# THE PRE-RELEASE REGULATORY FRAMEWORK<sup>1</sup>

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<sup>&</sup>lt;sup>1</sup> This paper is based, in part, on a study paper prepared for the Law Reform Commission of Canada by J.F. Castrilli and Toby Vigod entitled *Pesticides in Canada: an Examination of Federal Law and Policy* (Ottawa: LRCC, 1987).

### I. INTRODUCTION: THE NATURE OF THE PROBLEM

During the past two decades, there has been increasing concern over the environmental and human health effects posed by the widespread use of pesticides for food and fibre production. First, pesticide sales and use, both in Canada and world-wide, have increased substantially, if not dramatically. According to federal officials, between 1971 and 1981 total pesticide sales in Canada increased twelvefold in current dollars (\$57.3 million to \$698 million) and more than fourfold when adjusted according to the Statistics Canada price index for pesticides (\$57.3 million to \$243 million). In 1975, at least 10 million acres of land on the Canadian Prairies were treated with herbicides. By 1978, this had increased to at least 15.5 million acres. In 1976 alone, Canada imported almost 117,000,000 pounds of pesticides from the United States. This was almost as much as that imported from the United States by twenty Latin American republics or Western Europe. Unfortunately, information on exactly which pesticides are used, by whom, at what application rates, on how much acreage, where, and in what quantities is not systematically available nationally.

Second, in conjunction with the increasing quantities sold and used, the public is concerned with the fact that the use of pesticides involves the deliberate application to land or water of chemicals which are intended to be poisonous to selected organisms.

Generally, two main categories of undesirable effects resulting from pesticide use have been identified:

- (1) the development of resistance in pest species; and
- (2) the impact on non-target species and ecosystems.

With respect to non-target impacts, the United Nations Environment Program has stated that "even when properly used, chemical pesticides have a number of unavoidable side-effects." The Canadian public has been witness over the past few decades to the result of some of these "unavoidable side-effects":

- (1) In New Brunswick, during 1975, at least 3 million birds were killed from aerial spraying of approximately 7 million acres of forest with phosphamidon (later discontinued) and fenitrothion to combat the spruce budworm; vi
- (2) A 1983 survey conducted by the Alberta Department of Agriculture found that 10 percent of Alberta grain farmers may be experiencing pesticide poisoning symptoms every year. Government officials believe this may represent approximately 5000 grain farmers in the province; vii
- (3) In 1985, a Canada-Ontario report on pollution of the St. Clair river concluded that of the 2.5 million kilograms of agricultural pesticides used annually in the land draining into the Detroit and St. Clair rivers' connecting channels, approximately 70% of

these pesticides were identified as potentially environmentally hazardous. viii

These are but a few examples from across Canada. They indicate, however, that problems posed by pesticides are national in scope and the sources or pathways of possible contamination are numerous including air, water, land, food and drinking water. Moveover, problems have arisen at many stages in the regulatory process including registration, use and disposal.

Given the widespread use of pesticides in this country, many segments of society have an interest in the objectives and effectiveness of the regulatory and enforcement process for pesticides in Canada. This paper will focus on the existing federal framework for the regulation of pesticides and prospects for reform.

#### II. THE FEDERAL REGULATORY CONTROL REGIME

#### a) Overview

The need for a more systematically preventive regime for pesticide control than is provided by the principally reactive common law (or civil law) system has resulted in the development of a complex network of federal and provincial statutory control efforts on such products. Emphasis in these remarks will be on federal law, and in particular the *Pest Control Products Act* (PCPA), ix because it is the principal legal instrument establishing what pesticides may be registered in Canada and what uses of such products may be allowed.

Federal intervention in the market place to control pesticides dates from the 1920s and 1930s when the principal public concern centered on appropriate labelling requirements under which pesticides could be imported, manufactured or sold. The purpose of such legislation was to ensure product efficacy and to avoid fraud in product representation. It was not until the late 1960s, after the advent of synthetic organic chemicals in the 1940s, that the *Pest Control Products Act* of 1939<sup>xi</sup> was viewed by federal officials as needing amendment to increase government authority over pesticides substantially beyond the originally limited purposed of controlling product efficacy and misrepresentation. The statute that resulted from Parliament's efforts in the late 1960s is the statute that governs pesticides in Canada in the late 1980s. As a result, the statute lags far behind other environmental legislation in many respects.

The heart of the Act is the registration requirement. Section 4 of the Act prohibits any person from importing or selling any control product unless it has been registered, packaged and labelled according to prescribed conditions. Currently, over 5,000 products comprising 460 active ingredients are registered for use in Canada.

Pesticides may only be registered if the Minister of Agriculture is of the opinion that the control product has merit or value for the purposes claimed when used in accordance with label directions. In addition the pesticide's use must not lead to an "unacceptable risk of harm" to public health, plants or the environment. "Unacceptable risk" is not defined in the Act or regulations.

The company applying for registration must provide the Minister with sufficient information for a determination to be made of the product's "safety, merit and value". Generally, these scientific test studies must address occupational safety and exposure, residues, toxicity and related matters. The burden of proof is on the company to demonstrate that its product meets the tests of safety, merit and value.

Presently, Health and Welfare Canada (HWC), Environment Canada and Fisheries and Oceans Canada review and comment on the scientific data submitted by the applicant. Apart from administrative memoranda of understanding between HWC and Environment Canada and Agriculture Canada, there is no formal recognition of these three Departments' role in the PCPA.

The final decision rests with the Minister of Agriculture. There is at least a perceived conflict of interest for the Department as both a promoter of food production, and the protector of the public from unsafe pesticides and practices. The situation parallels the experience in the United States in the late 1960s when federal pesticide law was still administered by the U.S. Department of Agriculture. The authority for registration and control of pesticides was transferred to the U.S. Environmental Protection Agency in 1972.

In Canada, in the early 1980s, a coroner's jury in British Columbia and federal advisory consultants called for the removal of the PCPA from Agriculture Canada's sole authority. Suggestions have ranged from transferring authority to the Departments of Environment or Health and Welfare Canada to creating a stand-alone administrative agency analogous to the CRTC.

The Canadian Environmental Law Association (CELA) recently urged the House of Commons Standing Committee on Environment and Forestry currently conducting hearings into pesticide issues to seriously consider this matter. The determination of that issue will require a consideration of whether protection of Canadian public health and safety and the promotion of food production are best undertaken by one department which may be subject to political pressures and have fragmented expertise or by an independent agency which may be more insulated and be able to combine the relevant expertise.

In any event, the question of who administers the Act should not cloud or delay an examination of the substantive legislation which in my opinion is long overdue for major overhaul and reform.

### **B.** The Pesticide Registration Process

I would like to focus on just three aspects of the registration process: the adequacy of testing requirements; temporary registrations and the meaning of the regulatory standard of "unacceptable risk."

# 1. The Adequacy of Testing Requirements and Practices

Presently the federal government requires extensive data on animal toxicity before registering a pesticide. Both the active ingredient and the formulated control product are tested. Much of the safety data is generated either by pesticide manufacturers or private laboratories in other countries. Public confidence was much shaken in the reliability of this safety testing data in the late 1970s and early 1980s as a result of the Industrial Bio-test (IBT) Laboratories affair, in which many of the toxicological tests performed under contract from the pesticide industry by IBT in the U.S. were determined to be invalid: 86% of the tests IBT performed to determine if the pesticides tested caused birth defects were invalid; 83% of the tests for cancer were invalid; 79% of the tests for reproductive problems were invalid. Many of these invalid tests were also originally used to support, in whole or in part, the registration of over 100 pesticides in Canada.

From this experience, it has been argued that the U.S. did not have effective control or monitoring capacity over IBT, a large contract testing firm. It is also clear, however, that Canada lacked a system of independent testing checks, since over 100 pesticides tested by IBT were able to gain registration in this country. The IBT experience generally has served to underscore the need for ensuring good laboratory practices in firms doing pesticide testing. In 1979, Health and Welfare Canada entered into an inter-agency agreement with the U.S. FDA regarding good laboratory practices, and now have their own guidelines, though they are of no legal effect. The legacy of the IBT affair, however, is the recognition that Canada cannot ensure that these laboratories are producing quality work because most testing facilities are in the U.S. Moreover, according to a 1982 U.S. Congressional subcommittee report, even U.S. EPA "lacks information on how effective a deterrent the FDA audit program is against poor science in pesticide experiments."

In the area of environmental fate testing, the chemical industry has argued that field testing under controlled conditions is undertaken in Canada and submitted as part of the registration application. Damage to the Canadian environment has nonetheless been documented and attributed by federal environmental agencies to the lack of proper field testing of control products in the area of proposed use prior to registration. As recently as 1985, federal agencies reported that 25% of groundwater samples taken in Prince Edward Island showed residues of the insecticide, Temik. P.E.I. relies 100% on groundwater supplies as a source of drinking water. Indeed, Agriculture Canada stated in a July 1987 trade memorandum that it:

would like to see new data, particularly environmental studies, [because] with the increasing awareness of problems caused by pesticides in the environment, particularly in groundwater, more research in this area is clearly needed. xvi

In sum, improvement of the adequacy of testing requirements, controls and practices for new pesticides should be high on the agenda of federal regulatory reforms. This may include good laboratory practices legislation; independent government testing or verification capability and mandatory testing for environmental parameters such as groundwater contamination potential.

# 2. Departures from Full Registration: Temporary Registrations

Under the PCPA there are a number of ways in which pesticides may be sold or used in Canada without having to meet the full registration requirements of the Act. One method is the temporary registration of pesticides, where the applicant agrees to produce additional information on the product or where it is to be sold only for emergency control of infestations. This departure from the Act's full registration requirements is meant to meet a legitimate objective, such as controlling emergency pest situations. However, the possibility exists for abuse of this process. Current regulations under the PCPA authorize a temporary registration for one year provided the applicant meets the conditions specified above. Where a temporary registration is refused, it now appears that an applicant can trigger a hearing before a review board established under the regulations. XVII

During the IBT affair, at least one pesticide with pivotal invalid IBT data, including a three generation reproduction study, was granted temporary registration for forestry use for several years. xviii

It is arguable that the renewing of temporary registrations for several years in a row constitutes a back door to full registration for less than completely evaluated products. Moreover, pesticides that have at one time been temporarily registered have been the subject of negligence actions for inadequate testing. The 1984 Salter report to the federal Minister of Agriculture also noted that: "a system of temporary or emergency registration is easily misused to circumvent the full assessment now done before registration."

Early in 1988, the federal Department of Agriculture received a legal opinion indicating that the temporary registration provision should not be used where there are gaps in health and safety or environmental fate data. This opinion said that the Department's method of granting this category of temporary registrations for the past 15 years was wrong. However, rather than amending the regulations to remedy this perceived gap, the Department began to issue full registrations to companies with a set term of expiry. Once this became known, a number of environmental groups raised concerns about the legality of this new procedure. They argued that the Minister could not fulfil his mandate to evaluate the safety, merit and value of a product without receipt of a full data package. \*xxi

On May 19, 1988 the Department amended section 17(1)(a) to clarify this situation and returned to its practice of granting temporary registrations where data gaps existed. xxii

The use of similar departures from full registration requirements is not unique to Canada. Other jurisdictions, such as the United States also authorize a number of routes for the sale and use of pesticides that have not gone through a full registration procedure. Congressional investigations have suggested that these approaches were being used as vehicles for circumventing the safety evaluation requirements of full registration.

Because the possibility exists for misuse of the temporary registration procedure in attempts to avoid delays in registration and the provision of full environmental health and safety tests, the framework in which temporary registrations are issued must be reevaluated.

## 3. Unacceptable Risk of Harm

The key criterion under which the Minister of Agriculture may refuse to register a pest control product is where he is of the "opinion" that the use of the pesticide "would lead to an unacceptable risk of harm to [. . .] public health, plants, animals or the environment". The standard of "unacceptable risk of harm" is not defined in the Act or Regulation. Indeed, this standard only appears in the Regulation. A heated debate has taken place over the last few years as to the meaning of this standard and whether it mandates a risk-benefit or cost-benefit analysis to take place before a decision is made. While the Regulation clearly contemplates an evaluation of risk, it is not apparent on its face that it was intended to embrace the use of cost-benefit analysis as an instrument for pesticide decision-making. Agriculture Canada officials have testified in the Alachlor Review Board hearing that "there is no obligation to balance risks against benefits, nor is there a requirement to use formal risk-benefit analysis. The emphasis of section 3 of the PCPA is placed on demonstrating safety." The Alachlor Review Board muddied this conclusion by claiming it agreed with the federal government that the Minister is entitled to balance risks and benefits but needs not do so. The Board rejected the contention of Monsanto Canada Inc. that the Minister must balance risks and benefits in reaching a decision.

Federal pesticide law in other jurisdictions is clearly different in this regard. The U.S. Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires U.S. EPA to determine whether a pesticide causes "unreasonable adverse effects on the environment." This is further defined by the statute to mean "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide." Thus, it is clear that FIFRA requires the weighing of risk-benefit or cost-benefit considerations. This standard in FIFRA is different than tests set out in other U.S. environmental legislation which contemplate an examination of "risk" rather than a weighing of risks and benefits.

In practice, the Canadian government has been exploring the feasibility of such approaches. The agricultural chemical industry has also gone on record as embracing the use of risk-benefit analysis in pesticide registration decisions. With equal vigour the national environmental community has opposed this development. The problems identified with risk-benefit or cost-benefit analysis include:

- (a) uncertainties of quantifying risks, particularly given the delayed effects of pesticide toxins and the lack of epidemiological data;
- (b) the fact that the state of the art in quantifying benefits is primitive; studies estimating benefits may mislead agency decision-makers and the public, according to U.S. Congressional investigators;

- (c) the difficulty of balancing risks and benefits that are not equitably distributed and that favour some to the detriment of others; and
- (d) the inherent impossibility of placing a monetary value on clean water, air or good health. xxvii

It is also fair to say that the national environmental community has not been receptive to suggestions that risk-benefit analysis is a pressing need for the pesticide regulatory process, when its own agenda for opening up the process has largely gone unmet. That community perceives that the introduction of risk-benefit analysis into the process in the absence of other reforms can only serve to further lock-out environmental and citizen groups, without necessarily improving the decisions themselves.

Whether "unacceptable risk" should be determined with or without consideration of benefits, and if so, in what manner, is an issue that Parliament should resolve, following full public debate. My position is that a statute such as the PCPA which has fundamental impacts on the health of Canadians should have safety as its principle focus and not adopt a risk-benefit approach.

Unfortunately, the Free Trade Agreement may have taken us further along the path to adopting the American approach. Schedule 7 to the Agriculture chapter requires that Canada and the U.S. work towards "equivalency" in the "process of risk/benefit assessment." Since we presently do not have a statutory requirement to weigh risks and benefits, this clause would seem to move us in the direction of the U.S. approach, foreclosing the possibility of any debate in Canada as to whether risk/benefit assessment should be incorporated into our law. The deal also commits us to moving towards equivalency of regulatory policies concerning tumour-causing pesticides. While the U.S. does have a cancer policy, Canada presently does not. Again the trade agreement would seem to dictate that we adopt the made in U.S. policy. This is disturbing because in 1982, a congressional committee argued that U.S. EPA had changed the scientific principles underlying its risk assessment of carcinogenic pesticides, resulting in an approach that permitted greater exposure to cancer-causing agents. The committee noted, "more significant, however, is that the agency's use of [certain] approaches to decision-making appears systematically slanted towards less stringent regulation of suspected carcinogens."

# C. The Re-evaluation Process: The Problem of Ensuring the Safety of Existing Pesticides

Once a pesticide is registered under the PCPA, it retains its registration for a five-year period that may be renewed upon application to the Minister. At any time during this period a registered pesticide may be subjected to re-evaluation.

Two factors generally trigger the re-evaluation process: (1) a new study showing potential

problems not previously recognized; or (2) the need to bring the data base up to date for a long-registered pesticide. However, there are a number of problems with the existing re-evaluation process. First, the process is too slow. As of mid-1982, only 45 of the approximately 600 then existing pesticides active ingredients had been or were undergoing re-evaluation. These include the phenoxy herbicides, chlorophenols and fumigants. According to federal officials, the Department of Agriculture is capable of taking on only 10 to 15 chemicals a year in the re-evaluation process. Even assuming that re-evaluations for each chemical can be completed within one year and that no new chemicals are registered, it would appear that it will take between 30 to 50 years for the government to complete re-evaluation of just the remainder of the currently registered active ingredients. Health and Welfare Canada officials have suggested that "a more vigorous cyclical re-evaluation of all registered pesticide products should be pursued." They have suggested a 5 or 7 year cycle so that industry would keep its testing and data base more current. \*xxx\*

Second, setting priorities for re-evaluation is also a problem. Examination by Canada has been made of both the U.S. Registration Standards and the Special Review programs. The Registration Standards program makes broad regulatory decisions at one time for a group of pesticide products containing the same active ingredient, rather than on a product-by-product basis. Special Review, on the other hand, deals with a pesticide for which evidence suggests that it may pose "an unreasonable risk to man or the environment[...]" The burden at all times remains on the proponent of continued registration to demonstrate that the product does not pose such risks. SXXXII

These programs are not without their own problems within the U.S. regulatory framework. However, cyclical re-evaluation and prioritization of pesticides for review would appear to be fundamental areas in need of reform under federal law in Canada. The product specific registration (PSR) program of Agriculture Canada has not proven helpful in this regard. Federal officials, as recently as July 1987, indicated that while PSR has provided unlimited protection for data, it has provided "little incentive to manufacturers to keep data current and in some cases, has even discouraged submission of new data. Data bases for older compounds are often inadequate, and even partial additions would be an improvement."

# D. Suspension and Cancellation of Pesticide Registrations: The Role of the Review Board

The registration of a pest control product may be suspended or cancelled by the Minister of Agriculture when "the safety of the control product or its merit or value is no longer acceptable to him." Suspension of a registration is the less extreme of the two regulatory options as it affects the registrant, not the retailer or user. If the control product is only suspended, the registrant cannot distribute any further shipments of the suspended product. However, material that is already at retail outlets prior to the suspension may by legally sold.

Under the PCP Regulations, suspension or cancellation may be appealed by the registrant and a hearing requested within 30 days of a Minister's notice of intention to take one of the two regulatory actions. The Minister must appoint a Review Board to hold the hearing and the Board must give the registrant "and all other persons who may be affected by the subject matter of the hearing an opportunity to make representations to the Board [...]" The Board must prepare a report and file it with the Minister but can only make recommendations. The final decision rests with the Minister who can, after considering the Board's report, take any action he deems advisable and notify the registrant of his decision.

To date, there have been very few instances of suspension or cancellation of product registrations under the Act. Since the regulations were promulgated in 1972, Review Boards have been empanelled to hear a matter in only three instances. The Alachlor case was the first hearing that actually lasted more than a few days. In that case, the Board sat for 41 days and heard evidence from over 50 witnesses. I represented a farmwife whose wells had been contaminated by alachlor in the summer of 1985. At the hearing, we supported the Minister's decision to ban alachlor. Alachlor had been one of the pesticides whose registration had been supported, to a significant degree, by studies carried out by IBT. The pesticides manufacturers, including Monsanto in this case, were given the opportunity to repeat these studies in order to ensure that the product's registration would be maintained.

Starting in 1982, Monsanto submitted a number of replacement studies to Health and Welfare Canada detailing the toxicological effects of its chemical. These studies, done at two different laboratories, showed that alachlor caused multiply tumours in multiple sites in both sexes of test animals, at extremely low doses. Health and Welfare Canada raised concerns as early as 1982, but it was not until February 5, 1985 that Agriculture Canada actually decided to cancel alachlor. It should be noted that during that 3 year period, while there were numerous meetings between Monsanto, Agriculture Canada and Health and Welfare Canada officials, the public was virtually locked out of this process. Presently, the statute contains no provision to allow the public to trigger a re-evaluation of a pesticide.

The Review Board issued its report on November 13, 1987, recommending the reinstatement of alachlor. The Board made a number of findings including the fact that alachlor was a potential human carcinogen, and that the economic impact of maintaining the ban would be minor. Specifically, the Board noted that Monsanto's economic analysis was "suspect." However, the Board then went on to find that metolachlor, the alternative product, was also a carcinogen and that therefore the only so-called "equitable" options for the Minister to consider were to either cancel both chemicals or leave them both on the market. Since, in the Board's opinion, exposure to alachlor would be within a reasonable margin of safety, it recommended to the Minister that alachlor's registration should be reinstated. The Board's report met strong criticism from the national environmental community and Health and Welfare Canada and raised a number of issues which emphasized the need for regulatory reform.

Specifically, the Minister was urged to reject the Board's findings on metolachlor, as there was no data base before the Board to enable it to make that determination. Over 77 volumes of material had been filed by Monsanto pertaining to alachlor, including all raw data of the various toxicological tests. However, because this was not an inquiry into metolachlor, there was no such similar data base filed by Ciba-Geigy. In fact, Health and Welfare Canada, in its review of the material, had concluded that metolachlor was neither an animal nor a human carcinogen. In contrast, at the hearing a Health and Welfare Canada toxicologist had testified that: "In the global sense, I know of no chemical with which I have been involved where the evidence has been more convincing than it has been with alachlor."

It is submitted that the approach of comparing a cancelled product with other alternative pesticides should be specifically curtailed by statute. To do otherwise would mean that review board hearings could continue for years evaluating thousands of pages of material on any number of possible alternative pesticides. As well, the company whose product was actually cancelled would be able to try to take the heat off its product by raising doubts about the safety of other pesticides. It should also be noted that at the front end of the process, each product is evaluated on the basis of whether it meets the test of safety, merit and value. If evidence is later found to cast doubt on, for example, a product's safety, and it's registration is then cancelled, in our opinion, the product can only be rehabilitated by showing that it is safe and not by casting doubt on another product's safety. To do otherwise would bring the regulatory process in dealing with toxic chemicals to a standstill.

To remove any uncertainty, the PCPA should be amended to provide that where a product is cancelled on safety grounds, the subject matter of any review board hearing should be whether the cancelled product is safe.

Further, while the company who is appealing a cancellation or suspension decision should be allowed to set out the grounds of its appeal, it should not be allowed to broaden the scope of the inquiry beyond an examination of whether its specific product is safe.

The Board's report was also criticized for applying a "margin of safety" approach to a potential carcinogen. Health and Welfare Canada specifically noted in its letter of November 27, 1987 to Agriculture Canada, that "calculation of margins of safety does not represent the generally accepted approach to carcinogen risk assessment." In fact, the U.S. EPA's Cancer Assessment Group, the World Health Organization and Health and Welfare Canada all accept the principle that there are no safe threshold levels for carcinogens. Safety margins are usually applied to non-cancer end points and are not used in carcinogen risk assessment. Health and Welfare Canada concluded that the risk of cancer from exposure to alachlor was in the order of one in a thousand to one in ten thousand which, in their view was "appreciable."

On January 27, 1988 the Minister of Agriculture made a decision to maintain the ban on alachlor. He indicated that in his opinion the use of alachlor represents an unacceptable risk of harm to public health. He noted the fact that both Health and Welfare Canada and the Alachlor Review Board agreed that alachlor is an animal carcinogen and should be considered to be a potential human carcinogen for regulatory purposes. He also accepted Health and Welfare Canada's prudent approach to uncertainties and assumptions inherent in developing estimates for the purposes of decision making. Finally he noted that metolachlor, the alternative product was not considered to be a carcinogen by Health and Welfare Canada, and that a continued ban of alachlor would only be a small loss to farmers. \*\*xxxvi\*\*

The Alachlor case did not end after the Minister's decision. In the spring of 1988, Monsanto applied to the Federal Court of Appeal to set aside the decision of the Minister and reinstate the recommendations of the Alachlor Review Board. On December 6, 1988, the Federal Court of Appeal dismissed Monsanto's application. Finally, in May 1989 the Supreme Court of Canada denied Monsanto's leave to appeal. \*\*xxxvii\*\*

Monsanto's lobbying efforts have led both the House of Commons Standing Committee on Agriculture and the Standing Senate Committee on Agriculture and Forestry to consider the decision-making process involved in the alachlor case.

#### E. The Role of the Public in the Process

The PCPA is silent on the role of the public in the registration process for new pesticides as well as the re-evaluation of already registered pesticides. Public notice of a registration application for a new product or use is not required under the Act; nor is public access authorized to health and safety tests relied on in support of the registration application. While a pesticide company is guaranteed an administrative appeal to a review board under the regulations if a pesticide registration is denied or if a product is suspended or cancelled, no such right is provided to the public when a registration application is granted or maintained.

No statutory opportunity exists for the public to trigger a re-evaluation of a specific pesticide

product. Moreover, public intervention in review board proceedings, while permitted, is highly expensive and is effectively impossible without intervenor funding.

It is clear that the PCPA lags far beyond other public health and environmental statutes in providing for a meaningful role for the public in the process.

#### **CONCLUSION**

The increasing use of pesticides in recent years has coincided with a rise in environmental and public health concerns respecting these chemicals. The PCPA, which has not been significantly amended since 1969, and before that, 1939 is long overdue for major reform. Events over the last two decades have shown that health and the environment have been vulnerable to potential and actual damage arising from pesticides. Despite attention to the problem at all levels of government, the need for law reform, especially federal law reform has become evident. The focus of such law reform should be to both increase governmental authority to act and to provide, as a matter of law, an opportunity for individuals to participate in governmental decision-making and, where necessary, have redress to the courts.

#### **POSTSCRIPT**

On September 30, 1988, Agriculture Minister Don Mazankowski announced that a review of Canada's pesticide registration system would be undertaken. This announcement was in response to concerns with the existing system raised by a number of interested groups, including farmers and environmentalists. Ghislain Leblond, newly appointed Associate Deputy Minister of Agriculture, was appointed as Chairperson of a multistakeholder Pesticide Registration Review Team in March 1989. \*\*xxxviii\*\* The 12 members of the Review team included representatives from the agriculture and forestry sectors, the Canadian Environmental Network (CEN), Pesticide Registration Review Caucus, groups interested in biological controls/alternatives, the Crop Protection Institute of Canada, the Canadian Manufacturers of Chemical Specialties, the Consumer's Association of Canada, the Canadian Labour Congress and the public health sector. The Review Team issued a draft report in July 1990\*\*xxxix\* and public hearings were held across Canada during the fall of 1990. The Review Team heard from over 400 people and received 500 written submissions. The Final Report, "Recommendations for a Revised Federal Pesticide Management Regulatory System," was submitted to the Minister of Agriculture on December 21, 1990.\*\*

Only the labour representative dissented.

The report represents a significant shift in focus to ecologically sound, preventative approaches to pesticide management problems and encourages increased public input to the system. The Report specifically recognized the need for a reduction of pesticide use in Canada. To facilitate this, Agriculture Canada will establish a "Pest Management Promotion Office" which would set targets for pesticide reduction in all sectors. The Office will gather and disseminate data from

around the world, educate extension and field workers and initiate research on ecologically sound pest management strategies that will replace the use of pesticides, wherever possible.

The Report also recommended that decisions to register pesticides will be transferred from Agriculture Canada to an independent Pest Management Regulatory Agency reporting directly to the Minister of National Health and Welfare. Other recommendations included:

Access to information on health and safety data regarding a registered pesticide through the right of any citizen to all health and safety data providing they sign a confidentiality undertaking;

the right of citizens to appeal a decision to register a pest control product;

an export policy that would, subject to appeal, clearly not allow the export of cancelled or suspended products to other countries;

the creation of a national database for collecting information on pesticide use.

While most of the recommendations were clear improvements over the status quo, the environmental caucus registered concern in the report about the creation of a new registration type: user requested minor use of pesticides not registered in Canada while studies needed for completion of Canadian registration were being conducted.

The final chapter deals with implementation of the Report. It recommends the establishment of an advisory committee comprised of stakeholders familiar with the intent of the recommended system and the establishment of a legislative drafting committee. The Review Team is still waiting to hear from the Minister of Agriculture as to whether its recommendations will be implemented.

#### **FOOTNOTES**

- i. Interview with Phil Blagdon, Pesticides Officer, Environment Canada, Environmental Protection Service, Ontario Region, Toronto (27 May 1983).
- ii. The Honourable Eugene F. Whelan, former federal Minister of Agriculture, notes for an address to the CACA 24th annual conference (Ottawa, Ontario: 15 September 1976). Agricultural Institute of Canada, *Pesticides, Agriculture and the Environment* (Ottawa: AIC, January 1981) at 4.
- iii. US GAO, Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential, Report to Congress by the Comptroller General of the United States, CED-79-43 (Washington, D.C.: US GAO, June 1979) at 87.
- iv. One of the more comprehensive provincial surveys is the Ontario survey of pesticide use, begun in 1973. See, for example, *Survey of Pesticide Use in Ontario*, 1983 (Toronto: OMAF, September 1984). However, it is only published once every five years. Other provincial surveys, while they are published more frequently, offer only very general information such as total quantities of a particular pesticide sprayed by air or on the ground, in the province as a whole. See, for example, Environment New Brunswick, *Pesticide Usage in New Brunswick* (Fredericton, N.B.: ENB, 1982). Even Statistics Canada's annual pesticide sales surveys were discontinued in 1977.
- v. United Nations Environment Program, *The State of the Environment*, 1979 (Nairobi, Kenya: UNEP, 1979) at 10.
- vi. P.A Pearce, D.B. Peakall & A.J. Erskine, "Impact on Forest Birds of the 1975 Budworm Spray Operation in New Brunswick" in Environment Canada, *Canadian Wildlife Service* (March 1976) 62 Biology Notes 1 at 1-3. See also D. J. Forsyth, CWS, "Evaluation of Pesticides by the Canadian Wildlife Service" (address at the Canadian Council of Resource and Environment Ministers Workshop on Pesticide Use in Canada, *Proceedings*) (Ottawa: CCREM, 1982) at 97.
- vii. P. McLoughlin, "Poisoning Mentioned by 1 in 10" (26 January 1984) Western Producer 1.
- viii. Environment Canada and the Ontario Ministry of the Environment, *Pollution of the St. Clair River (Sarnia Area)*, Situation Report prepared under the Canada-Ontario Agreement respecting Great Lakes Water Quality) (Toronto: EC/OME, November 1985) at 5.
- ix. R.S.C. 1985, c. P-9.
- x. See T. Curren, Science and Technology Division, Research Branch, *Evaluation and Regulation of Pesticides in Canada* (Ottawa: Library of Parliament, September 1980) at 5.
- xi. S.C. 1939, c. 21.
- xii. Pest Control Products Regulations, C.R.C., c. 1253 [hereinafter PCP Regulations] s. 18(c).
- xiii. *Ibid.*, s. 18(d)(i) and (ii).
- xiv. US EPA, Office of Pesticide Programs, *Summary of the IBT Program* (Washington, D.C.: US EPA, July 1983) at l.
- xv. U.S. House of Representatives, Committee on Agriculture, *EPA Pesticide Regulatory Program Study*, Hearing before the Subcommittee on Department Operations, Research, and Foreign Agriculture, 97th Cong., 2d Sess. (17 December 1982) at 209.

- xvi. Trade Memorandum Re: Product Specific Registration and Proprietary Rights to Data T-1-249 (Agriculture Canada, July 8, 1987) at 2.
- xvii. Monsanto Canada Inc. v. Minister of Agriculture (1986), 1 F.T.R. 63 (F.C.T.D.).
- xviii. Correspondence from the Honourable E. F. Whelan, then Federal Minister of Agriculture to the Honourable J.E. Miller, Alberta Minister of Energy and Natural Resources, Ottawa (1 November 1982) and correspondence from the Honourable M. Begin, then Federal Minister of National Health and Welfare to the Honourable N. Hardy, Chairman, CCREM, Ottawa (26 October 1982).
- xix. E.g., Willis v. F.M.C. Machinery and Chemicals Ltd. (1976), 68 D.L.R. (3d) 127 (P.E.I.S.C.).
- xx. L. Salter & W. Leiss, Consultation in the Assessment and Registration of Pesticides: Final Report and Recommendations to the Minister of Agriculture (Ottawa: 31 March 1984) at 10.
- xxi. Correspondence from the Canadian Coalition for Alternatives to Pesticides to the Honourable J. Wise, Minister of Agriculture, Ottawa (May 25, 1988).
- xxii. SOR/88-285. The amended s. 17(1)(a) provides that "the applicant agrees to endeavour to produce additional scientific or technical information in relation to the control product". The former section 17(1)(a) had read "[...]in relation to the use for which the control product is to be sold".
- xxiii. PCP Regulations, s. 18(d)ii).
- xxiv. *Alachlor Review Board Hearings* (Toronto: November 1986) Exhibit 155 at 6, witness statement of W. Ormrod, Director, Pesticides Division, Agriculture Canada.
- xxv. Alachlor Review Board, *Report* submitted to The Honourable J. Wise, Minister of Agriculture (Ottawa, October 1987) at 26.
- xxvi. Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C., s.136, s. 2(bb) (1978).
- xxvii. See for example, U.S. Senate and House of Representatives, *Risk-Benefit Analysis in the Legislative Process: Summary of a Congress-Science Joint Forum,* prepared by the Congressional Research Service, Library of Congress for the House Subcommittee on Science, Research and Technology of the Committee on Science and Technology and the Senate Subcommittee on Science, Technology, and Space of the Committee on Commerce, Science and Transportation, 96th Cong., 2d Sess. (March 1980) at 3-6.
  - Similar problems have been identified with respect to cost-benefit analysis. U.S., House of Representatives, *Cost-Benefit Analysis: Wonder Tool or Mirage*, Report together with Minority View by the Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce, 96th Cong., 2d Sess. (December 1980) at 1-36.
- xxviii. The Canada-U.S. Free Trade Agreement, Ottawa, 1987 at 129.
- xxix. U.S. House of Representatives, Committee on Agriculture, *EPA Pesticide Regulatory Program Study*, Hearing before the Subcommittee on Department Operations, Research, and Foreign Agriculture, 97th Cong., 2d Sess. (17 December 1982) at 87.
- xxx. Interview with C.A. Franklin, Chief, Pesticides Division, Environmental Health Directorate, Health and Welfare Canada, Ottawa (28 June 1983).
- xxxi. US EPA, Office of Pesticides Programs, *Registration Standards Program* (Washington, D.C.: US EPA, 1983) at 1.

- xxxii. US FIFRA Regulations, 40 CFR, Part 162, Subpart A (registration, reregistration and classification procedures), section l62.11 (criteria for determinations of unreasonable adverse effects) [hereinafter 40 CFR 162.11].
- xxxiii. Agriculture Canada, Trade Memorandum, T-1-249 (July 8, 1987) at 3.
- xxxiv. PCP Regulations, s. 20.
- xxxv. PCP Regulations, s. 25(1).
- xxxvi. Correspondence from the Honourable J. Wise to T. Vigod, Ottawa (27 January, 1988).
- xxxvii. Monsanto Canada Inc. v. Canada Minister of Agriculture (1988), 98 N.R. 154 (F.C.A.); (1989), 100 N.R. 158 (S.C.C.).
- xxxviii. Agriculture Canada, "Pesticide Registration Review Appointments" (Ottawa: Agriculture Canada, March 21, 1989).
- xxxix. Pesticide Registration Review, A Proposal for a Revised Federal Pest Management Regulatory System (Ottawa: PRR, July 1990).
- xl. Pesticide Registration Review, *Recommendations for a Revised Federal Pest Management Regulatory System* (Ottawa: PRR, December 1990).