REGULATION OF PESTICIDES: THE CANADIAN EXPERIENCE

*Sherwin Lyman**

I. Constitutional Perspective

Like the United States, Canada has a federal form of government. Much has been written on the historical differences between the American form and the Canadian form, especially with the latter having had the advantage of the former's experience.[1]

The Canadian Constitution began in 1867 as the British North America Act[2] and has since, in 1982, become the Constitution Act, 1867.[3] In that year Canada finally completely patriated its constitution and removed the last, albeit nominal, vestige of the "old country." Canada still retains Queen Elizabeth as the Monarch and the third part of the government (*i.e.*, the House of Commons, the Senate, and the Crown), but she is Canada's Queen separately from her other roles.

The Constitution Act, 1867, in arguably its most important function, defines the scope of federal and provincial legislative powers.[4] Jurisdiction over pesticide regulation is not granted per se to either the federal or the provincial legislatures. But both levels of government derive jurisdiction from a number of provisions, the principal one of which is Section 95, which provides for concurrent jurisdiction over agriculture. Under that section, each level may legislate in relation to agriculture, but where a provincial law is repugnant to a federal law, the federal prevails.

Provinces take jurisdictional comfort from other authorities, such as control of provincial lands,[5] property and civil rights in the province,[6] matters of a merely local or private nature in the province,[7] and local works and undertakings.[8] Federal authority through Section 95 is supplemented by au-

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1. *See, e.g.*, A. Smith, The Commerce Power in Canada and the United States (1963).
2. 30 & 31 Vict., ch. 3.
3. Canada Act, 1982, Eliz. II, ch. 11 (1982) [hereinafter Canada Act].
4. *See generally* Canada Act, *supra* note 3, at §§ 91 and 92.
5. *Id.* at § 92(5).
6. *Id.* at § 92(13).
7. *Id.* at § 92(16).
8. *Id.* at § 92(10).

thority over criminal law,[9] trade and commerce,[10] and the power to make laws for peace, order, and good government.[11] In terms of jurisprudence, while the Pest Control Products Act itself has not been adjudicated *intra vires*, a similar statute, the Fertilizers Act,[12] has been held to be a law in relation to agriculture and thus valid federal legislation.[13]

In practice, the regulation of pesticides has been treated in Canada, by both federal and provincial authorities, as a team effort. In 1982, when the Constitution was repatriated, one further section was added: the Canadian Charter of Rights and Freedoms. A former government had passed a federal act called the Canadian Bill of Rights,[14] but that was not constitutionally entrenched and had limited effect. The Charter, which became fully effective April 17, 1985, when the equality rights provision came into force, differs in some substantial ways from the American Bill of Rights, but, since this is about regulation of pesticides, let me just say that property rights are not protected by the Charter.

II. The Regulation of Pesticides

A. *Federal Regulation*

Since agriculture is the significant basis for jurisdiction over pesticides, it should not be surprising that, in Canada, the Minister of Agriculture bears the most responsibility for regulation. But as was indicated, it is teamwork which has been effective. The Canadian regulatory process has as its key players, at the federal level, the Departments of Agriculture, National Health and Welfare, Environment, and Fisheries and Oceans.

The primary federal legislative tool is the Pest Control Products Act[15] [hereinafter PCPA] administered by the Department of Agriculture. The Departments of Fisheries and Oceans, and Environment are concerned with the effects of pesticides on fisheries, aquatic ecosystems, wildlife, etc., and the prevention of contamination of the environment. This includes questions of disposal instructions. Health and Welfare is concerned, not surprisingly, with the human health aspects in two major respects: that of people involved in manufacturing, handling, and applying the pesticides; and that of others who may be exposed indirectly, such as through residues on food.

The list of departments above is not exhaustive. Others having interests include the Department of Indian and Northern Affairs, which is concerned

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9. *Id.* at § 91(27).
10. *Id.* at § 91(2).
11. *Id.* at § 91.
12. Can. Rev. Stat. ch. F-9 (1970).
13. R. v. Bradford Fertilizer Co., [1972] 1 O.R. 229 (Can. 1972).
14. Can. Stat. ch. 44 (1960).
15. Can. Rev. Stat. ch. P-10 (1970) [hereinafter PCPA].

with Arctic waters pollution,[16] and the Department of Transportation, which regulates the transportation of dangerous goods.[17] The teamwork moves down, as well, into committees which play a regulatory role. The Federal Interdepartmental Committee on Pesticides consists of representatives of all of the federal departments mentioned plus others having a less direct interest. Among its tasks is an annual review of federal projects involving pesticide use. Its policy recommendations influence the PCPA's administration.

In addition, the Canadian Association of Pesticide Control Officials (CAPCO) is made up of representatives from each of the provinces and territories, plus Agriculture Canada, Environment Canada, and Health and Welfare Canada. This committee facilitates the information flow between the levels of government and ensures coordination of federal and provincial regulatory efforts.

B. *Provincial Regulation*

Federal regulation consists primarily of pre-sale evaluation and registration. The provinces exercise their authority by controlling actual use through licenses and permits, specifically including control over applicators. Also, while the federal regulations provide for classification of registered pest control products, the provinces are not prevented from fine tuning by their own, stricter, classifications. The federal regulations classify the products as either domestic, commercial, or restricted. The Province of Ontario, on the other hand, has six schedules of classification.[18] Schedule I pesticides are highly toxic and can only be used by a licensed exterminator and with a specific permit for each individual application; schedule III pesticides can be used by the general public but can only be sold by licensed vendors; schedule IV pesticides are relatively innocuous to humans and can be sold by anyone; and so on. No pesticide can be used in an extermination in Ontario unless it is registered under the federal PCPA and is classified under the regulations pursuant to the Pesticides Act of Ontario.

C. *The Pest Control Products Act*

The importation and sale of products used for controlling pests has been regulated in Canada since 1927. It began with a federal "Act to Regulate the Sale and Inspection of Agricultural Economic Poisons."[19] This was replaced, in 1939, by the Pest Control Products Act.[20] The intent of both of these acts was to ensure the efficacy of pesticides and similar products. Dur-

16. Arctic Waters Pollution Preventing Act, CAN. REV. STAT. ch. 2, 1st supp. (1970).
17. Transportation of Dangerous Goods Act, Can. Stat. ch. 36 (1980).
18. ONT. REV. REGS. 751 (1980), enacted pursuant to Pesticides Act, CAN. REV. STAT. ch. 373 (1980).
19. Can. Stat. ch. 5 (1927).
20. *Id.* at ch. 21.

ing the 1950s, however, a general recognition developed of the harmful effects of these products. In 1954 the Pest Control Products Regulations were revised to require applicants to provide evidence of the safety as well as efficacy of their product.[21] In 1968 the Act was further revised so that the major focus shifted from efficacy to safety.[22]

The intent and philosophy of the current Pest Control Products Act is expressed clearly in Section 3(1) of the Act: "No person shall manufacture, store, display, distribute or use any control product under unsafe conditions." The remaining elements of the PCPA and the regulations promulgated thereunder are oriented to provide authority to achieve that intent. Thus, "unsafe conditions" applies to a control product that is not manufactured, stored, displayed, distributed, or used as prescribed, or that is manufactured, stored, displayed, distributed, or used contrary to the regulations.[23] The products are deemed to be unsafe if they don't comply with the regulations.

Similarly, packaging, labelling, and advertising must comply with regulations enacted for the purpose of preventing false, misleading, or deceptive practices, and for preventing the creation of an erroneous impression regarding the product's character, value, quantity, composition, merit, or safety.[24]

The definition of control product is very broad.[25] However, the regulations do not apply to control products (other than live organisms) imported for the importer's own use, provided the quantity is small (500 grams by mass and 500 milliliters by volume or less) and the price is low (under $10 Canadian).[26] Also exempted from the Act are certain products regulated by the Food and Drug Act.[27] Furthermore, there are exemptions from registration, usually because the product is regulated elsewhere, *e.g.*, when it is subject to further manufacturing.[28] There is also an exemption dealing with research permits.[29]

Registration of the product, the essential ingredient of the Act and regulations, is well explained in a registration kit prepared by the Department of Agriculture. The kit contains application forms, guidelines for completing the forms, labelling advice, trade memoranda, and, of course, a copy of the Act and regulations.

The guidelines are for the applicant since it is he who has the obligation to generate the information to begin the process. The general principle in operation in the Pesticides Directorate is that the product is guilty until

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21. *See* CAN. CONS. REGS. at 2536 *et seq.* (1955).
22. Can. Stat. ch. 50 (1968-69).
23. PCPA, *supra* note 15, at § 3(3).
24. *Id.* at § 3(4).
25. *Id.* at § 2.
26. PCP REG. § 4.
27. *Id.* at § 3(a).
28. *Id.* at § 5(a).
29. *Id.* at § 5(b).

proven innocent, so that data generated must be such as to satisfy the Minister as to the safety and merit of the product.[30] Those data are scientifically complex and very expensive. They must include detailed product chemistry, product performance, occupational exposure, effect on non-target organisms, and residues. This kind of examination is not only expensive but it is extremely time-consuming. At a 1985 Pesticides Workshop, an industry spokesperson estimated that developing the requisite data can take ten years and cost some $20 million.[31] Slightly earlier, another industry group had estimated the average turnaround time for registration as 800 days.[32] Registration itself, if granted, is normally for five years.[33] This has raised questions concerning the confidentiality of the data provided, especially in the light of relatively recent freedom of information legislation in Canada (we call it Access to Information), as well as patent protection.

While the Access to Information Act[34] does protect confidential information in such circumstances,[35] the Department of Agriculture added a technique which it calls "product specific registration." This approach, according to the Director General of the Pesticides Directorate,[36] ties each individually formulated product to the unique data package supporting the technical active ingredient from which it is made. Traditionally, the Canadian system had operated on a generic basis, whereby all sources of active ingredients were considered equivalent and identical. As a result of the Directorate's experience with micro-contaminants, it became apparent that this approach was too simplistic. The Directorate then swung around to a position on data ownership similar to that taken by the United States: the manufacturer of the active ingredient must have his own basic data to obtain registration. More work is being done in this area.

Registration can be renewed,[37] but at renewal time, and indeed at any time, the Minister may require new information for a re-evaluation of the product sufficient to satisfy him that the product's availability will not lead to an unacceptable risk of harm to: (a) things on or in relation to which the control product is intended to be used; or (b) public health, plants, animals,

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30. *Id.* at § 9.

31. H. W. Major, president of Canadian Agricultural Chemicals Assoc., *The Contribution of the Industry to the Information Required for Registration*, PESTICIDES WORKSHOP PROCEEDINGS (Canadian Council of Resource and Environment Ministers Workshop on Pesticide Use and Control) (1980).

32. CANADIAN HORTICULTURE COUNCIL, REPORT OF THE PESTICIDES REVIEW COMMITTEE TO THE 62ND ANNUAL MEETING (March 4-7, 1984).

33. PCP REG. § 14.

34. Can. Stat. ch. 111 (1980-83).

35. *Id.* at § 20.

36. Address by Director General of the Pesticides Directorate, International Symposium on Health and Safety in Agriculture, Saskatoon, Saskatchewan (October 9, 1985).

37. PCP REG. § 14(2).

or the environment.[38]

When the Minister, based on current information available to him, determines that the control product's safety or its merit or value is no longer acceptable, he may, on such terms and conditions as he may specify, cancel or suspend the registration.[39] Cancellation means the product is unregistered and cannot be manufactured, imported, sold, or used. Suspension means only that the registrant cannot import or sell the product.[40] Thus, a dealer can dispose of his current product.

The legislation also provides that where the Minister cancels or suspends the registration, or where he refuses to register a product, he must provide reasons therefor,[41] and the applicant or registrant can apply for a hearing in relation to that action.[42]

Section 17 of the current regulations provides that the Minister may, on such terms and conditions as he may specify, register a control product for up to one year, where the applicant agrees to produce additional scientific or technical information in relation to the use for which the control product is sold, or where the control product is to be sold only for the emergency control of infestations that are seriously detrimental to public health, domestic animals, natural resources, or other things. To give some insight into these procedures, the balance of this article will discuss the most recent case to arise under these sections: the Alachlor Review Board.[43]

III. ALACHLOR

Alachlor is a herbicide used to control weeds in corn, soybeans, and potato crops. It is manufactured by Monsanto and is marketed in Canada under the trade name "Lasso." It had long been in use in Canada, registered as required by the legislation. Late in the 70's, however, it was discovered that Industrial Bio-Test Laboratories [hereinafter IBT], which had provided test results and data used for registration for many compounds, Alachlor among them, had falsified its data. Among others, Monsanto was required to repeat toxicity studies. Subsequently received data revealed that Alachlor caused cancer in laboratory animals (both mice and rats).[44] Also, traces of Alachlor were found in southern Ontario water supplies.

For some time Alachlor has been the leading herbicide among corn and

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38. *Id.* at § 19.
39. *Id.* at § 20.
40. *Id.* at § 22.
41. *Id.* at § 21.
42. *Id.* at § 23.
43. In actuality, since the 1972 PCP regulations were promulgated, three review boards have been empanelled. *See* CASTRILLI & VIGOD, PESTICIDES IN CANADA: AN EXAMINATION OF FEDERAL LAW & POLICY 83-85 (1987). The pesticides involved were: Leptophos, Phosphamidoy, and Alachlor. *Id.*
44. The Alachlor Review Board disagreed with this conclusion.

soybean producers. Recently another product, Metolachlor, entered the market and succeeded, in a relatively short time, in gaining virtually an equal market share. The Minister of Agriculture was faced with a product, the data for which could, indeed did, give him cause to be satisfied that the availability of the product would lead to an unacceptable risk of harm to public health and the environment. He also had available what Health and Welfare Canada considered to be a reasonable substitute for the industry. Accordingly, by letter dated February 5, 1985 (almost two years of notice and discussion in depth between government officials and Monsanto), the Minister cancelled the registration of Alachlor. However, at the same time the Minister also granted a temporary registration related to "balanced supplies" until December 31, 1985.

Upon receiving the cancellation notice, Monsanto exercised its rights under Section 23 and wrote to the Minister requesting a hearing and, in accordance with the same section, setting out nine issues it intended to raise before the Review Board. Of these nine issues, several related to matters or data which had not been before the Minister at the time of his decision and which, in fact, were not available to him even at the time of the request for the hearing. In effect Monsanto established the terms of reference for the Review Board, and they did not necessarily relate to the words of Section 20 of the regulations, which provides that the Minister may cancel or suspend when, based on current information available to him, he is satisfied that the safety or merit or value of the product is no longer acceptable.

Monsanto suggested that the Board be composed of a team of experts and the Minister accepted this concept. Accordingly, a board consisting of four experts in appropriate disciplines, plus a supernumerary judge, was appointed, though not until November 1985.[45] In the meantime, concerned that its temporary registration would expire before the hearing could be concluded, Monsanto requested an extension. In fact, on the same day that the Minister appointed the Review Board, Monsanto wrote to the Minister asking that as its first order of business, the Board consider the temporary registration extension.

In a preliminary meeting of the Review Board early in December, before the Minister responded to Monsanto's request, Monsanto unilaterally raised the matter with the Board. The Board responded that it had no jurisdiction in this regard. Eight days later the Minister responded to the written request by saying that he would not alter the expiration date. Monsanto treated that action of the Minister as a refusal to register under Section 21(a) and tried again to put the issue before the Board pursuant to Section 23. The Minister refused and Monsanto brought an action for a mandamus

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45. The four experts were: Dr. Emmanuel Farber (pathology and biochemistry), Dr. David Freshwater (agricultural economics), Dr. Gabrial Plaa (toxicology), and Dr. William Rowe (risk analysis). The original chairman was the Honorable Gregory Evans, but he was replaced early on, due to illness, by the Honorable B. Barry Shapiro.

against the Minister—and succeeded.[46] Inasmuch as the regulations could be amended to reclarify the intent to distinguish between temporary and normal registration, an appeal was not filed. Accordingly, the Minister referred the matter to the Review Board.

After five days of hearings, in February 1986, and four days of consideration, the Board submitted to the Minister a report recommending that temporary registration be granted. The Minister, pursuant to his prerogative under Section 25(3) of the regulations, refused again to extend the now defunct temporary registration. Another court action by Monsanto for certiorari to quash the Minister's decision[47] succeeded on a technical ground[48] but availed Monsanto no real advantage since the Minister again refused to renew the temporary registration.

In July of 1986 the Board began hearing evidence on the main questions. Almost immediately Monsanto took the position that the hearing was private and no other party should be allowed to intervene. The Board denied that motion. Furthermore, authority was granted to provide some intervenor funding. In the end $75,000 was granted.

Then Monsanto raised the issue of the confidentiality of its material—both the data previously submitted to the Crown and the new data to be submitted during the course of the hearings. The final ruling in this regard divided the data into classes and all parties agreed to respect the confidentiality of the classified documents.

The thirty-seven actual days of the hearings were spread over several months, due to the schedules of the Board members, some of whom were university professors.

IV. Conclusion

On November 16 the Alachlor Review Board submitted its report to the Minister. The Report, comprising 164 pages including annexes, made recommendations in two principal areas: the safety, merit, and value of Alachlor (and its leading competitor, Metolachlor), and the regulatory process. From the perspective of this article dealing with the regulation of pesticides, the latter area bears the greater interest.

The Board raised questions in its report respecting the safety, merit, and value of the alternative product, Metolachlor. Accordingly, in its recommendations on regulatory issues, the Board recommended that whenever a pesticide which is a member of a class of pesticides of the same structural family is being examined for registration purposes or for cancellation or sus-

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46. Monsanto Canada v. Minister of Agriculture, 1 F.T.R. 63, 8 C.P.R. 517 (1986).

47. Interestingly, on the same day, a public interest group filed a motion to prohibit the Minister from acting on the Board's recommendation, but it was withdrawn before being heard. Van Engelen v. Minister of Agriculture, No. T-513-86 (Federal Court Trial Division 1986).

48. Monsanto Canada v. Minister of Agriculture, ___ F.C. ___ (April 8, 1986).

pension purposes, all members of that family which are substitutes should be reviewed critically to establish any similarity of toxicological patterns.

The Board recommended that the benefits evaluation procedure become more explicit and perhaps more formalized. There was agreement that the approach currently used by the Health Protection Branch of Health and Welfare Canada, referred to as the "weight of evidence" approach, is preferable to quantitative risk assessment techniques, although the Board suggested that the range of uncertainties and margins of safety applied be made explicit to the Minister of Agriculture and to the public. In connection with the "weight of evidence" approach, the Board recommended that Agriculture Canada establish an independent expert review panel to provide a "second opinion" respecting the safety of a chemical for which cancellation of registration is contemplated.

The Board proposed an improved system for assembling and maintaining records of decisions and the data leading to those decisions. Thus, in cases of proposed cancellation, a fully documented proposed decision, with reasons identifying the arguments and data supporting the proposed cancellation, could be produced for public comment prior to the final decision. Finally, the Board recognized that the process followed in the Alachlor case was lengthy and costly and that procedures should be developed to expedite the review process. Needless to say, the Alachlor Review Board Report is now being studied by the Minister and the Department and decisions will be made in due course concerning the regulatory process as well as the subject matter per se.