#103

CAPTAN: THE LEGACY OF THE IBT AFFAIR

Submissions on Pesticide Law and Policy
to the Consultative Committee on IBT Pesticides
on behalf of the Canadian Environmental Law
Association and Pollution Probe.

BY

Toby Vigod
Counsel
Canadian Environmental
Law Association
8 York St., 5th Floor
Toronto, Ontario
(416)366-9717

Anne Wordsworth
Researcher
Pollution Probe
12 Madison Avenue
Toronto, Ontario
(416)978-6155

February, 1982

TABLE OF CONTENTS

TABLE OF CONTENTS

I. INTRODUCTION

Pollution Probe and the Canadian Environmental Law Association are both committed to the principles of preventing degradation of the environment and of protecting public health. In order to promote these objectives, we have pursued a general policy designed to minimize or eliminate the presence of toxic chemicals in the environment.

Pesticides occupy a prominent place in the field of toxic chemicals for several reasons -- they are inherently poisonous by design, since they are intended to destroy organisms which are perceived to adversely affect our economic interests; they are deliberately dispersed into the environment; and, the manufacturing wastes from their production are particularly damaging to the water bodies into which they are discharged. Therefore, they consitute a major threat to both the environment and to public health.

When the fraudulent pesticide testing performed by the Industrial Biotest Laboratories (IBT) first came to light, Pollution Probe and the Canadian Environmental Law Association (CELA) urged the provincial Pesticides Advisory Committee in October 1980 to actively seek remedies for the situation.[1]

In May, 1981, CELA was asked to become a member of the Consultative Committee on Captan, but declined due to the fact that certain minimum conditions we had placed on our acceptance were not met.[2] However, as we view the IBT affair and its implications to be of national concern, we would like to take this opportunity to place recommendations before the Committee on pesticide law and policy, as well as on the specific pesticide, Captan.

II. THE PUBLIC IS GENERALLY AWARE AND CONCERNED ABOUT THE WAY IN WHICH PESTICIDES ARE PRESENTLY REGISTERED AND USED

We would first like to caution this Committee that there has been an inherent tendency on the part of government agencies to misunderstand and consequently to misrepresent the public concern for the way in which pesticides are presently registered and used. Many agencies, such as Agriculture Canada, do not comprehend the degree of sophistication or the depth of public concern for safety. Therefore, these government agencies continue to perpetuate the same policies and conditions under which they have operated for the last twenty years with only minor modifications.

These policies do not have the full support or the confidence of the public.

These policies assume that the risks, which have been perpetrated by and which are acceptable to, the users and regulators of pesticides are equally acceptable to the general public. However, the nature of these risks has never been accurately portrayed by government agencies -- in some cases, because the agencies themselves do not have complete information, and in other cases, because there has been a deliberate understatement of the risks. This has only served to fuel public fears regarding the safety of pesticides.

The deliberate falsification of data by the IBT Laboratory has increased public distrust of the procedures by which pesticides are introduced onto the market. We feel that this Committee must consider not only the use of Captan but the crucial issues relevant also to the registration and use of pesticides. These issues, as we see them, include the refusal of government agencies to allow public access to information on the health effects of pesticides, the failure to encourage research into and use of

integrated pest management practices which would reduce pesticide use, and the lack of public participation in the decision-making process regarding pesticide registration and regulation.

As requested by the Consultative Committee, this brief will make specific recommendations on the use of Captan, the first pesticide to be re-evaluated as a result of the IBT affair.

Then we will briefly outline the current legislative scheme relating to pesticides, make comparisons with the American legislation where appropriate, and suggest general recommendations for reform to both current federal pesticide law and policy. We feel that the implementation of these general recommendations would effectively preclude the situation in which we now find ourselves -- acting in retrospect to avoid the use of inadequately tested pesticides with damaging impacts on human health and the environment.

III. CAPTAN SHOULD BE BANNED IMMEDIATELY FOR HOUSEHOLD USES AND SHOULD BE PHASED OUT IN AGRICULTURAL APPLICATIONS

Captan is currently allowed in Canada, as it is in the United States, for a diverse and surprising variety of uses that could affect a large number of Canadians.

It is estimated that 600,000 to 700,000 pounds of Captan are used annually in Canada. Of the total volume, the breakdown by use is: 80-90% Foliar and Fruit, 10% Seed Treatment, 5% Home and Garden, and 2-5% Non-Agricultural/Industrial.[3]

The most significant use of Captan is to prevent the growth of mould on fruit crops. This accounts for about 95% of the Captan used in fruit treatment. Of the Captan used on fruit, about 70% is applied to apples, 10% on peaches, 10% on strawberries and 10% on grapes and other fruit.

Approximately 75% of all the Captan used on fruit is applied in Ontario.[4]

In trying to arrive at recommendations for this Committee, our task has been made difficult by the lack of information available or the lack of a proper evaluation of the importance of Captan to the production of food.

However, the available health studies implicate Captan as a mutagenic, teratogenic, and carcinogenic substance. Bacterial and mammalian cell culture assays indicate that Captan is a gene (point) mutagen (able to cause heritable genetic alterations).[5] Captan has also shown itself to be teratogenic (capable of causing birth defects) in a variety of species, including rabbits, hamsters, and chicks.[6] Most recently, a study submitted to Health and Welfare on January 20, 1981, demonstrated that Captan leads to the induction of tumours in mice.[7]

We are convinced by these studies that Captan must be removed from use. A ban is the only way in which the public can be assured that their health will not be adversely affected by the potentially damaging effects of this chemical.

However, we recognize that an immediate ban could result in the desperate and ill-advised adoption of equally undesirable alternatives. Therefore, we recommend that, for practical purposes, this Committee should proceed in two ways. First, this Committee should advise the Canadian government to act as expeditiously as possible to ban Captan immediately in areas of use where the removal of this pesticide will have a negligible effect. Secondly, this Committee should develop a program that results in the gradual phasing out of Captan in all areas of use over a reasonable period of time. We believe that such a program should encourage the incorporation of integrated pest management practices.

A. Garden and Household Uses

A Commission of the United States Department of Health, Education, and Welfare recommended unanimously that "human exposure to Captan be considered a potential health hazard",[8] and the Canadian Department of Health and Welfare has made recommendations to limit public exposure to Captan. We concur with the recommendation from Health and Welfare that all products containing Captan for use in or around the home be banned. This would include household uses such as cosmetics and pharmaceuticals; wallpaper paste; vinyl textiles; plasticizers and polyethylene used in garbage bags and pond liners.

Consumers of products such as wallpaper paste, would have no warning of the possible danger to health represented by these products. It would be impossible to judge the number of invididuals exposed by such a route; nor would there be any way of undertaking epidemiological studies to evaluate the health risks.

We submit that these uses of Captan are unnecessary, and that there is no justification for government agencies exposing such a large population to virtually unknown and involuntary health risks.

Captan has also been the mainstay of the home gardener. It is believed to be the most heavily-used fungicide on the home garden market, and it is estimated that 5% of the total volume of Captan used in Canada is purchased by home gardeners. Rose bush and fruit tree sprays marketed under such innocuous trade names as "Swiss Farms Rose and Flower Spray" or "Bonide Complete Fruit Tree Spray" have been used without warnings or restrictions by unsuspecting gardeners for many years.

Although there is no basis for assuming any pesticide is safe, most members of the public do not realize the potency or toxicity of sprays that are readily available in hardware stores or gardening centres. There is a general misunderstanding on the part of the public that a product is "safe" when used under the proper conditions. There is also an assumption that if a product is marketed and has been approved for use by the government, then its absolute safety is assured. These assumptions, are no longer valid as our understanding of the long-term health effects of pesticides improves.

Many cases of pesticide poisonings happen through the mishandling of pesticides by home gardeners. In such cases, the exposure could be particularly high, exceeding tolerance levels many times because the sprays are being used under uncontrolled conditions and in much heavier concentrations than those used by commercial farmers.

Although Agriculture Canada will be placing warnings on products containing Captan, we do not consider this sufficient to protect the public from exposure to Captan.

B. Pick-Your-Own Operations

Another area which particularly concerns us is the exposure of individuals who patronize "pick-your-own" fruit operations. Again, as with the backyard fruit spraying, families, or individuals picking fruit in the fields may be exposed to residues much higher than the tolerance levels set by Agriculture Canada. It is estimated that residues on fruit that has not been washed in preparation for market could be 5 to 10 times higher than the legal residues.[9]

Since Captan is known to have teratogenic and mutagenic effects, it poses a particular hazard to pregnant women. It also poses a hazard to young children whose body weight is considerably less than the average adult. Therefore, the exposure would be far more serious for a child, especially since a child is likely to be eating and picking at the same time.

We recommend that Captan not be available for use by farmers who run pick-your-own operations. We also support the recommendations made by Dr. Joseph Cummins to this Committee that family health practitioners and medical units be educated to analyse and treat cases of pesticide poisonings.

C. Market Produce

We also agree with Health and Welfare's recommendation that all food sold at the retail level be free of Captan residues.

The most serious exposure to the general public is through their exposure to pesticide residues on fruit and other produce marketed commercially. We do not intend to prove the case for potential adverse health effects by reiterating the significant number of health studies that have revealed the toxicity of Captan. We feel these tests are conclusive enough to warrant considerable public concern and to justify the elimination of Captan.

However, there is one study that we wish to raise before this Committee that particularly concerns us. Health and Welfare have recently conducted a study on food that shows the potent mutagenicity of Captan residues on raspberries.[10] These studies were conducted on fruit that had very low residues of Captan, well within the acceptable tolerance limits set under the Food and Drug Act. We feel this raises serious questions about the present tolerance levels set out for Captan.

The public should not be expected to protect their own health in terms of the food they buy. There is a reasonable expectation that food will not be presented commercially that is not safe for consumption. Although washing food is a common practice, it is by no means the rule for every household. Many people believe that washing fruit is primarily intended to remove dirt, and don't realize that it is also necessary for the removal of pesticide residues. They may also be skeptical about the usefulness of trying to wash away pesticides. Therefore, while the public can assist in making food safer, the onus should not be on the public to bear the responsibility for safeguarding their own health.

The regulatory agencies and Agriculture Canada, in particular, must bear this responsibility.

This responsibility must also be extended to the importation of fruits and vegetables. No imported fruit containing Captan residues should be allowed into Canada for the same reasons.

IV. SIGNIFICANT AMENDMENTS TO FEDERAL PESTICIDE LEGISLATION AND POLICY ARE URGENTLY NEEDED

The next sections will address the question the Consultative Committee has raised as to whether pesticides are well regulated in Canada.[11] It is CELA's and Probe's contention that significant amendments are needed to the Pest Control Products Act (PCPA)[12] in order to meet the current problems posed by pesticides in the environment. Pesticides have become more heavily scrutinized both for their impact on public health and the environment and their long term effectiveness as primary pest control agents during the past few years.

However, the legislation, as presently enacted, has effectively locked the public out of the regulatory process and has not kept pace with changing perceptions of the need to control the manufacture and use of toxic chemicals in the environment. The IBT affair, which cannot be regarded as a mere aberration, points out the specific failure of the current regulatory scheme to deal with pesticides which have been registered on the basis of fraudulent data.

A. Present Legislative Scheme - Overview

The British North America Act, 1867, section 95 provides for agriculture to be a matter of joint legislative responsibility of the Federal and Provincial governments.[13] The federal PCPA and Regulations[14] are the major pieces of legislation governing the registration, classification, and labelling of all pesticides used in Canada. The PCPA sets minimum standards for the whole of Canada. The provinces are free to set more stringent standards. For example, under the Pesticides Act,[15] Ontario controls the use of federally registered products through a system of permits and licenses.

To qualify for registration under the PCPA, a new control product must satisfy the criteria of safety, merit, and value.[16]

Applicants must also provide the Minister with data regarding new ingredients, including information on the safety of the product for those who may be occupationally exposed to it; the degree of persistence of the control product and its residues; methods for disposal; how to detect significant amounts of it in food and in the environment; its stable shelf life; and its compatibility with other control products with which it is likely to be mixed.[17]

Section 19 of the regulations also provides that during the period of registration, the registrants must be able to satisfy the Minister that its pest control product will not lead to an unacceptable risk of harm to public health, plants, animals, or the environment.

The Minister may suspend or cancel a pesticide's registration when, based on the current information available to him, the safety, merit, or value is no longer acceptable.[18]

It is clear that under the existing legislation, the Minister has the power to cancel or suspend the use of Captan, on such terms or conditions as he may specify. What is also interesting to note is that a basis for which the Minister may refuse to register a control product is if "the information provided to the Minister on the application is insufficient to enable the control product to be assessed or evaluated", and if "the use of the control product would lead to an unacceptable risk of harm to public health, plants, animals, or the environment".[19] It is certainly arguable that if Captan was put forward today as a new pesticide to be registered in the absence of valid studies showing its safety, it could not be registered.

CELA and Probe submit that one problem is that the Minister's power to suspend, cancel, or, in the first instance, to refuse to register a pest control product, is discretionary and not subject to judicial review in the absence of some showing that the discretion was improperly exercised.

CELA and Probe recommend that sections 18 and 20 of the Pest Control Products Regulations be amended to provide for a mandatory requirement for the Minister to refuse to register, suspend, or cancel the registration of a pest control product if the conditions presently set out in those sections are not met. In addition, the Act should provide for standing for any person to bring an application for judicial review of any requirement under the Act or Regulation.

B. The Pest Control Products Act should be jointly administered by Health and Welfare and Environment Canada

Presently, the PCPA is administered solely by the Minister of Agriculture. CELA and Probe submit that there is a conflict of interest between the Department of Agriculture's activities to promote the use of pesticides to increase food production, and the protection of public health and the environment which historically has not been emphasized. This conflict has been recognized in the past decade and has resulted in the transferring of responsibility for pesticide legislation from Ministries of Agriculture to Ministries of the Environment in a number of provinces and the United States.[20]

Due to the existing responsibility of Health and Welfare to set pesticide residue levels under the Food and Drug Act,[21] and the responsibility of Environment Canada for environmental protection, CELA and Probe recommend that, at a minimum, an amended PCPA should be administered by these two departments, with Agriculture Canada in an advisory role.[22]

More recently, the Canadian Environmental Advisory Council has recommended the creation of a Pest Control Evaluation Commission, jointly administered by the Departments of Environment, Agriculture, and National Health and Welfare, empowered to examine pest control problems in their totality.[23] CELA and Probe would certainly accept this holistic approach.

In any event, it is clear that major revisions to the PCPA are required and that sole control of the regulation of pesticides should be taken out of the hands of Agriculture Canada.

V. AN INTEGRATED PEST MANAGEMENT (IPM) STRATEGY AND THE SEARCH FOR ALTERNATIVES TO CHEMICAL PESTICIDES MUST BE GIVEN STRONG GOVERNMENT SUPPORT

The increase in the worldwide use of pesticides since World War II has resulted in many unforeseen environmental problems. These problems include increased pest resistance to pesticides,[24] secondary pest damage[25] and increased threats to human health and the environment.

Integrated Pest Management (IPM) is a strategy which involves the carefully managed use of multiple pest control tactics. It minimizes the use of chemical control and maximizes the use of natural processes, thereby avoiding many of the problems associated with pesticide use. Cultural methods of pest control include crop rotation, tillage, and removal of crop residues which shelter pests after harvest, while biological controls may include the use of the pests' natural enemies, and the use of pheromones.[26] Ironically, Canada's lead role in the developing of biological methods of pest control was allowed to lapse in the 1950s when pesticides were seen as a panacea.[27]

The Canadian Agricultural Chemicals Association (CACA) often states that crop losses would be between 30-50% of current production if chemical pesticides were banned, although it admits that its figures are based on the premise that no alternatives to chemical pesticides would be used.[28] Other commentators estimate that these losses would be much less.

Dr. David Pimental, Professor of Agriculture and Life Sciences, estimates that there would only be about a 9% increase in crop loss due to the withdrawal of pesticides. He points out that, despite the millions of pounds of pesticides used on agricultural land each year, approximately one third of the crops planted in the U.S. failed to reach harvest due to pest damage.[29]

He estimates that losses specifically due to crop diseases if fungicides were withdrawn were estimated to increase from the current 12% to 15%. The Additional crop loss of 3% is not as large as the 5% estimated loss due to the withdrawal of fungicides because less than 1% of crop acres is treated with fungicides.[30] It is also clear that Dr. Pimental's 9% crop loss figure only addresses the situation where pesticides are withdrawn, without alternatives implemented in their place.

A demonstration tree fruit IPM program in New York State resulted in decreased use of pesticides, including fungicides, without decline in fruit quantity or quality.[31]

A 1979 report from the U.S. Office of Technology Assessment entitled "Pest Management Strategies and Crop Protection" states that the adoption of Integrated Pest Management Strategies will not take place in a signficant way without government involvement. The report makes several recommendations that we feel should be made the subject of either clear federal policy or incorporated into legislative amendments to the Pest Control Products Act to provide for a requirement that a percentage of Environment Canada's and Health and Welfare's budget be spent on IPM research.[32]

Specifically, there should be increased federal support for:

1. research into pest and crop biology, crop production and pest control methods;

2. coordinated pest and weather monitoring programs and public information programs so that problems are discovered early;

3. more education and practical demonstrations of IPM methods;

4. biological control and biological resistant development programs.

VI. THERE IS A NEED FOR CANADA TO DEVELOP ITS OWN TESTING CAPABILITY

The Saskatchewan Environmental Advisory Council in its 1977-78 annual report states that there are "major deficiencies in the present research and regulatory process" with respect to pesticides.

> "At the federal level, the main regulatory bodies (Agriculture and Health) do not conduct sufficient independent research. Both Departments are forced to rely in part on laboratory tests by chemical manufacturers. It is not competence, but rather objectivity and credibility which are absent in this arrangement.'[33]

Unfortunately, the IBT affair underscores this.

CELA and Probe recommend that all testing for the efficacy and safety of a pesticide should be conducted ideally by a Canadian independent testing facility run by a Crown corporation, or, alternatively, by government laboratories and university and private laboratories under contract to the government. In any event, the contract to test new pesticides should be between the government, not the company promoting the chemicals, and the testing facility.

The company making an application for registration of a pesticide should bear all costs associated with the testing. A federal Crown corporation should be established to administer the money and initially contract out all tests. The corporation should also be given the responsibility of establishing a central testing facility. The financing should come from a tax on the pesticide manufacturing industry. This facility could be set up to test all new chemicals, not just pesticides, before they enter the market. If this is the case, the tax base could also include the general chemical industry.

The need for an independent Canadian facility cannot be ignored. IBT was not an aberration, but was found to be just the tip of the iceberg in terms of faulty and even fraudulent laboratory procedures in the testing of pesticides in the U.S. and, often, their subsequent registration in Canada.[34]

Documents obtained through U.S. Freedom of Information requests revealed that 25 out of 82 laboratories audited by the Environmental Protection Agency revealed serious deficiencies in their work.[35]

There is also the need for Canadian testing to reproduce Canadian natural conditions.[36] These would include, for example, testing pesticide persistence in our generally colder climate, as well as the effect of pesticides on Canadian soils. Presently, environmental effects under Canadian conditions have not been and are not being assessed.[37]

VII. THE PCPA SHOULD BE AMENDED TO ENSURE PUBLIC ACCESS TO ALL PESTICIDE HEALTH AND SAFETY DATA

This issue of access to information has been a recurring problem throughout the entire IBT affair. Ironically, CELA received the results of the joint U.S.-Canada audit of the IBT Captan studies done by Canada from the California Rural Legal Assistance (CRLA) in Marysville, California and not from Canadian authorities.

CRLA obtained the documents under the U.S. Freedom of Information Legislation (FOIA) in November, 1980. The reason for requesting the records was "to determine which pesticide registrations and tolerances are supported by fraudulent tests data, to determine if there is any rational basis for EPA's refusal to cancel the registrations and tolerances for those pesticides supported by fraudulent test data, and to determine, if possible, why Swedish EPA found it prudent to cancel registrations after learning of the fraudulent data and the U.S. EPA did not."[38]

If one substitutes "Agriculture Canada" for "EPA", it is clear that the same reasons for public access to scrutinize these documents exist in Canada. While originally these documents were withheld because of the FOIA exemption for investigatory records compiled through law enforcement, they were released, on appeal to the California group. Further, EPA held that a FOIA exemption enabling the government to withhold intra and inter agency communications of advice, recommendation, and similar deliberative materials, as well as the exemption protecting trade secrets and other types of confidential business information from disclosure, were not applicable.[39]

The substance of the Canadian audit on the Captan studies and U.S. acceptance of the audits received from the California Rural Legal Assistance reveal that, as of January 1980, all 12 studies reviewed by Canada were invalid. Many of the studies were invalid due to "fabrication of the data, lack of supporting data, discrepancies between available raw data and the final report".[40]

What is even more disturbing are the findings, for example, of an audit of a study on rhesus monkeys. There it was found that "the audit and validation of this study not only show that the raw data do not support the report, but that the test material (Captan) has a significant embryo toxic effect in causing abortions at the lowest level studies of 10mg/kg/day".[41]

Other audits also question some of the sponsoring company, Chevron's, activities in their involvement with IBT. Health and Welfare officials, in commenting on a dominant lethal study in mice found to be invalid, noted "it was also disturbing to find little difference between the mutation rate of treated and control animals after the company had complained that there were differences and later had this page replaced by IBT".[42]

Health and Welfare has refused to release any of this data on the basis of a Department of Justice Department opinion that the information supplied to the Crown (including any IBT studies) under the PCPA is confidential and subject to the common law protecting trade secrets and intellectual property. Further, if the studies were released, the Crown would be open to legal action from manufacturers and laboratories who could claim that their reputations have been damaged.[43]

However, in unofficial representations to the West Coast Environmental Law Association, it appears that the Department of Justice had told Health and Welfare not to release the IBT audits, because it would open the floodgates to information requests, not because the audits involved trade secrets.[44] One may also query whether 'false information' can be protected as a trade secret.[45]

The government's hiding behind the veil of 'trade secrets' becomes especially suspect in the Captan case, when we know that Chevron waived their claim of confidentiality to their studies to U.S. EPA.[46]

Certainly, it is clear that amendments to the PCPA are needed to provide for public access to information about health and safety data concerning pesticides. Testimony by Steven B. Jellinek, former Assistant Administrator, Office of Pesticides and Toxic Substances, EPA, before an Oversight Committee sets forth EPA's position and provides an excellent review of the competing interests of the public and industry.[47]

Jellinek says there are two basic issues: (1) what data may be used by any producer to support product registration, and (2) what data should be accessible to the public. He says that EPA's long-held position, which Congress affirmed in the 1978 amendments to the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) is that information about pesticide health effects should be available to the public. He maintains that only a narrowly limited class of information, primarily manufacturing and quality control data and confidential formulas, should be withheld from public scrutiny. Jellinek states that FIFRA substitutes one system for protection of data (compensation or exclusive care) for that which the industry has always preferred (secrecy).[48] He notes that the Act's "carefully balanced data scheme takes into account societal goals other than protection of proprietary interests".[49]

On the issue of public access, Jellinek states "we continue to believe that public access to the test data upon which the agency made its decision is vitally important. It is the public which must bear the cost of our decisions. Public understanding of the decision-making process and its complexities is crucial to public acceptance of the risk/benefit approach which underlies the regulation of pesticides. Moreover, public involvement in the regulatory process can improve the quality of our decisions".[50]

He also makes the important point that in one and a half years since the amendments to FIFRA, EPA has seen no evidence that the pesticide-producing industry is suffering from unscrupulous competition resulting from the new definition of trade secrets.[51]

We contend that the public must have access to data on pesticides with which they can assess the risk to their environment and personal health.

CELA and Probe therefore recommend that the PCPA be amended to clearly provide for public access to pesticide health and safety data.

VIII. THE PCPA MUST BE AMENDED TO PROVIDE FOR PUBLIC PARTICIPATION IN THE REGISTRATION AND REGULATION-MAKING PROCESS

The 1980 Environmental Contaminants Board of Review's Report on Outside Review and Public Participation observed that there are some federal statutes under which there is "the naked power to create regulations without any obligation whatsoever to consult or even reveal what is contemplated until it is a fait accompli".[52] The PCPA is such a statute, including no statutory mechanisms for input into either the regulation-making or perhaps, more important, the registration process.

The Board of Review also cited the pesticide example as an area where public demand is growing for a participatory role.[53]

CELA and Probe recommend that the Pest Control Products Act be amended to provide for:

- public notification of and access to any application for the registration of a pesticide;
- an opportunity within a set time period for any person to file written submissions on the chemical proposed for registration;
- the ability of the public to bring to the attention of the Minister(s) responsible for the administration of the Act, new information about adverse health or environmental impacts of any registered pesticide; the ability to cause a hearing by a Review Board to inquire whether a chemical should be suspended or cancelled or its registration continued;[54]
- a requirement that a registrant notify the government immediately if one of its registered products may cause or contribute a danger to human health or the environment;

- a provision for citizen standing to bring an application for judicial review of any requirement under Act or regulations;[55]

- public participation in the regulation-making process. (This would include the publication of draft regulations in the Canada Gazette with an appropriate time frame established for public submissions.)

The amendments would be significant improvements towards ensuring that the users, applicators, and the public who are often exposed unwillingly to pesticides have a say in the decision-making process.

IX. THE PEST CONTROL PRODUCTS ACT SHOULD BE AMENDED TO PROVIDE FOR THE MANDATORY SUSPENSION OF REGISTERED PESTICIDES WHEN IT IS SHOWN THAT THE SAFETY TESTS SUPPORTING THE REGISTRATION ARE INVALID; THE SUSPENSION SHOULD CONTINUE UNTIL NEW SAFETY TESTS ARE PROVIDED

The General Accounting Office of the U.S. Congress in a 1980 Report entitled "Delays and Unresolved Issues Plague New Pesticide Protection Programs",[56] discuss the IBT affair and the validation program. The G.A.O. found that EPA did not have the authority under FIFRA to suspend or cancel the use of pesticides on the sole basis that they were unsupported by valid safety tests.[57] The G.A.O. was concerned that this lack of authority could result in public exposure to dangerous pesticides for a period of years, during which time EPA would not be fulfilling their mandate to protect the public and environment from hazardous pesticides.[58]

The G.A.O. notes that Section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA)[59] does allow the Food and Drug Administration to withdraw approval of a drug when it is determined that the original drug approval application "contains any untrue statement of a material fact".

To remedy this gap in the legislation, the G.A.O. recommended that EPA submit to Congress an amendment to FIFRA to authorize EPA to take appropriate regulatory action, including suspension, of pesticides which were not supported by valid safety tests when registered.[60]

While it is arguable that the Canadian Minister of Agriculture's present power to suspend a pesticide on the basis that "the safety of the control product or its merit or value for its intended purposes is no longer acceptable to him",[61] could include the fact that the data provided for registration was false, it is not entirely clear that false data alone could be the sole basis for suspension.

For this reason, CELA and Probe recommend that the PCPA be specifically amended to provide for the automatic suspension of

pesticides whose registration was found to be based on invalid studies. This suspension should continue until such time as valid replacement tests are provided to show that the pesticides are safe.

While we contend that this would have been an appropriate approach to deal with the IBT chemicals when the fraudulent data was first discovered in 1977, we recognize the difficulties in suspending the use of the IBT chemicals at the present time. However, we think that in the future there should be clear statutory authority for the suspension of pesticides whose registration is found to be based on invalid studies.

In addition, we would urge that regulatory action be taken as soon as possible to restrict the use of other IBT chemicals where the company has not come forward with valid replacement tests.

We suggest that in light of the time that has already lapsed since the IBT fraudulent testing results were discovered, only a further short period be allowed for validation. Any IBT pesticides not validated within one year's time, should be suspended.

X. THERE SHOULD BE NO DETECTABLE RESIDUES ALLOWED FOR CAPTAN ON FOOD: AMENDMENTS TO FOOD AND DRUG LEGISLATION URGED

A. The Residue Question

Pesticide residue amounts in agricultural produce are controlled by regulations under the Federal Food and Drugs Act (FDA)[62] which is administered by Health and Welfare. Maximum permissible amounts of pesticides (expressed in parts per million) are specified in the Regulations for particular fruits and vegetables. On fruit, Captan tolerances are either 25 or 40 ppm depending on the type of fruit.[63]

Apparently, there are no administrative procedural manuals or documents used by Health and Welfare which outline the types of scientific information required to support the establishment of pesticide residue limits in food.[64] The Health Protection Branch considers that the applicant is responsible for proving the chemical nature, level, and safety of any pesticide residues in food.[65]

The methods by which tolerances are set have been criticized both in Canada[66] and in the U.S. In the U.S., the California Department of Food and Agriculture has been criticized for using statisticial averages that grossly underestimate the consumers' pesticide exposure.[67] To set the tolerance levels, EPA first calculates how much of each variety of food and vegetable the typical American consumes. The total U.S. production of fruit and vegetables is divided by the total population to arrive at an average annual consumption level.[68] This procedure of setting tolerances ignores the fact that many people, including chemical workers, farmers, agricultural labourers, and people who live near farms, are exposed to pesticides on the job or at home as well as in foods.[69]

The marketbasket surveys used for determining pesticide intake have also come under attack by the General Accounting Office branch of the U.S. Congress. For example, it was found that a person would have to eat two pounds of raisins a day to exceed the

acceptable daily intake of Captan, but only two medium sized apples a day would easily provide a person with more than the accepted level of the chemical.[70]

On February 5, 1980, a coalition of 21 plaintiffs launched a suit against the California Department of Food and Agriculture claiming that the Department had failed to keep food in the State free from pesticides that cause cancer, birth defects, sterility, and mutations.[71] The plaintiffs demanded that the State eliminate 37 of the most harmful pesticides from food supplies and tighten its regulations on 244 other pesticides. They want California to adopt the principle that no residue of any pesticide proven to be carcinogenic, mutagenic, or teratogenic should be tolerated on produce.[72]

CELA and Probe strongly urge that the Canadian Food and Drugs Act be amended to provide that no residue levels shall be established where a pesticide has been found to be carcinogenic, mutagenic or teratogenic in human beings or animals.

B. Public Participation in the Residue Setting Process under the Food and Drugs Act

As in the case of the PCPA, the FDA does not provide for public input into the regulation-making process. Under the FDA, the regulations are the teeth of the Act, setting out the acceptable residue limits. CELA and Probe recommend that the FDA should be amended to provide for:

- public participation in the regulation-making process including publication of draft regulations in the Canada Gazette with an appropriate time frame established for public submissions;

- a mechanism to allow any person to bring to the attention of the Minister of Health and Welfare, new information about adverse health or environmental impacts of any registered pesticide with an established tolerance and to require that the tolerance level be re-examined.

XI. REGULATORY DECISIONS REGARDING IBT PESTICIDES SHOULD BE BASED ON HUMAN AND ENVIRONMENTAL HEALTH CONCERNS, NOT ECONOMICS

Presently, under the terms of the Pest Control Products Act (PCPA) the Minister may refuse to register a control product if "the use of the control product would lead to an unacceptable risk of harm to public health, plants, animals, or the environment".[73] During the period of registration, the Minister may also require a registrant to "satisfy the Minister that the availability of the control product will not lead to an unacceptable risk of harm to public health, plants, animals, or the environment".[74]

There is no specific statutory requirement for the Minister to weigh economic matters against health concerns in the determination of whether a control product should be registered, cancelled, or suspended. It need only be determined that use of the control product would lead to "an unacceptable risk of harm to public health, plants, animals, or the environment". This should be the standard used to determine the regulatory action to be taken in regard to Captan.

Yet we note in the Terms of Reference establishing the Consultative Committee that the Committee is to "determine to the fullest extent possible in the light of existing scientific knowledge whether the chemical presents any unreasonable risks for use as a pesticide; i.e. that the chemical meets safety standards and its use does not present any unreasonable risk to man or the environment, taking into account the human health, environmental, and socio-economic costs and benefits of the use of the pesticide". (emphasis added)[75]

Mr. Lussier, Deputy Minister of Agriculture has also been quoted as saying that "...the economic implications have to be considered as well"[76] in deciding the fate of Captan.

CELA and Probe believe that the issue of whether Captan poses an unreasonable risk of harm to human beings, plants, animals, or the environment, is the applicable standard established under the legislation that should govern in regard to all IBT pesticides, including Captan.

It is our contention that this standard has not been met, and that measures must be taken to immediately curtail the use of this pesticide.

XII. CONCLUSIONS AND RECOMMENDATIONS

Public confidence in the regulation and use of pesticides can only be restored by the adoption of significant changes in the laws and policies relating to pesticides.

Public health and the environment have both been needlessly exposed to and damaged by the careless use and disposal of hazardous pesticides.

In order to avoid further damage to the environment and to reduce the risk to public health, CELA and Probe urge the Consultative Committee to accept the following recommendations for regulatory action to be taken in regard to Captan:

Recommendation		Discussion at Page Infra.
1.	Captan should be banned immediately for household uses and should be phased out in agricultural applications.	4-5
2.	Captan should not be used by farmers who run pick-your-own operations.	7
3.	There should be no detectable residues allowed for Captan on food.	7-8

CELA and Probe also urge the Consultative Committee to accept the following general recommendations in regard to pesticide law and policy:

1.	The Pest Control Products Act (PCPA) should be jointly administered by Health and Welfare and Environment Canada or by a Pest Control Evaluation Commission.	11

Recommendation	Discussion at Page Infra.
2. An Integrated Pest Management Strategy and the search for alternatives to chemical pesticides must be given strong government support. Specifically, it should be a clear government policy or there should be amendments to the PCPA to provide for a requirement that a percentage of Environment Canada's and Health and Welfare's budget be spent on IPM research.	13-14
3. Canada should develop its own testing capability. Specifically, all pesticide testing should be conducted ideally by a Canadian independent testing facility run by a Crown corporation, or, alternatively, by laboratories under contract to the government.	15-16
4. The PCPA should be amended to ensure public access to pesticide health and safety data.	17-20
5. The Pest Control Products Regulations should be amended to provide for a mandatory requirement for the Minister to refuse to register, suspend, or cancel the registration of a pest control product if the conditions presently set out in section 18 and 20 are not met.	10-11
6. The PCPA should also be amended to provide for: • public notification of and access to any application for the registration of a pesticide; • an opportunity within a set time period for any person to file written submissions on the chemical proposed for registration;	21-22

Recommendation	Discussion at Page Infra.

- the ability of the public to bring to the attention of the Minister(s) responsible for the administration of the Act, new information about adverse health or environmental impacts of any registered pesticide; the ability to cause a hearing by a Review Board to inquire whether a chemical should be suspended or cancelled or its registration continued;
- a requirement that a registrant notify the government immediately if one of its registered products may cause or contribute a danger to human health or the environment;
- a provision for citizen standing to bring an application for judicial review of any requirement under the Act or regulations;
- public participation in the regulation-making process. (This would include the publication of draft regulations in the Canada Gazette with an appropriate time frame established for public submissions.)

7. The Pest Control Products Act should be amended to provide for the mandatory suspension of registered pesticides when it is shown that the safety tests supporting the registration are invalid. The suspension should continue until new safety tests are provided. 23-24

Recommendations	Discussion at Page Infra.
8. The Food and Drugs Act should be amended to provide that no residue levels be established where a pesticide has been found to be carcinogenic, mutagenic, or teratogenic in human beings or animals.	25
9. The Food and Drugs Act should also be amended to provide for: • public participation in the regulation-making process including publication of draft regulations in the Canada Gazette with an appropriate time frame established for public submissions; • a mechanism to allow any person to bring to the attention of the Minister of Health and Welfare, new information about adverse health or environmental impacts of any registered pesticide with an established tolerance and to require that the tolerance level be re-examined.	26

XIII. NOTES

1. See Canadian Environmental Law Association and Pollution Probe. The IBT Affair Submissions to the Ontario Pesticides Advisory Committee, October 1980.

2. See correspondence between Joe Castrilli (CELA) and Mr. Gaetan Lussier, Deputy Minister of Agriculture, for the period from May 29, 1981 to September 10, 1981.

   These conditions included: A more balanced representation on the Committee itself; access to information, including agency memos, etc.; an assurance that the government would not waste Committee time in trying to distinquish between a 'carcinogen' and an 'animal carcinogen'; paid expenses; and finally, option to publish a minority report.

   On the issue of access to information, Mr. Lussier, in a letter to CELA dated July 27, 1981, noted that "detailed toxicological tests and environmental studies will not be included nor will inter/intra agency and intergovernmental correspondence. Such information is voluminous (emphasis added) and considered unnecessary for the deliberations."

3. Correspondence from Frank Cedar, Secretary, Consultative Committee on Industrial Bio-Test Pesticides to Pollution Probe, January 26, 1982.

4. Ibid.

5. U.S. Federal Register, Vol.45, No. 161, August 18, 1980, Washington, D.C.

6. Correspondence from Dr. Joseph Cummins, University of Western Ontario, to Dr. D. Clegg, Health Protection Branch, Department of Health and Welfare, Ottawa, January 29, 1979.

7. Rationale for the Recommendations of March 31, 1981 on the Status of Captan, Health Protection Branch, Department of Health and Welfare, June 3, 1981, Ottawa, Ontario.

8. Supra note 5.

9. Joseph E. Cummins, A Brief on Captan Submitted to the Consultative Committee on IBT Pesticides: Human Exposure to Captan in Relation to Pick-Your-Own Operations, University of Western Ontario, January 28, 1982, London, Ontario.

10. D.R. Stoltz et al, Mutagens in Foods: Statistical Analysis of Beverage Data and Preliminary Results with Fruit and Vegetables, Food Directorate, Health Protection Branch, Tunney's Pasture, Ottawa, Ontario.

11. Consultative Committee on IBT Pesticides, Request for Submissions on Captan, at page 4, Question #7, December 30, 1981. Ottawa.

12. R.S.C. 1970, c.P-10 as amended.

13. The B.N.A. Act, 1867, s.95 also provides that federal legislation is paramount; specifically a provincial law shall take effect "as long and as far as it is not repugnant to any Act of the Parliament of Canada".

14. C.R.C. 1978, c.1253 as amended.

15. R.S.O. 1980, c.376 as amended.

16. Supra note 14, s.9(1)

17. Ibid. s.9(2)

18. Ibid. s.20

19. Ibid. s.18(b) and 18(d)

20. Ontario is one such province. Presently, in Canada, seven of the ten provinces assign their pesticide legislation to the jurisdiction of their Ministries of the Environment. The U.S. pesticide legislation, The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 7 U.S.C. 136 et seq., is also now administered by the Environmental Protection Agency and not the Department of Agriculture.

21. Food and Drugs Act, R.S.C. 1970, c.F-27 as amended.

22. The Environmental Contaminants Act, R.S.C. 1974-75-76, c.47 as amended which regulates contaminants of national concern is administered jointly by Health and Welfare and Environment Canada. This precedent is particularly relevant, in that the point beyond which a registered pest control product under the PCPA may become an environmental contaminant under the terms of the Environmental Contaminants Act is an area of virtually unexplored territory. For example, currently the Environmental Contaminants Act controls the manufacture and use of Mirex. This chemical, while only used as a fire retardant in Canada, was used as a pesticide in the U.S.

23. See Ross H. Hall. A New Approach to Pest Control in Canada. Canadian Environmental Advisory Council. Report No. 10. July, 1981 at page 37. This report notes the 'obvious bias' that exists in Agriculture Canada towards crop production.

24. See U.S. EPA Research Summary: Integrated Pest Management, Office of Research and Development, September, 1980. Washington, D.C. It has been estimated that more than 300 species of insects, mites, and ticks throughout the world possess genetic strains which are resistant to one or more pesticides.

25. Ibid. at page 2. Pesticides have been found to kill not only target pests but also insects which help control other pests.

26. Ibid.

27. David Thomas "The Spread of Silent Springs", Macleans, May 18, 1981 at page 34. However, one often-cited example of a successful IPM program is that of apple growers in Nova Scotia and Eastern Quebec who have used IPM since the 1950s.

28. See Peter von Stackelberg, "Chemical Industry's Figures Questioned", Regina Leader Post, November 12, 1980.

29. See Dr. David Pimental et al, "Benefits and Costs of Pesticide Use in U.S. Food Production", Bio-Science, Volume 28, No. 12, December, 1978. See also Supra note 24.

30. Ibid. at page 780.

31. The IPM Practitioner, Vol.2, No.8, August, 1980, Berkeley, California.

32. Supra note 28, In order to facilitate this, a percentage of the research budget should be taken from Agriculture Canada.

33. Saskatchewan Environmental Advisory Council. Annual Report. 1977-78. Regina, Saskatchewan.

34. See Peter von Stackelberg, "Report Show Tests by 25 More Laboratories Deficient", Regina Leader Post, June 6, 1981

While Sandy St. Clair, President of CACA, stated that IBT was an aberration and that he had never heard of any major problems at other testing laboratories, and Health and Welfare officials told reporters that IBT was an isolated event; documents obtained through a U.S. Freedom of Information request revealed otherwise.

35. U.S. Environmental Protection Agency and Food and Drug Administration. Health Effects Data Quality Status Report. October 19, 1979. IBT is #34 on the list.

36. Hansard. House of Commons Debates, Volume 124, No. 280, p.14232, Friday, December 18, 1981. Tom McMillan speaking on the recent amendments to the PCPA stressed that we could not go on relying on other countries for research and development in the pesticide area.

37. Supra note 22, at page 4

38. See March 18, 1980 correspondence from Martin Flam, California Rural Legal Assistance (CLRA), to U.S. EPA. Sweden banned the use of Captan in 1978, correspondence from Maria McMillan, Royal Swedish Embassy, Ottawa, Ontario to CELA, August 12, 1980.

39. See November 18, 1980 correspondence from David O. Bickart, Deputy General Counsel, U.S. EPA to Martin Flam, CLRA. The inter/intra agency memo exemption s.552(b)(5) did not apply as (a) the Canadian Government is not an agency, and (b) the materials are not deliberative in nature. The trade secret exemption did not apply because, while the Canadian-U.S. reviews of IBT Captan studies incorporated a limited amount of information originally submitted to EPA by Chevron Corporation under a claim of confidentiality, Chevron waived its claim to the records in question.

40. See, for example, memo from Dr. Ruddick to Mr. Clegg re IBT study, p.5398, teratology/hamsters. Health and Welfare Canada, July 15, 1979. Five pups in the raw data were described as having 'no eyes' which the final report describes as 'lack of eye pigementation'.

41. See memo from Dr. Cunningham to Mr. Clegg, Health and Welfare Canada, June 26, 1979 re IBT study 621-05519, teratology/rhesus monkeys.

42. See memo from Dr. Cunningham to Mr. Clegg, Health and Welfare Canada. July 9, 1979, re 623-05998. Dormant lethal studies in mice.

43. See telex to West Coast Environmental Law Association (WCELA) from W.P. McKinley Senior Policy Advisor, Health and Welfare Canada, March 12, 1981.

44. Correspondence from West Coast Environmental Law Association to CELA, April 15, 1981.

45. Heather Mitchell, Proceedings from a Roundtable Discussion on Toxic Chemicals Law and Policy in Canada, CELA/CELRF, June 15-16, 1981, Toronto. At page 64.

46. Supra note 39 at p.11.

47. See Extension of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Hearings before the Subcommittee on Department Investigations, Oversight and Research of the Committee on Agriculture, House of Representatives, 96th Congress, 2nd Session. April 15 and May 1, 1980.

48. Ibid. at p.149. See FIFRA s.3(c)(1)(d). All data submitted from 1970 on is eligible for compensation for a period of 15 years following the submission of the data. This means that subsequent applicants must offer to pay compensation to data originators in order to rely on their data. Ten years' exclusive use of data is given to the original registrant after a new chemical is first registered.

49. Ibid. p.149

50. Ibid.

51. Ibid.

52. Environmental Contaminants Board of Review. Report on Outside Review and Public Participation, Ottawa, July 1980 at page 12. This was the second report of the Board of Review which was established as a result of objections to PCB regulations proposed under the Environmental Contaminants Act.

53. Ibid. at page 111. Professor Maxwell Cohen, Chairman of the Board of Review has indicated that in all the years the Federal government has been making regulations to control pesticides, not a single public hearing has been held.

54. Presently, only an applicant or registrant can apply for a hearing by a Review Board if the Minister of Agriculture refuses to register or cancels or suspends the registration of a control product. See C.R.C. 1978, c.1253, sections 21-25.

55. See page 11 infra..

56. United States General Accounting Office, Delays and Unresolved Issues Plague New Pesticide Protection Programs. February 15, 1980. Washington, D.C.

57. Ibid. at page 54

58. Ibid. at page 56

59. 21 U.S.C. 301 as amended

60. Ibid. at page 57

61. Pest Control Products Regulation, C.R.C. 1978, c.1253, s.20

62. R.S.C. 1970, c.F-27 as amended.

63. Food and Drug Regulations, C.R.C. 1978, c.870 as amended. Part B, Division 15, Table II.

64. See Correspondence with Mr. Ian Munro, Director General, Food Directorate, Health and Welfare Canada, to Mr.Joe Castrilli, CELA, December 9, 1980

65. Ibid. Data is required from the applicant on items including; specifications for the chemical and its physical/chemical properties; evidence that the product is effective and practical; the amount to be applied; frequency and times of application; satisfactory methods of analysis for determining residues in food; plant and animal metabolism studies; data on the quantity and chemical nature of residues remaining on foods at harvest, slaughter, or point of sale; toxicity studies designed to evaluate the hazards of residues to experimental animals; and proposed residue limits in food.

66. See Peter von Stackelberg "Those Juicy Fruits May Be Juicier Than You Think", Regina Leader Post, September 10, 1980. See also Linda R. Pim, The Invisible Additives. Doubleday, Toronto, 1981.

67. Ibid.

68. See "Pesticidal Produce" San Jose Mercury, Editorial, February 12, 1980. The editorial comments that the method of setting tolerance levels "makes as much sense as taking the average length of all American feet and then marketing only one shoe."

69. Ibid.

70. Supra note 66.

71. Peter von Stackelberg, "Examining the Data on Pesticides Difficult" Regina Leader Post, September 10, 1980. The suit does not seek a ban on the use of effective pesticides but simply wants them to be kept out of food.

72. This is similar to the Delaney Amendment to the U.S. Food and Drug Act which prohibits the use of any food additive that has been shown to cause cancer in human beings or animals.

73. PCP Regulations, C.R.C. 1978, s.19

74. Ibid. s.20

75. Consultative Committee on IBT Pesticides Terms of Reference, November 19, 1981.

76. See David Thomas "The Spread of Silent Springs" Macleans May 18, 1981 at page 33 in which Mr. Lussier is quoted as saying "we are probably as much concerned as anyone elase about the health of the Canadian population. But a dilemma occurs because the economic implications have to be considered as well."