156

Publication #156
ISBN# 978-1-77189-573-6

FEDERAL PESTICIDES LAW: PROSPECTS FOR REFORM

SUBMISSIONS TO THE STANDING COMMITTEE ON ENVIRONMENT AND FORESTRY

by

Joseph F. Castrilli * and Toby Vigod+
of the Ontario Bar

February 25, 1988

* DOUGLAS G. EDWARD
Barristers & Solicitors
Suite 707, Queen's Square Bldg.
24 Queen Street East
Brampton, Ontario
L6V 1A3

+ Counsel
CANADIAN ENVIRONMENTAL
LAW ASSOCIATION
243 Queen Street West
4th Floor
Toronto, Ontario
M5V 1Z4

FEDERAL PESTICIDES LAW: PROSPECTS FOR REFORM *

TABLE OF CONTENTS

* These submissions are based, in part, on the study paper prepared for the Law Reform Commission of Canada by the authors entitled, Pesticides in Canada: An Examination of Federal Law and Policy (Ottawa: LRCC, 1987).

FEDERAL PESTICIDES LAW: PROSPECTS FOR REFORM

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, there has been a substantial, if not dramatic increase in pesticide sales and use both in Canada and world-wide. 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). At least 10 million acres in 1975 were treated with herbicides on the Canadian Prairies. 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.

Second, in conjunction with the increasing quantities sold and used, the public is of course 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. These are (1) the development of resistence in pest species; and (2) the impact on non-target species and ecosystems. With respect to non- target impacts, the United Nations Environment Programme 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 results of some of these "unavoidable side-effects":

- 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;

- In 1983, a coroner's inquest into the death of a twenty year old British Columbia farm worker ended in a jury finding that his pesticide poisoning was the result of a preventable homicide. Testimony at the inquest indicated that: the farm worker was poisoned by the chemical, Monitor, at a farm where pesticides were sprayed while workers harvested nearby; pesticide containers were disposed of haphazardly; little protective clothing or washing facilities were provided to workers; and workers were transported in vans that carried pesticides.

- 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.

- In 1985 a Canada- Ontario report on pollution of the St. Clair river concluded that of the estimated 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.

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. Moreover, problems have arisen at many stages in the regulatory process including registration, use and disposal.

Inevitably, given the widespread use of pesticides in this country, many segments of society including farmers, farm workers, industry, the medical and public health community, governments, environmental, consumer, and citizen groups, have an interest in the objectives and effectiveness of the regulatory and enforcement process for pesticides in Canada.

The focus of our comments will be directed to the existing federal framework for regulation of pesticides and the 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, 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 centred 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 was viewed by federal officials as needing amendment to increase government authority over pesticides substantially beyond the originally limited purposes 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.

A key component 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. Under the Act, pesticides may only be registered if the

Minister of Agricultre is of the opinion that the control product has merit or value for the purposes claimed when used in accordance with label directions (Regulations, s. 18) In addition the pesticide's use must not lead to an "unacceptable risk of harm" to public health, plants, animals or the environment (s. 18(d)). "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 (Reg. s. 9) Generally, these scientific test studies must address occupational safety and exposure, residues, toxicity and related matters.

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 an administrative memorandum of understanding between HWC 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. It is here that 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 1960's when federal pesticide law was still administered by the US Department of Agriculture.

The authority for registration and control of pesticides was transferred to the US Environmental Protection Agency in 1972.

In Canada, in the early 1980s, a coronor'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 to creating a stand-alone administrative agency analogous to the CRTC.

In our opinion, serious consideration should be given by this Parliamentary Committee as to whether it is appropriate to transfer authority for administration of the Act from the Minister of Agriculture to either other federal departments or a stand-alone agency. 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 our opinion is long overdue for major overhaul and reform.

The Act's registration and re-evaluation requirements for new and existing pesticides respectively, constitute the heart of the statute. In our opinion, these are two key areas that would be high on any agenda for reform.

B. The Registration Process: Testing Requirements and the Basis for Decision Making on New Pesticides

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

1. Adequacy of Testing Requirements and Practices

Two areas of pesticide testing required by the federal government under the Act and regulations deserve special consideration: animal toxicological testing, and environmental toxicological testing.

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 1970's and early 1980's 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 mutations were invalid; and 71% 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. For example, in 1969 studies performed on the pesticide leptophos by IBT, concluded that an examination of tissue from chickens fed leptophos "did not reveal any evidence of nerve damage in any of the chickens tested." The body of the report, however, included numerous descriptions of such neurotoxic symptons as "no control of legs", "very unsteady","cannot remain standing", and "extreme staggering". A 1974 U.S. EPA review of the same tissue slides found them "impossible to evaluate from the time they were prepared." In 1975- 76, workers at one chemical plant in the U.S. showed neurotoxic and related health problems as a result of exposure to leptophos which was being manufactured and packaged there. While leptophos

was used only experimentally in the U.S., it was exported to as many as 50 countries, including Canada, between 1971 and 1976. It was eventually banned in Canada in 1977.

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 fact that because most testing facilities are in the U.S., Canada cannot ensure that these laboratories are producing quality work. 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."

With regard to environmental toxicology testing, the scarcity of standard test protocols for both laboratory and field studies has been regarded as a serious impediment to the evaluation of the environmental hazards of new pesticides. Environment Canada has itself admitted that: (1) it is not privy to all information in Agriculture Canada files; and (2) its monitoring of pesticides is often in reaction to the registration of pesticides rather than prior to registration approval, particularly where it has judged the registration information to be insufficient.

While the 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 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."

In sum, improvement of the adequacy of animal and environmental 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 new environmental parameters such as groundwater contamination potential.

2. 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. 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 also 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 Review Board muddied this conclusion by agreeing with the federal government that the Minister is entitled to balance risks and benefits but need not to 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.

In practice, as you are undoubtedly aware, 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 vigor the national environmental community has opposed this development. Among the problems that investigators and researchers have with risk-benefit or cost-benefit analysis include:

- 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; and
- these analyses cannot easily deal with questions of equity, that is, that costs, risks and benefits are often borne by different groups within society.

It is also fair to say that the national environmmental 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. It is the perception of that community 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. It is our position 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.

3. 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 that of temporarily registered 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 that are seriously detrimental to public health, domestic animals, natural resources or other things. 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 (section 17). Where a temporary registration is refused, it now appears that an applicant can trigger a hearing before a review board established under the regulations (Monsanto Canada Inc. v. Minister of Agriculture (23 January 1986), Toronto T-669-86 (F.C.T.D.), Cullen J. [unreported]). In our opinion, refusals to issue temporary registrations should not result in a review board hearing as, by definition, applicants seeking temporary registration for their products will as a matter of course not have a full safety data package. The Monsanto decision is an aberration in that a temporary registration had been given at the same time as the permanent registration of the product was being cancelled. In the normal course, an applicant seeking a temporary registration for a product would not previously have had a full registration for that product.

During the IBT matter 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. 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.

(Willis v. F.M.C. Machinery & Chemicals Ltd. (1976), 68 D.L.R. (3d) 127 (P.E.I.S.C.)).

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."

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. However, from 1978 to 1982, annual emergency exemptions under FIFRA grew 430 per cent, and were characterized by a Congressional subcommittee report as a "marked upward trend" in the use of approaches that were not intended to substitute for full registration. Earlier Congressional investigations 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 registration delays and the provision of full environmental health and safey tests, greater safeguards will likely be necessary in the Act or regulations on this issue.

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 existing pesticide 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- 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 30-50 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.

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 Rebuttable Presumption Against Registration (RPAR) programs, the latter now called Special Review. 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.

These programs are not without their own problems within the U.S. regulatory framework. However, cyclical re-evalution and priortization 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. Date bases for older compounds are often inadequate, and even partial additions would be an improvement" (Ag. Can. Trade Memorandum, T-1-249, July 8, 1987, at 3).

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" (Reg. s. 20). 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 be 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 (Reg. ss. 21,22). 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..." (Reg. s. 25(1). The Board must prepare a report and file it with the Minister but can only make recommendations. The final decision rests with the Mnister 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. There have only been three instances since the regulations were promulgated in 1972 in which Review Boards have been empanelled to hear a matter. The Alachlor Review Board was the first hearing that actually lasted more than a few days. In fact the Board sat for 41 days and heard evidence from over 50 witnesses. We represented clients who 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 pesticide manufacturers, including Monsanto 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 studiies, done at two different laboratories, showed that alachlor caused multiple tumours in multiple sites in both sexes of test animals, at extremely low doses. Concerns were raised with

Health and Welfare Canada as early as 1982, but it was not until February 5, 1985 that Agriculture Canada actually made its decision to cancel alachlor. It should be noted that during that 3 year period, while there were numerous meetings between Monsanto and Agriculture Canada and Health and Welfare Canada officials, the public was virtually locked out of this process. Presently, there is no provision in the statute 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 was met with strong criticism from the national environmental community and Health and Welfare Canada and raised a number of issues which point out the need for regulatory reform.

Specifically, the Minister was urged to reject the Board's findings on metolachlor, as there was not the 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. Because this was not an inquiry into metolachlor, there was no such similar data base filed by Ciba- Geigy. In fact, Health and Welfare, in its review of the material, had concluded that metolachlor was neither an animal nor a human carcinogen. In contrast, at the hearings a Health and Welfare 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 this 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. However, it should be remembered that at the front end of the process, each product is evaluated on the basis of whether it meets the test of safety, value and merit. If evidence is later found to cast doubt on, for example, a product' safety and it's registration is

cancelled then in our opinion the product can only be rehabilitated by showing that it is safe and not by casting doubt on another's product's safety. To do otherwise, would bring the regulatory process in dealing with toxic chemicals to a standstill.

In order 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 product cancelled 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 specifically noted in it's letter of November 27, 1987 letter to Agriculture Canada, that "the calculation of margins of safety does not represent the generally accepted approach to carcinogen risk assessment." In fact, the US 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 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."

It is our opinion, that rather than having an ad hoc board make cancer policy for Canada, the federal government should develop a cancer decision-making policy.

E. Access to Information

The PCPA is silent on the release of health and safety information gathered under its auspices. Industry's position has been that data submitted to government for registration of a product are submitted in confidence. The chemical industry sees the data they've developed as their intellectual property and fear that if is is publically released, commercial competitors could use that data for the purposes of obtaining a registration in Canada or other countries without doing the necessary testing themselves. Environmental groups, on the other hand, are not content to see summaries of such information prepared by government or industry. They will want to see the raw data in order to independently assess the appropriateness of the tests and test methods used and the interpretations and conclusions to be drawn therefrom.

Notwithstanding the passage of the federal Access to Information Act, the situation is unclear respecting the treatment of health and safety data under that statute. The

purpose of the AIA is to extend the present laws of Canada to provide a right of access to information in records under the control of government in accordance with the principles that government information should be available to the public and that exceptions to the right of access should be limited and specific.

Under s. 20 (1)(a), the head of a government institution must refuse to disclose any record requested under the Act that contains the "trade secrets of a third party..." However, there is no definition of "trade secret" under the Act. This is important because trade secrets are treated differently than "financial, commercial, scientific or technical information..." and other types of information supplied by third parties to the government. There is a general exemption from disclosure for all the heads of section 20(1), but in the case of third-party information supplied under sections 20(1)(b), (c) and (d) there is discretion available for the head of a government institution to disclose this information under the balancing test in section 20(6). This test permits disclosure if it would be in the public interest as it relates to public health, safety and the environment, and if such public interest in disclosure clearly outweighs in importance any financial loss or gain to, or prejudice to the competitive position of a third party. Whether the courts will apply a broad or narrow definition of trade secrets is therefore critical under this statute.

From the environmental and national health perspective, the preferable approach is not a balancing test but rather the imposition of safeguards in the PCPA itself which protect raw data from being given to commercial competitors, but allow it to be released to the public. Such regimes exist in the laws of other countries and in our opinion it is time that Canada legislated a requirement that pesticide health and safety data be public information.

F. 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. There is also no statutory opportunity for the public to trigger a re-evaluation of a specific pesticide product. Intervention in review board proceedings, while permitted, moreover is highly expensive and is effectively impossible without intervenor funding.

It is clear that the PCPA lags far behind other public health and environmental statutes in providing for a meaningful role for the public in the process. We have recommended a number of amendments to the legislation which we would urge this committee to consider.

III. CONCLUSIONS

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.

The establishment of the Pest Management Advisory Board by the federal Minister of Agriculture represents an opportunity for government, industry, the environmental community and others to commence a dialogue that is long overdue, and that will lead to substantive law reform in the form of amendments to the PCPA in the near- not the far-future.

We would urge this Committee to recommend to Parliament that reform of the PCPA be made a high priority. As a contribution to the deliberations of this Committee we are attaching the recommendations from our 1987 Law Reform Commission of Canada study paper (Appendix A) which expand upon the matters we have raised with you today.

2. **The *PCPA* or the *PCP Regulations* should be amended to specify the criteria the Minister must use in granting temporary registrations, including the information that must be submitted in support of such an application and the number of renewals permitted. Opportunity for notice and public comment should also be required, including public availability of health and safety data in support of such applications as well as applications respecting research permits.** [See discussion *supra* at 61-65.]

3. **The *PCPA* or *PCP Regulations* should be amended to provide for public notice of registration applications for a new product or for significant new use and re-evaluation of older chemicals. The *PCPA* or *PCP Regulations* should be further amended to provide for: public access to health and safety tests relied on in support of a registration application or a re-evaluation of an older chemical; a sixty- to ninety-day comment period; and a right to request a hearing before a board of review prior to a pesticide registration application's being granted. Appropriate safeguards to prevent frivolous hearing applications should be included.** [See discussion *supra* at 65-66.]

4. **The *PCPA* or *PCP Regulations* should be amended by adding a schedule that would incorporate specific timetables for cyclical re-evaluation of all registered pesticides. There should be the authority to suspend or cancel a pesticide registration if the registrant fails to comply with the timetable where the pesticide lacks scientifically valid studies respecting cancer, birth defects, mutations, neurotoxic or reproductive effects.** [See discussion *supra* at 66-73.]

5. **The *PCPA* or *PCP Regulations* should be amended to authorize the establishment of a system of prioritization for pesticide re-evaluation reviews and to screen registered pesticides to identify those registrations which are based on old or incomplete safety data and for which new evidence suggests they may endanger human health or the environment. Where a pesticide meets or exceeds a critical risk standard (for example, as a potential cause of cancer), the federal government should be required to publish a notice announcing to the relevant registrants that they must submit evidence rebutting the presumption of "unacceptable risk" or the government will proceed to apply appropriate restrictions, including suspension or cancellation.** [See discussion *supra* at 66-73.]

6. **Registrants should be statutorily required to notify the government immediately of studies or other evidence within their knowledge that indicate that one of their registered pesticides may cause or contribute to the endangerment of human health or the environment.** [See discussion *supra* at 76.]

7. **The *PCPA* should be amended to provide that the Minister shall suspend or cancel any pesticide when it is shown that material safety tests supporting the application are invalid. Such suspension or cancellation should continue until new**

APPENDIX A

CHAPTER FOUR

Summary of Recommendations for Legal and Regulatory Pesticide Reforms in Canada

In the almost fifteen years since major amendments to Canada's principal pesticide law, the *PCPA*, were last enacted, problems surrounding pesticides have not abated. They have merely shifted from an older generation of persistent pesticides, such as DDT, to a newer generation of products whose health and environmental effects may be more subtle, but no less critical. Pesticide laws, particularly at the federal level, have not kept pace with the challenges posed by the number, diversity and impacts of pesticides that are used in agricultural production, forestry and the home.

Protection of the food- and fiber-producing sectors of the economy is an important societal goal, but it is doubtful that Parliament's intention in the 1969 amendments to the *PCPA* was to achieve this aim at the expense of health and the environment. Events over the last decade and a half have frequently shown, however, 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, if not acute. The focus of such law reform should be twofold: (1) increasing governmental authority to act; and (2) providing, as a matter of law, opportunity to individuals for participation in governmental decision making and, where necessary, redress to the courts. The summary of recommendations that follows is proposed with these dual objectives in mind. These recommendations have, in many instances, been part of pesticide regulatory programmes in other jurisdictions for years, without causing undue financial strain on regulatory resources. In addition, because many of these recommendations are reflected in international requirements, they will not result in substantial duplication in regulatory or registrants' costs attributable to any *PCPA* amendments alone.

I. The *Pest Control Products Act*

1. The *PCPA* or the *PCP Regulations* should be amended to require consideration of groundwater contamination potential when pesticides are proposed for registration or re-evaluation. [See discussion *supra* at 52.]

valid tests are submitted demonstrating the product's safety.[717] [See discussion *supra* at 75-76.]

8. Under the *PCPA*, any member of the public should be allowed:

(a) to petition the Minister to initiate investigations or restrictions on a registered pesticide about which new data have come to light regarding adverse health or environmental effects; and

(b) to cause a board of review hearing to be held as to whether a pesticide should be suspended, cancelled or its registration continued.[718]

In regard to either (a) or (b), the Minister shall initiate investigations or cause a board of review hearing to be held unless in his opinion such request is not made in good faith or is frivolous or vexatious. [See discussion *supra* at 65-66 and 85.]

9. Fines under the *PCPA* should be increased substantially, at least up to the levels in the *FA* or the *ECA*. [See discussion *supra* at 89.]

10. The *PCPA* should be amended to authorize the use of civil penalties as an inducement to compliance, without any diminution in the right publicly or privately to prosecute for violations of the Act's provisions. [See discussion *supra* at 90-91.]

11. The *PCPA* should be amended to provide ministerial authority and citizen standing to seek a restraining order to prevent violations of the Act. Citizens should also be granted standing under the *PCPA* to bring an application for judicial review to enforce any duty under the Act or regulations. [See discussion *supra* at 91-93.]

12. The *PCPA* or *PCP Regulations* should be amended to require the annual reporting to Parliament of the following information:

---

717 This proposed amendment would ensure that in a situation where it has been found that a registration has taken place on the basis of false data and invalid tests, the Minister shall suspend or cancel the use of the pesticide until new valid tests are in place demonstrating the product's safety. Presently, the statute is unclear as to whether false data also could be a sufficient basis for suspension or cancellation.

This issue arose in the United States where it was determined that the US EPA did not have the authority to suspend or cancel registered pesticides where the safety tests supporting the registration were invalid. The US GAO recommended amendments to the US *FIFRA* that would authorize the US EPA to take regulatory action, including suspension where it was determined that the registration of a pesticide was not supported by valid safety tests at the time of registration. Presently, the US *FFDCS* does allow the US FDA to withdraw approval of a drug when it is determined that the original drug application "contains any untrue statement of a material fact."

718 See also the *Combines Investigation Act*, R.S.C. 1970, c. C-23, s. 7(1) which authorizes any six persons resident in Canada to apply to the Director of Investigation for an inquiry where they are of the opinion that a person has contravened or failed to comply with orders under the Act. Paragraph 8(*a*) requires the Director to cause an inquiry to be made upon the filing of the subsection 7(1) application.

(a) the number of registration applications received by relevant category of application (for example, new product, new use of existing product, and so forth);

(b) the number of such registrations granted including the type of approval (that is, domestic, commercial, restricted);

(c) the number of applications denied or withdrawn and why;

(d) the time for handling applications;

(e) the number of research and temporary registration applications, including

(i) the number of applications by type of exemption sought (for example, emergency) and the disposition of these applications;

(ii) the total kilograms of each active ingredient and the area authorized for application, by province, and

(iii) the actual amount used and area to which applied;

(f) the status of re-evaluation reviews for each active ingredient;

(g) a complete and updated list and summary of suspended, cancelled or otherwise restricted pesticides and other enforcement actions taken; and

(h) a list of notices transmitted to officials of foreign governments with respect to exports of banned or restricted products (proposed below).[719] [See discussion *supra* at 8 and 86-88.]

13. The *PCPA* should be amended to require registrants to submit to the government annually information concerning the production and sales of active ingredients, and to estimate the usage of each such pesticide by province. The Act should be further amended to require the government to publish this information annually in aggregate form by province. [See discussion *supra* at 8 and 86-88.]

14. The *PCPA* should be amended to require the listing of inert as well as active ingredients on the product label,[720] **and at least the same information concerning environmental hazard and appropriate use as appears on the labels of the product in its country of origin.** [See discussion *supra* at 91-92.]

---

719 This type of reform has specifically been proposed by an American Congressional subcommittee, *supra*, note 528 at 7-8.

720 Saskatchewan officials, in *supra*, note 702 at 22, have noted that "Existing labelling of pesticides in Canada under the [*PCPA*] requires that only 'active ingredients' be listed. This means that many ingredients of formulated pesticides need not be listed on the label since legally they are not defined as an 'active ingredient'." Inerts may be biologically active. See *ibid.* at 23.

15. The *PCPA* should be amended generally:

(a) to mandate public access to, and government and agency sharing of, pesticide health and safety data (concerning both active and inert ingredients); and

(b) to authorize compensation or a period of exclusive use to protect the initial data submittor from competitors seeking access to information, including trade secrets. [See discussion *supra* at 47 and 94-98.]

16. The *PCPA* and the *ECA* should be amended to require, at a minimum, that any exporter give notice to foreign governments of the restrictions that exist domestically on pesticides exported to their countries. Exports should not take place until the exporter submits written evidence to the appropriate Canadian authority that the importing country has received the notice. [See discussion *supra* at 99-102.]

17. The *PCPA* should be amended to require that a substantial percentage of Agriculture Canada's pest control research budget, including outside contracts, be spent on research into non-chemical alternatives to pest control, such as further research into integrated pest management strategies that place less reliance on chemical pesticides. [See discussion *supra* at 118-19.]

II. The *Food and Drugs Act*

18. The *FDA* should be amended to require that no detectable residue levels be allowed where a pesticide has been found to be carcinogenic, mutagenic, teratogenic or to produce adverse neurotoxic or reproductive effects in human beings or animals.[721] [See discussion *supra* at 103-110.]

19. The *FDA* should be amended to establish a review board to hear appeals of tolerance-setting decisions. Any member of the public should be allowed:

(a) to petition the Minister to initiate investigations or restrictions on a registered pesticide about which new data have come to light regarding adverse health or environmental effects; and

(b) to cause a review board hearing to be held as to whether a pesticide tolerance should be established or re-examined.

In regard to either (a) or (b) the Minister shall initiate investigations or cause a board of review hearing to be held unless in his opinion such request is not made in good faith or is frivolous or vexatious. [See discussion *supra* at 110.]

---

721 This recommendation reflects the policy that one should err on the side of caution and limit exposure to carcinogens and other irreversible health effects as much as possible

20. The *FDA* should be amended to require public notice and opportunity for comment on revisions to the agricultural chemical MRLs under the regulations. [See discussion *supra* at 110.]

21. The *FDA* should be amended to authorize the use of civil penalties as an inducement to compliance without any diminution in the right to prosecute publicly or privately for violations of the Act's provisions. [See discussion *supra* at 111-113.]

III. Other Recommendations for Federal Law and Policy

22. Health and Welfare Canada should introduce good laboratory practice legislation compatible with international principles. In conjunction with this, the federal government should establish by law an independent testing facility financed in substantial part by a tax on annual quantities of chemicals and pesticides imported, manufactured, formulated or used in Canada. Such facility should be a principal source of testing data on new pesticides and uses. Further, it should develop environmental testing data under Canadian conditions. [See discussion *supra* at 50-52 and 80-82.]

23. The federal government should outline in detail and publish a cancer decision-making policy that is consistent with federal statutory mandates under the *PCPA*, the *FDA* and the *ECA*. This policy should deal with mutagenic and teratogenic effects of regulated substances as well. The components of a Canadian carcinogens policy should include:

(a) a definition of carcinogenic chemicals (for example, those chemicals which have been shown to cause cancer in two well-controlled animal experiments using different rodent species, or in human beings);

(b) a discussion of how standards for carcinogenic chemicals should be set; and

(c) a role for the public in the decision-making process. [See discussion *supra* at 53-60.]