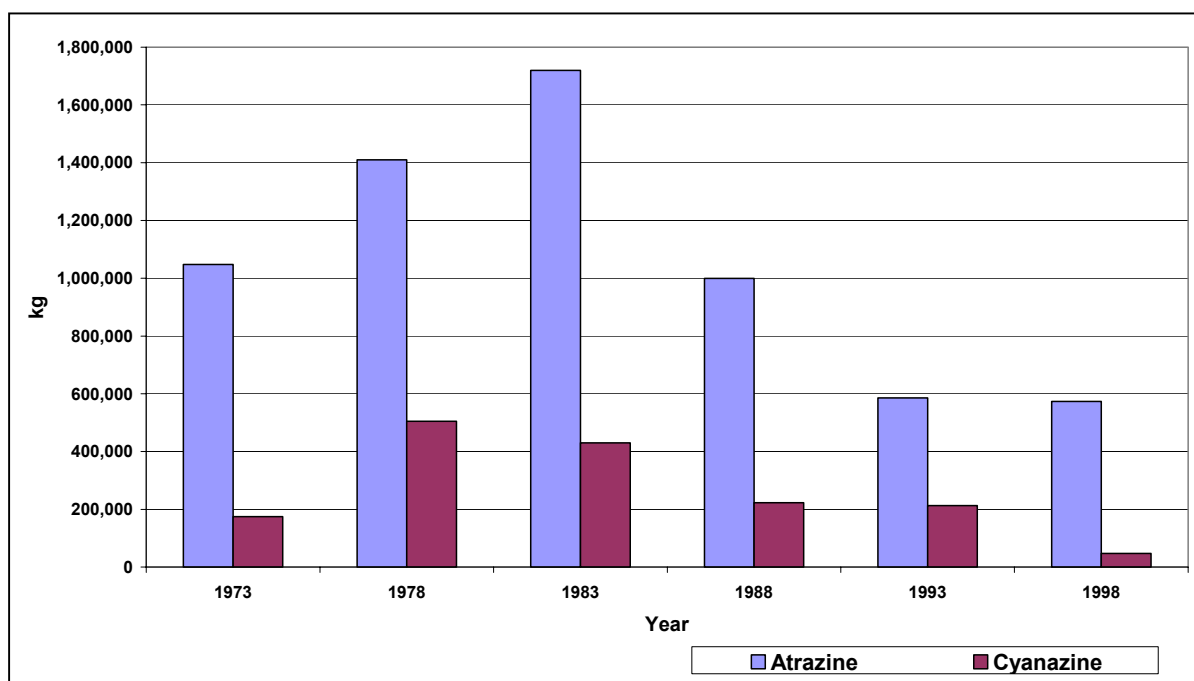
Figure 2: Applications of Active Ingredient More Toxic* Than Glyphosate, Ontario Soybeans



*Active ingredient with lower oral and dermal LD 50 rating than Glyphosate.

Source: Survey of Pesticide Use in Ontario, Ontario Ministry of Agriculture and Food

Figure 3: Use of Triazine Active Ingredients in Ontario Corn



Source: Survey of Pesticide Use in Ontario, Ontario Ministry of Agriculture and Food

Related Regulatory Problems in Canadian Agriculture

These findings bear a remarkable resemblance to those obtained in recent research by Rainnie (2002) and Brethour *et al* at the George Morris Centre (forthcoming) concerning the Veterinary Drugs Directorate (VDD) Health Canada. In particular, the following were observed:

- Inconsistent application of the registration framework
- Failure of VDD to meet its own targets for product approval decisions
- Significant problems directly related to human resources within VDD

The inconsistency in the framework for registering pesticide approvals is very similar to the inconsistencies in the processes at VDD. The Environmental Commissioner notes that in some cases steps were skipped, but in others a substantial amount of additional information was required. A comparative study conducted by D.J. Rainnie at the Atlantic Veterinary College showed similar results (Rainnie, 2002). It compared the regulatory requirements of the Centre for Veterinary Medicine (CVM) in the United States to VDD with respect to drugs for use in companion animals². Rainnie concluded that although the regulatory requirements for both agencies are essentially the same, the CVM documents that lay out the requirements are more specific, numerous and detailed and are therefore less open to interpretation which results in more consistency in CVM reviews. The study conducted by Brethour *et al* at the George Morris Centre (GMC) highlighted similar findings.

The Canadian administrative performance standard for a 'New Drug Submission' (NDS) to obtain an approval decision within the Veterinary Drugs Directorate is 180 days (internal guideline). An independent report by Regulatory Data Services (RDS) analyzed the market access times for veterinary drug products in Canada between 1995 and May 2003. The report found that NDS approval times exceeded the 180-day performance standard 87% of the time and applications had been in the queue in some cases as long as five years. Recall that the Environment Commissioner found that 33% of all submissions to PMRA were overdue and that some applications had been waiting in the queue over 5 years.

Rainnie's report also highlighted that the CVM was more formally standardized and less flexible in all processes throughout the approval process. Therefore, quality control and consistency in the approval process was always higher in CVM when compared to VDD. Rainnie also found the review process at CVM to be team oriented, but at VDD it was more individualistic. This was consistent with the GMC finding regarding the human resources issues at VDD and their capacity to prolong the approval process. Finally, Rainnie found that the interpretation of data from the research studies was generally the same in both agencies. This finding should encourage more collaboration between the two agencies thereby reducing the need to generate additional research data specific to one country and reducing the amount of time required during the approval decision process.

Conclusions and Implications

The Environment Commissioner had a powerful message regarding PMRA and the pesticide approval process in Canada, and apparently many people missed it. The failure of the pesticide product approval system to meet its own standards, let alone those of other developed

² Companion animal and livestock drugs are approved within the same departments of VDD.

countries, is having material impacts on Canadian agriculture, and, potentially, on the Canadian environment. Canadian farmers do not have access to the same pesticide products as farmers in the US and other countries, and the issue is not that Canada has tougher or better pesticide safety standards. On the contrary, it is that the Canadian system is unduly time consuming and inefficient in expediting product approval decisions. As a result, some products are delayed in being submitted for registration in Canada (or are not submitted at all), because pesticide manufacturers know the perils of the Canadian system.

Media coverage of the Environment Commissioners report has, instead, positioned the discussion around whether Canada's pesticide regulatory system is tough enough. This has been countered by defensive responses from the farm lobby that suggest the system is already too tough, or at least tough enough. Both assertions miss the mark.

The pesticide approval process places Canadian farmers at a disadvantage relative to their competitors in international markets. Farmers in other countries, whom Canadian farmers compete with, frequently do have access to new pesticide products in advance of Canadians. This means that Canadian farmers do not face a level playing field in world markets. To exacerbate the issue, Canada freely imports farm products from countries that have access to pesticides that have not yet been approved in Canada. Thus, the disadvantage occurs both in export and domestic markets.

The Canadian pesticide approval process potentially places the Canadian environment at risk. Newer products tend to be safer products, because today's standards are higher and measurement technology is better. Pesticide technology has improved to deliver efficacy with less toxicity and safety risk. Data on pesticide applications to Ontario corn and soybeans, and the kaolin clay example support this argument.

The picture that emerges is that, if PMRA was more efficient and consistent at approving new product registrations, producers would have had more choices of newer technologies that could not only be less toxic to humans but also more target specific, or require a reduced amount of application. The real message in the Environmental Commissioner's Report is that PMRA must work to improve its operations and procedures in order that improvements not only in the environment but also in human health and producer competitiveness can result.

However, the problem is clearly not isolated to PMRA, as it appears to apply much further to the 'regulatory approval process' in Canada. We illustrated the similar problems with transparency, consistency and timeliness within PMRA and the Veterinary Drug Directorate. The question that remains, are more industries within agriculture facing the same product approval battles? We suspect they are, which are likely resulting in significant direct and indirect costs to the agriculture industry. The Report from the Environmental Commissioner (2003), Rainnie's report (2002) and the Brethour *et al* (2003) George Morris Centre study illustrate that product approval processes in Canada require reform, and that it is essential for Canadian agriculture to remain competitive.

A potential resolution could be obtained from a system harmonized with that in other countries. Ideally, we would harmonize the Canadian regulatory system with the toughest, most efficient and expeditious regulatory systems in the world. The benefits of such a system could include decreased replication of experimental trials and research work, fewer border issues, and equal access for all. At a minimum, harmonization with the US product regulatory system should be

considered, because of the sheer volume of product traded between the two countries that currently do not occur on a level playing field because of differences in product registration systems.

During his Liberal leadership campaign, assumed soon-to-be Prime Minister Paul Martin has stressed that innovation, research and investment are keys to invigorating Canada's economy (Paul Martin, 2003). In order to see his vision through, Mr. Martin must ensure that Canada has the necessary conditions to attract research and development. Without improvement in regulatory processes, in pesticides/crop protection and animal health products, it does not. The loss in research and development opportunities demonstrates that inefficiencies in the regulatory process not only affects farmers but also implies a lost opportunity of many R&D jobs within the Canadian economy. This suggests that the Government's Smart Regulation³ Initiative to improve Canada's regulatory approval processes and the External Advisory Committee on Smart Regulation that will come under Mr. Martin's leadership will have a big job ahead of them.

³ For more information on Smart Regulations: www.smartregulation.gc.ca

References:

Agrimor International Co. webpage. <http://www.agrimor.com> Viewed on 11/17/03.

Brethour C, A. Mussel, L. Martin, K. Stefielmeyer and T. Moore. 2003. *The Competitiveness Impacts of Canada's Agricultural Product Approval Regulations*. Completed for the Canadian Animal Health Institute. George Morris Centre – Forthcoming.

Cornell University, Pest Management Education Program.
<http://pmep.cce.cornell.edu/profiles/index.html> Viewed on 11/17/03.

HorizonOnline MSDS webpage. <http://www.horizononline.com/services/msds.phtml> Viewed on 11/17/03.

Hunter, C. and B. McGee. 1994. Survey of pesticide use in Ontario, 1993. Economics Information Report No. 94-01. Policy Analysis Branch, Ontario Ministry of Agriculture Food and Rural Affairs, Toronto, Ontario, Canada.

McGee, Bill. 1984. Survey of pesticide use in Ontario, 1983. Economics Information Report No. 84-05. Economics and Policy Coordination Branch, Ontario Ministry of Agriculture and Food, Toronto, Ontario, Canada.

Moxley, J. 1989. Survey of pesticide use in Ontario, 1988. Economics Information Report No. 84-08. Economics and Policy Coordination Branch, Ontario Ministry of Agriculture and Food, Toronto, Ontario, Canada.

Nova Scotia Agriculture and Fisheries. 2001. Farm Well Water Quality Assurance Study: Final Report. <http://www.gov.ns.ca/nsaf/rs/envman/randd/water/wellrep.htm> Viewed on 11/17/03.

Office of the Auditor General of Canada. 2003 Report of the Commissioner of the Environment and Sustainable Development. Chapter 1: Managing the Safety and Accessibility of Pesticides. [http://www.oag-bvg.gc.ca/domino/reports.nsf/html/c20031001ce.html/\\$file/c20031001ce.pdf](http://www.oag-bvg.gc.ca/domino/reports.nsf/html/c20031001ce.html/$file/c20031001ce.pdf)

Ontario Ministry of the Environment, Pesticides Section. 1986. Pesticides Safety Handbook.

Paul Martin Liberal Leadership Candidate website. September 18/03. "Innovation, research and investment key to invigorating Canada's new economy: Paul Martin. www.paulmartintimes.ca.

Rainnie, D.J. 2002. A Comparison of the Regulatory Requirements and Processes of the Center for Veterinary Medicine and the Veterinary Drugs Directorate as Applied to Veterinary Drugs for Use in Companion Animals.
http://www.hc-sc.gc.ca/vetdrugs-medsvet/rainnie_report_cp_e.html

RIAS Inc. "Why We Need to Fix the Canadian Federal Regulatory Process."
www.riasinc.com

- Roller, N.F. 1975. Survey of Pesticide Use in Ontario, 1973. Economics Information. Economics Branch, Ontario Ministry of Agriculture and Food, Toronto, Ontario, Canada.
- Roller, N.F. 1979. Survey of Pesticide Use in Ontario, 1978. Economics Information. Economics Branch, Ontario Ministry of Agriculture and Food, Toronto, Ontario, Canada.
- Sekutowski, Dennis. 2003. In conversation. Development Officer, Engelhard Corporation.
- Terralink Horticulture Inc. MSDS webpage. <http://www.terralink-horticulture.com> Viewed on 11/17/03.
- United States Environmental Protection Agency. Federal Register Pesticides webpage. <http://www.epa.gov/fedrgstr/EPA-PEST/index.html> Viewed on 11/17/03.
- University of California Davis. The Extension Toxicology Network. <http://ace.orst.edu/info/extoxnet/> Viewed on 11/17/03.
- University of Manchester Environment Centre. <http://www.man.ac.uk/umec/extra/list.html> Viewed on 11/17/03.

Appendix A - CASE STUDY: Chronology of the process of PMRA approval of *Surround*

Surround crop protectant products were developed by the Engelhard Corporation of the United States and launched in 1999 for use on many horticultural crops. In the United States *Surround* has been recognized as regulated for use in organic production by the Organic Material Review Institute (OMRI). OMRI approval criteria include environmental safety, toxicity, and whether the product is non-synthetic.

Surround is comprised mainly of kaolin clay that has been modified. It is mixed with water and then sprayed onto crops at a rate of approximately 50 pounds of clay per acre. Kaolin is a very benign active ingredient and has been used for many different purposes including use as an ingredient in adhesives, toothpaste, polymeric coatings, rubber articles, cellophane, health products and toiletries, and antiperspirants.

The kaolin clay in *Surround* protects fruit by creating a covering on it that repels insects. It also disguises the host so that the insects do not recognize it and do not settle on the fruit to lay their eggs. The clay covering also provides a protective barrier from UV rays and sun damage, yet allows enough light through for continued growth and development of the fruit and vegetables. Therefore this product cannot only being utilized as a pest control product, for which it was initially developed, but also as a product to protect against sun damage.

This product is currently registered in the United States, Chile and Argentina as a pesticide and in other countries including New Zealand, Australia, Spain, Italy and Chile as a product to protect against sunburn. Fruit and vegetable producers in Canada would have benefited from this product, yet Engelhard Corp. had extreme difficulty registering it with the PMRA.

Because *Surround* is considered benign to the environment, registered for use in organic production in the United States, and that it is for use by small acreage producers, Dennis Sekutowski, Englehard's Commercial Development Officer, assumed that these qualities would aid in ensuring a swift and efficient approval process. Overall, Engelhard's experience with PMRA has left the manufacturing company frustrated, and skeptical about the effort put into the approval process in Canada for such a small market.

In February 1999, Sekutowski attempted to set up a pre-registration meeting with PMRA officials so that Engelhard would have a complete understanding of what was required to register the product from the onset of the process. The meeting did not take place until September 1999 due to numerous PMRA delays. Sekutowski was not very encouraged by PMRA's non-interest in beginning the registration process, and admits that due to the attitude of PMRA and the strict rules and regulations in Canada, he was ready to give up on the small market here.

Once the registration process got underway, efficacy testing became the major hurdle. Sekutowski and his team had to reproduce research that had been conducted for approval in the United States. Due to *Surround's* ability to repel insects from the host instead of killing them, standard efficacy trials do not necessarily show its effectiveness and the testing and subsequent approval was made complicated.

During this process in the United States, the Minor Crop Pesticide Management IR-4 Program worked with Engelhard Corporation to complete its submission package and oversaw the

approval process because the Program understood the value of a product that was non-toxic. The IR-4 Program was created by the FDA to promote registrations of newer, safer, minor-use products by helping development companies through the approval process, conduct trials and develop field safety data. With the help of the IR-4 Program, *Surround* was registered quickly and is used extensively in minor crop protection.

The IR-4 program also got EPA to accept kaolin as a biopesticide. All biopesticides have reduced data set requirements with EPA thus *Surround* did not require all of the extensive studies that a conventional pesticide would need for registration. PMRA does not have this distinction between conventional pesticides and biopesticides, thus for PMRA the company had to request waivers for all of these additional studies.

Canadian fruit and vegetable growers have voiced their opinions on the need for safe, non-toxic products such as this one. They also feel that in order to compete with imported products they should have access to the same newer, effective and safe pesticides that are used on US imports. With respect to *Surround*, the Ontario Ministry of Agriculture and Food (OMAF) agreed, lobbying for the registration of the product and putting pressure on the PMRA to be more efficient. OMAF contacted Sekutowksi and filed the research permit on behalf of Engelhard Corporation. OMAF also conducted the required Canadian field trials. Sekutowski admits that if it weren't for OMAF he would have given up on the registration process.

With respect to *Surround's* ability to protect against sunburn and sun damage, it took PMRA over a year to inform Engelhard that this use was out of its jurisdiction for regulation. There are no other regulatory bodies in Canada that deal with this issue either; as a result in June 2003 the product became available in Canada as a non-regulated sun damage protectant.

In July 2003, four years after Engelhard began actively seeking approval, PMRA finally approved *Surround* for use as an insecticide. Currently, Engelhard is awaiting approval on the label. *Surround* will initially be approved for use on pears and apples, although additional efficacy trials will be conducted so that it can be used on other fruits and vegetables. Currently the company is waiting for the spring to resume efficacy testing. Although approval has finally been given, Sekutowski stated that this has been a long and frustrating process and he endured a number of hurdles throughout his efforts to obtain registration of the product through the PMRA.

Appendix B - List of Active Ingredients, Oral and Dermal LD50 used on Ontario Corn and Soybeans 1973-1998

Pesticide	Oral LD50	Dermal LD50
2,4-D amines, salts, and acids	650	1150
2,4-DB	1100	800
acifluorfen	2025	>2000
acrolein	46	
agral 90	2460	4240
alachlor	1200	3500
amilon	5620	>3160
amino triazole + ammonium thiocyanate		
amitrol-t (cytrol)	>5000	200
amitrole (amino triazole)	>5000	200
atrazine	3080	7500
bentazon	1100	2500
bromoxynil	230	>3660
butylate		>2000
chloramben		>3160
chlorbromuron	2150	
chlorimuron-ethyl	>5000	>2000
chloroxuron	3000	
clomazone	2077	2000
cyanazine	149	>1200
dicamba	1040	>1000
dicamba + mecoprop +2,4-D amine		
dichlofop-methyl	598	>5000
dimethenamid	2140	
dinitramine	3000	
diquat	420	500
EPTC	1630	1460
EPTC/R25788		
ekko	3080	7500
ethalfluralin	10000	
fenoxaprop-ethyl	2357	>1000
fenoxaprop-p-ethyl	3040	>2000
fluazifop-butyl	3888	>2400
glyphosate	4320	>7940
imazethapyr	>5000	>2000
kil-mor (Banvel-3)	1040	>1000
linuron	2250	
linuron + atrazine		
MCPA	850	>1000
MCPB	680	
mecoprop	1070	>4000

mecoprop salts	930	900
metobromuron	2000	
metolachlor	2780	>3170
Metribuzin	2141	
Monolinuron	2100	
		168
monlinuron + dinoseb	33 (dinoseb)	(dinoseb)
Nicosulfuron	>5000	>2000
Outfox	1400	
Pendimethalin	1250	5000
quizalofop-ethyl	1440	2052
Rimsulfuron		
Sethoxydim	2850	5000
Simazine	>5000	>10000
Tenoran	3700	1000
thifensulfuron-methyl	5000	2000
Trifluralin	3700	>5000
trimethyl sulfonium salt of glyphosate	4320	>7940
Vernolate	1710	>2995

(Source: Ontario Ministry of the Environment, Pesticides Section. 1986. Pesticides Safety Handbook.; and The Extension Toxicology Network. <http://ace.orst.edu/info/extoxnet/>)