

"THE IBT AFFAIR"

SUBMISSIONS
TO THE
ONTARIO
PESTICIDES ADVISORY COMMITTEE

by
POLLUTION PROBE
AND THE
CANADIAN ENVIRONMENTAL LAW ASSOCIATION

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TABLE OF CONTENTS

<u>Part</u>		<u>Page</u>
I.	INTRODUCTION	1
II.	BACKGROUND TO THE IBT AFFAIR	1
	Origins in the United States	1
III.	IMPACT ON CANADA AND THE ROLE OF THE FEDERAL GOVERNMENT TO DATE	3
IV.	THE ACTIONS OF OTHER NATIONAL GOVERNMENTS	5
V.	THE ROLE OF PROVINCIAL GOVERNMENTS	6
VI.	THE ROLE OF THE PESTICIDES ADVISORY COMMITTEE	8
VII.	RECOMMENDATIONS	8
VIII.	CONCLUSIONS	9
XI.	NOTES	10

I. INTRODUCTION

Pollution Probe, founded in 1969, is committed to the long-term well being of man and the environment. Our objectives are to promote sane management of our resources and sound policies to reduce environmental pollution.

The Canadian Environmental Law Association, founded in 1970, is a non-profit organization that uses existing laws to protect the environment and where necessary advocates appropriate environmental law reforms.

Since their inception, both organizations have become involved in particular pesticide problems largely through contact with members of the public who have experienced or were concerned about potential public health or environmental problems arising from the use or misuse of particular pest control products.

This brief will focus on the problem of pest control products in use in Ontario whose federal registration is based, in whole or in part, on fraudulent or questionable studies performed by Industrial Biotest Laboratories (hereinafter IBT), an Illinois-based testing firm. In reviewing the background to the IBT affair, our submissions will discuss the roles of the federal and provincial governments to date on this matter, examine the potential role of the Pesticides Advisory Committee in resolution of the problem and conclude with recommendations regarding IBT and pesticides policy and law reform.

II. BACKGROUND TO THE IBT AFFAIR

Origins in the United States

Over three years ago, the United States Environmental Protection Agency (US EPA), as a result of a joint audit undertaken

with the U.S. Food and Drug Administration regarding chemical safety testing practices at U.S. laboratories, reported finding "deficiencies" in some of the pesticide safety tests that IBT performed for pesticide manufacturers. The IBT testing deficiencies related to whether the manufacturers' products cause such adverse effects as cancer, birth defects, nerve damage or metabolic problems.¹ Earlier in 1977, IBT, which was already under U.S. federal investigation for submission of questionable test data and possible fraud, admitted shredding critical research documents that supported many federally approved herbicides and pesticides. The president of IBT admitted ordering the documents shredded after the investigation began but said this was due to a "misunderstanding." U.S. investigators said at the time that the shredded documents could cause serious problems in determining whether some products on the market are actually safe.²

U.S. federal agencies subsequently reported that they had evidence to establish that IBT deliberately falsified data submitted to the U.S. government on potential carcinogens and that at least four major pesticide manufacturers may have been aware of the problem when they submitted the test data as part of their applications in support of product registrations.³ It is our understanding that a U.S. federal grand jury is in the final stages of determining whether to return criminal indictments against IBT and its officers for submission of fraudulent test data.⁴

Because of these irregularities and testing deficiencies, US EPA initially asked in 1977 approximately 30 pesticide manufacturers and several U.S. federal agencies that employed IBT, to review and certify the accuracy of the tests done for them.⁵ In the case of these 30 or so organizations alone, IBT tests were reported to support, in whole or in part, US EPA approval for sale of 123 pesticide ingredients and 160

tolerances. Shortly after the US EPA announcement it also made public the list of pesticides whose safety testing was in doubt.⁶

III. IMPACT ON CANADA AND THE ROLE OF THE FEDERAL GOVERNMENT TO DATE

Many countries, including Canada, rely upon tolerances based on IBT data. The magnitude of the problem is suggested by the fact that international agencies, such as the World Health Organization, have also used IBT data which have been recommended to member countries to aid in establishing acceptable daily intake and exposure levels for various chemicals and pesticides. In August 1977, Health and Welfare Minister Marc Lalonde indicated that Canada's Health Protection Branch was initiating investigations of toxicity tests conducted by IBT. However, Health and Welfare Canada did not make public the list of pesticides that were under investigation until 1980. It did note in 1977, however, that it anticipated that IBT-generated information on more than 200 chemicals might be scrutinized.⁷

When irregularities in IBT's data were discovered in 1977, the Canadian and U.S. governments began joint investigations to re-examine the studies on all pesticides whose registrations were supported by IBT data,⁸ and sought further information from the manufacturers. Yet two and a half years later, R.O. Read, chairman of a federal working group on IBT pesticides, acknowledged that many registrants had failed to submit the information requested by the US EPA and Health and Welfare Canada. In a recent letter to the Canadian Agricultural Chemicals Association, Mr. Read advised that the validity of all IBT studies remained in doubt until successfully demonstrated by the sponsoring registrant to be otherwise; and that all long-term rodent studies and multigeneration reproduction studies performed by IBT were considered

invalid; and unless results from long-term animal testing by labs other than IBT could clear the pesticides in question, their safety would remain in doubt.⁹

However, notwithstanding these problems, the position of both the U.S. and Canadian governments has been that pesticides supported in whole or in part by IBT generated data may continue to be used while government re-testing takes place regardless of the type of data that is missing. Yet many years may yet pass before all re-testing is completed. Moreover, there appear to be discrepancies between the U.S. and Canada as to the number of studies and pesticides requiring review as well as confusion as to the meaning of the results obtained to date. For example in June 1980, Health and Welfare Canada Minister Monique Begin advised Dennis Timbrell, Ontario's Health Minister, that the federal government's review program had been underway for about three years. She went on to note that:

"Officers of the Health Protection Branch working cooperatively with their counterparts in the US EPA have determined that 97 pesticides are involved. Safety evaluation of these is supported in whole or in part by studies conducted by IBT. 405 IBT studies had been examined by March 28, 1980 and of these 157 had been declared valid, 15 are usable in part and 233 have been declared invalid. A further 410 studies remain to be examined (160 by Canada and the remaining 250 by US EPA). It is anticipated that the final review of all the studies to be examined by HPB will be completed by 1981. On the basis of results to date, 8 pesticides have been declared free of any further concern."¹⁰

The department also advised, however, that another 4 years would be required to do a detailed assessment of the future availability of IBT pesticides.¹¹

However, CELA has recently been advised by US EPA that as many as 1600 studies not 800 are involved and that approximately 1000 studies not 410 remain to be reviewed by the two countries. Moreover, over 200 chemicals were now said to be under examination.¹² Indeed, in August 1980, Madame Begin sent a letter to the Saskatchewan government advising it that nine additional chemicals were involved in the IBT affair in addition to the list of 97 that the Government of Canada had released for the first time in June 1980.¹³

The federal government has also never identified which studies have been declared valid usable in part or invalid nor does its list of suspect pesticides describe the deficiencies in IBT data for each chemical. This has been a particular concern of the Saskatchewan Government whose Environment Minister, the Hon. Ted Bowerman, has argued that: "Continued use of the chemicals in question with no public statement as to the particular flaws in the chemicals is an unsatisfactory position."¹⁴

Other inconsistencies in the Canadian-U.S. regulatory approaches to IBT tested products include the fact that captan, a fungicide available for use in Canada and on the IBT list is highly suspected in the U.S. of being a carcinogen, and is currently subject to the U.S. EPA's rebuttable presumption against registration (RPAR) process.¹⁵ RPAR is a regulatory review procedure under U.S. federal pesticides law, reserved for substances that demonstrate chronic or acute health effects in humans and wildlife. Another inconsistency between U.S. and Canadian IBT review procedures is the fact that the herbicide 2,4-D appears on the U.S. IBT list but not on the Canadian list.

IV. THE ACTIONS OF OTHER NATIONAL GOVERNMENTS

While the position of the Canadian and U.S. governments has been to permit continued use of pesticides supported in whole

or in part by IBT data while re-testing proceeds, other national governments have specifically rejected this approach, at least in part. For example, the Government of Sweden, in September 1978, banned the use of 9 pest control products, including captan and meta bromuron, that had been registered on the basis of tests conducted by IBT.¹⁶

V. THE ROLE OF PROVINCIAL GOVERNMENTS

The Ontario Government has long recognized its authority to undertake stronger remedial regulatory action under its pesticides law when, for whatever reasons, it believes the federal government is not taking adequate action under the Pest Control Products Act. The provincial government placed greater restrictions on the use of DDT in the province long before the federal government took similar action nationwide.

Given the provincial government's authority to impose more stringent controls than those set by Ottawa, it is disturbing to hear provincial pesticide advisors characterize the IBT matter as a "federal matter."¹⁷

It is of equal, if not greater concern, when Ministry of Environment pesticide officer John Onderdonk states that the Pesticide Advisory Committee's job is to find out about pesticide hazards and advise the minister. "We rely on the committee, and the feds."¹⁸

Compounding the problem of who's responsible for what is the apparently poor flow of information from the federal to the provincial level. Dr. Richard Frank, a member of the Pesticide Advisory Committee, indicated that despite his requests, it was difficult to get information on which pesticides were suspect. He stated that Health and Welfare Canada "kept the

information pretty well to themselves. I drew blanks on where to get the information."¹⁹

Doug Wilson, Supervisor of the Pest Control Section of MOE was perplexed by the list of 89 suspect pesticides released by the federal government in late June. "I don't recognize half the compounds on the list. The list is very confusing ...some are generic names...others are trade names."²⁰

Pollution Probe sent a letter to Environment Minister Harry Parrott in July 1980 asking that the MOE indicate publicly strategy in dealing with each suspect pesticides available in Ontario. The Minister's response basically restated the province's reliance on the federal government for information and guidance and added that the province would act "if evidence of a health hazard is produced."²¹ Since we are talking about pesticides that have been on the market for years, such a response can hardly instill public confidence in governmental management of the IBT problem at the provincial level. Ontario's response to date has simply not been good enough.

In contrast to Ontario's passive reliance on Ottawa for information on the IBT controversy, the government of Saskatchewan has been actively in pursuit of more detailed information. The Hon. Ted Bowerman, Saskatchewan Environment Minister, has stated:

"If I do not receive more information promptly or if I am not satisfied that the federal officials are taking appropriate measures to re-establish the status of the chemicals in question, I will be consulting with my colleagues in provincial health and agriculture to consider what measures Saskatchewan should take on its own."²²

The Saskatchewan Environmental Advisory Council in its 1977-78 annual report also notes 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."²³

The City of Toronto health department has also criticized the federal government for withholding information about IBT tested pesticides.²⁴

VI. THE ROLE OF THE PESTICIDES ADVISORY COMMITTEE

Under Ontario's Pesticides Act, 1973, the Pesticides Advisory Committee's functions include the authority to:

- annually review the content and operation of the Act and regulations and recommend changes or amendments to the Minister; and
- inquire into and consider any matter the Committee considers advisable concerning pesticides and the control of pests and report to the Minister.²⁵

In light of these statutory powers and the problems we have raised respecting the IBT affair and those of which the committee is already aware, we would submit that the committee is in a unique position to assist in expediting the finding of solutions to this problem. These are suggested in the next section.

VII. RECOMMENDATIONS

We would recommend that the Pesticides Advisory Committee advise the Minister of Environment to:

- (1) immediately place in Schedule I of the Pesticides Act those pesticides found on the IBT list for which
- no scientifically valid mutagenic studies exist; or
 - no scientifically valid chronic/oncogenicity studies exist; or
 - no scientifically valid reproductive studies exist; or
 - no scientifically valid teratologic studies exist; or
 - no scientifically valid neurotoxicity studies exist.

Such pest control products should remain in Schedule I until such time as scientifically valid studies are completed in the appropriate areas and demonstrate that the pesticide does not possess such adverse effects.

- (2) immediately publish, or have the committee publish, both a generic and a trade name list of IBT pesticides including a description of which types of data are lacking for each pesticide on the list and the environmental and health implications of each such gap including which such products are to be placed in Schedule I;
- (3) immediately investigate and publish, or have the committee investigate and publish, a report or circular outlining suitable and safe alternative pesticides or other techniques that may be used in place of IBT pesticides;
- (4) give immediate notice to all licensed applicators, vendors and other users or interested parties respecting IBT pesticides of the information noted in recommendations (2) and (3);
- (5) amend the Act to permit the public to make submissions to the Pesticide Advisory Committee concerning a specific pesticide or regulation under the Pesticides Act.

VIII. CONCLUSIONS

In light of the problems posed by the IBT affair, and the province's substantial jurisdiction in the area we urge the committee to take an active role in this matter.

IX. NOTES

1. U.S. Environmental Protection Agency. News Release. "Deficiencies in Pesticide Safety Tests Reported By EPA; Audit Requested," August 25, 1977, Washington, D.C.
2. Bill Richards, "Lab in Probe Admits Data Was Shredded," The Washington Post, September 20, 1977.
3. Bill Richards, "Probers Say Pesticide Makers Knew of Faulty Lab Test Data," The Washington Post, March 9, 1978.
4. CELA telephone interview with Mary Miller, special pesticide review division, US EPA, Washington, D.C. October 6, 1980.
5. See form letter sent to first 33 pesticide registrants who relied on IBT data by US EPA, office of Pesticide Programs, July 27, 1977, Washington, D.C.
6. Supra note 1. See also attached list of pesticides.
7. Health and Welfare Canada. Communique. "Validity of Data on the Safety of Numerous Chemicals Being Investigated," August 15, 1977, Ottawa, Ontario.
8. Health and Welfare Canada. News Release. "Pesticide Safety Being Reassessed," June 23, 1980. Ottawa, Ontario.
9. Correspondence from R.O. Read, health protection branch, Health and Welfare Canada to J. Chevalier, executive secretary, Canadian Agricultural Chemicals Association, January 25, 1980, Ottawa, Ontario.
10. Correspondence from the Hon. Monique Begin, federal Minister of Health and Welfare to the Hon. Dennis Timbrell, Ontario Minister of Health, June 17, 1980.
11. Supra notes 8 and 10.
12. Supra note 4.
13. Government of Saskatchewan. News Release, "Nine More Chemicals Suspect in the IBT Affair," August 27, 1980, Regina, Saskatchewan.
14. Supra note 13. See also Peter von Stackelberg, "Province Awaits News on Pesticide Tests," The Leader-Post, Regina, Saskatchewan, June 21, 1980.
15. U.S. Environmental Protection Agency. Office of Pesticide Programs. "RPAR Issued on Captan." Weekly Report from OPP. Vol. iv, No. 32. August 6, 1980. Washington, D.C.

16. Correspondence from Maria McMillan, Information Officer, Royal Swedish Embassy, Ottawa, Ontario to CELA, August 12, 1980.
17. See Peter von Stackelberg, "Safety last: tests that fail the test," Macleans August 25, 1980. Dr. George Cooper, chairman of the province's pesticide advisory committee is quoted as stating: "We have known all about this (the IBT issue) for the last 3 years. We feel it is a federal matter."
18. Ross Howard, "Ottawa kept pesticide facts secret for 3 years," The Toronto Star, August 24, 1980.
19. Telephone conversation with Moni Campbell, September 8, 1980, Guelph, Ontario.
20. Telephone conversation with Moni Campbell, July 9, 1980, Toronto, Ontario.
21. Correspondence from the Hon. Harry Parrott to Pollution Probe July 24, 1980.
22. Government of Saskatchewan. News Release. "Little New Information in Federal Health Minister's Letter," June 20, 1980, Regina, Saskatchewan.
23. Saskatchewan Environmental Advisory Council. Annual Report. 1977-78. Regina, Saskatchewan.
24. Ross Howard, "City criticizes Ottawa for silence on pesticide risk," The Toronto Star, August 28, 1980.
25. S.O. 1973, ch. 25 section 9(a)(b).