Legislative Summary **LS-436E**

BILL C-8: AN ACT TO PROTECT HUMAN HEALTH AND SAFETY AND THE ENVIRONMENT BY REGULATING PRODUCTS USED FOR THE CONTROL OF PESTS

Monique Hébert
Law and Government Division

10 October 2002

Library of Parliament
Bibliothèque du Parlement

Parliamentary Research Branch

LEGISLATIVE HISTORY OF BILL C-8

HOUSE OF COMMONS		SENATE	
Bill Stage	**Date**	**Bill Stage**	**Date**
First Reading:	9 October 2002	First Reading:	10 October 2002
Second Reading:	9 October 2002	Second Reading:	23 October 2002
Committee Report:	9 October 2002	Committee Report:	10 December 2002
Report Stage:	9 October 2002	Report Stage:	
Third Reading:	9 October 2002	Third Reading:	12 December 2002

Royal Assent: 12 December 2002

Statutes of Canada 2002, c.28

N.B. Any substantive changes in this Legislative Summary which have been made since the preceding issue are indicated in **bold print.**

Legislative history by Peter Niemczak

CE DOCUMENT EST AUSSI PUBLIÉ EN FRANÇAIS

TABLE OF CONTENTS

Page

CANADA

LIBRARY OF PARLIAMENT
BIBLIOTHÈQUE DU PARLEMENT

BILL C-8: AN ACT TO PROTECT HUMAN HEALTH AND SAFETY AND THE ENVIRONMENT BY REGULATING PRODUCTS USED FOR THE CONTROL OF PESTS*

Bill C-8, An Act to protect human health and safety and the environment by regulating products used for the control of pests, was introduced in the House of Commons and deemed to have passed all stages on 9 October 2002.(1) Sponsored by the Minister of Health, the bill replaces the current *Pest Control Products Act*, which was passed in 1969.

BACKGROUND

Pest control products (also called pesticides) are chemicals, organisms and devices designed to kill or control unwanted pests. They encompass a broad spectrum of products, including insecticides, herbicides, fungicides, algicides, insect repellents, wood preservatives and rodent traps.

Pest control products are used primarily in the agricultural sector to protect crops from ravaging diseases and other risks (about 90% of pesticide sales in Canada). In the non-agricultural sector (where the other 10% of sales are made), sales are highest in the domestic-use sector (about 56% of sales), followed by turf and ornamental uses (about 16% of sales), forestry (about 10% of sales) and industrial uses (about 10% of sales).

---

* Notice: For clarity of exposition, the legislative proposals set out in the Bill described in this Legislative Summary are stated as if they had already been adopted or were in force. It is important to note, however, that bills may be amended during their consideration by the House of Commons and Senate, and have no force or effect unless and until they are passed by both Houses of Parliament, receive Royal Assent, and come into force.

(1) The bill was originally introduced in the 1st session of the 37th Parliament as Bill C-53, but died on the *Order Paper* when Parliament was prorogued on 16 September 2002. By motion adopted 7 October 2002, the House of Commons provided for the reintroduction in the 2nd session of legislation that had not received Royal Assent. The bills would be reinstated at the same stage in the legislative process they had reached when the previous session was prorogued.

The regulation of pest control products in Canada is an area of shared jurisdiction. The federal government is responsible for:

- pre-market assessment and registration;
- compliance and enforcement; and
- re-evaluation, where warranted.

The provinces and territories, in turn, are responsible for:

- post-registration transportation, sale, use, storage and disposal;
- licensing and training;
- spills and accidents;
- permits and use restrictions; and
- compliance and enforcement.

The federal government derives its authority to regulate pest control products from the *Pest Control Products Act*, a short statute consisting of only 13 sections. This Act generally prohibits the manufacture, importation, sale and use in Canada of any pest control product that contravenes the Act or the regulations. Notably, section 5 of the Act prohibits the sale and importation into Canada of any pest control product unless the product:

- has been registered;
- conforms to the prescribed standards; and
- is properly packaged and labelled.

The current *Pest Control Products Act* is essentially "framework" legislation. It is supplemented by the *Pest Control Products Regulations,* which set out detailed provisions under which the products are assessed and registered for use in this country.

The Minister of Agriculture and Agri-Food was initially responsible for administering the Act. However, this responsibility was transferred to the Minister of Health by Order in Council on 28 May 1995. The Pest Management Regulatory Agency (the PMRA) was

also created within Health Canada that year to assist the Minister of Health in administering the Act.

Although the Act has not been materially amended since its passage in 1969, it has been under active review for over a decade:

1987 The Law Reform Commission of Canada studied the legislation and made material recommendations for change in a study paper entitled *Pesticides in Canada: An Examination of Federal Law and Policy*.

1990 The Pesticide Registration Review Team, a multi-disciplinary task force established in 1989 by the federal government to study and make recommendations to improve pesticide regulation in Canada, issued a report entitled *Recommendations for a Revised Federal Pest Management Regulatory System, Final Report* (known as the "Blue Book"), which recommended a complete overhaul of the system.

1994 The federal government issued *Government Proposal for the Pest Management Regulatory System* (known as the "Purple Book"), which set out the steps that the government proposed to take in response to the recommendations of the Pesticide Registration Review Team.

1999 The federal Commissioner of the Environment and Sustainable Development issued a report, entitled *Managing Toxic Substances* (chapters 3 and 4), which criticized the federal government's regulation of toxic substances, including pesticides.

In June 1999, the House of Commons Standing Committee on Environment and Sustainable Development undertook a study on pesticides due in part to growing concerns about the safety of these products.

Indeed, an increasing number of published studies are linking pesticide exposure to a variety of diseases and developmental abnormalities, including various forms of cancer (brain, breast, stomach, prostate and testicles), childhood leukemia, non-Hodgkin's lymphoma, Parkinson's disease, reduced fertility, damage to the thyroid and pituitary glands, lowered immunity, and behavioural problems. Children, especially the very young, are considered to be particularly vulnerable because of their specific developmental and physiological characteristics:

- they eat more food, drink more water, and breathe more air per kilogram of body weight than do adults;

- their diet consists of more fruit and vegetables, which may contain pesticide residues and other contaminants; and

- they live and play on the ground to a far greater extent than do adults, and they engage in more hand-to-mouth activity.

The Committee tabled its 200-page report, entitled *Pesticides: Making the Right Choice for the Protection of Health and the Environment*, in May 2000. In general terms, it expressed concern that Canada's pesticide-approval process places too much emphasis on the pesticide needs of producers and growers and not enough on human health and the environment. The Committee urged that human health and the environment be given top priority in the decision-making process and it pressed for more research on pesticides to gauge their effects on human health and the environment, particularly their effects on children and other vulnerable groups (e.g., the unborn, the elderly, people in poor health, high-exposure workers, etc.).

Stressing the importance of reducing reliance on pesticides, the Committee also advocated the promotion of and reliance on less-polluting strategies, such as organic farming and integrated pest management.

In total, the Committee made 77 recommendations for change. Its first recommendation called on the federal government to introduce new pesticide legislation as a matter of top priority. Its second recommendation urged that the new Act be based on the following guiding principles:

- to protect human health and the environment as the absolute priority in all pest management decisions;

- to apply the precautionary principle;

- to promote and increase reliance on pollution prevention strategies in order to eliminate or minimize the use of pesticides; and

- to foster public confidence by actively informing and educating Canadians about pesticide use and by involving them in the decision-making process.

The Committee emphasized that these guiding principles should be "operationalized" in the new Act, as opposed to simply being set out in the preamble. Other noteworthy recommendations called for:

- the evaluation of cumulative and aggregate risks in the pesticide assessment process, as well as the interaction between pesticides;
- the inclusion of an additional safety factor in the pesticide assessment process to better protect children and other vulnerable groups;
- the re-evaluation of all older pesticides by 2006, together with a mandatory re-evaluation of all registered pesticides at least every 15 years;
- the increased disclosure of information on pesticides to the public;
- the creation of three databases (pesticide sales; adverse effects; and alternatives to pesticides); and
- a five-year phase-out of pesticides used for cosmetic purposes (i.e., lawn and garden care).

This last recommendation sparked considerable public debate and proved to be the most controversial of the Committee's recommendations.

The Committee's report was not unanimous. The Official Opposition filed a dissenting opinion in which, among other things, it criticized the majority report for failing to weigh the necessity and value of pesticides.

The federal government tabled its response to the Committee's recommendations on 16 October 2000. Although it was generally supportive of the Committee's report, in many instances it failed to discuss the recommendations in sufficient detail to indicate what specific measures it would take and whether such measures would be enshrined in the new legislation, as opposed to the regulations or policy directives. One noteworthy exception was in relation to the Committee's proposed phase-out of pesticides for cosmetic purposes. The federal government rejected this recommendation, opting instead to work with the provinces and territories to develop and promote approaches to pest management in lawns that would be consistent with the principles of integrated pest management. It also undertook to carry out a priority re-evaluation of the most commonly available insecticides and herbicides now registered for lawn and turf care.

Acting on this commitment, the Honourable Allan Rock, former Minister of Health, announced a federal/provincial/territorial Action Plan for Urban Use Pesticides on 16 October 2000. This plan includes a Healthy Lawns Strategy, as well as a Healthy Lawns website (http://www.healthylawns.net/).

In introducing Bill C-8's predecessor, Bill C-53, the Honourable Anne McLellan, Minister of Health, stated in the companion press release that the bill would safeguard Canadians, especially children, and would help ensure a safe and abundant food supply. She also affirmed the federal government's commitment to ensuring that Canadians are better protected from health and environmental risks posed by pesticides, observing that the bill reflected this commitment by modernizing and strengthening pesticide regulation and making the system more transparent.

A. Bill C-8: An Overview

In contrast to the current Act, which contains only 13 sections, Bill C-8 contains over 90 clauses, although seven of these make consequential amendments to other statutes (clauses 82 to 88, inclusive) and one is transitional in nature (clause 81).

1. The Preamble

The bill begins with a relatively lengthy preamble, consisting of 7 recitals, the sixth of which contains 10 sub-recitals.

The opening recital indicates that there are potential risks, both direct and indirect, associated with the use of pest control products. The second states that pest management plays a significant role in diverse areas of the economy and other aspects of the quality of life throughout Canada. The third notes the significant contribution that pest control products of acceptable risk and value can make to the attainment of the goals of sustainable pest management. The fourth defines the goals of sustainable pest management, whereas the fifth recognizes that the regulation of pest control products has traditionally been an area of shared responsibility between the federal government and the provinces and territories, and underscores the importance of continuing the current complementary approach in order to achieve mutually desired results efficiently, without regulatory conflict or duplication.

The sixth recital is the first one to place specific emphasis on the protection of human life and the environment. Its first sub-recital provides that it is in the national interest that the primary objective of the federal regulatory system must be to prevent unacceptable risks to people and the environment from the use of pest control products. The other sub-recitals deal with a variety of matters also considered to be in the national interest, including:

- the application of a science-based approach that addresses risks to human health and the environment both before and after registration;

- the registration of pest control products of acceptable risk only if they are shown to be efficacious and if conditions of registration can be established to prevent adverse health impacts and environmental pollution;

- consideration of aggregate risk and cumulative effects, as well as the different sensitivities of major identifiable subgroups (pregnant women, infants, children, women and seniors), when assessing risks to humans;

- the regulation of pest control products in a manner that supports sustainable development;

- the need to have a federal regulatory system designed to minimize risk and to encourage the development and implementation of innovative, sustainable pest management strategies;

- the need for inter-departmental cooperation within the federal government in the development of policies to pursue the attainment of the Act's objectives, taking into account advice from diverse other sources;

- the provision – to provinces, territories and other interested parties – of a reasonable opportunity to participate in the regulatory system; and

- the administration of the federal regulatory system in an efficient and effective manner that accords with the foregoing principles and objectives, that recognizes the various affected interests and concerns and that, where consistent with the system's primary objective of preventing unacceptable risks to people and the environment, minimizes the negative impact on economic viability and competitiveness.

The last recital stipulates that Canada must be able to fulfil its international obligations in relation to pest management.

2. Definitions: Clause 2

Clause 2 defines some of the key terms used throughout the bill. Notably, it defines "pest" and "pest control product" in the following manner:

> ''pest'' means an animal, a plant or other organism that is injurious, noxious or troublesome, whether directly or indirectly, and an injurious, noxious or troublesome condition or organic function of an animal, a plant or other organism.
>
> ''pest control product'' means (*a*) a product, an organism or a substance, including a product, an organism or a substance derived through biotechnology, that consists of its active ingredient,

> formulants and contaminants, and that is manufactured, represented, distributed or used as a means for directly or indirectly controlling, destroying, attracting or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects; (*b*) an active ingredient that is used to manufacture anything described in paragraph (*a*); or (*c*) any other thing that is prescribed to be a pest control product.

Clause 2(2) provides the following definition of "acceptable risks," which is the standard that must be met for a product to be approved for registration:

> 2(2) For the purposes of this Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.

3. Application to the Crown: Clause 3

Clause 3 provides that the Act is binding on both the federal and provincial Crown.

4. Minister's Mandate: Clause 4

Clause 4 makes the prevention of unacceptable risks to people and the environment from the use of pest control products the Minister's primary objective in administering the Act. Consistent with and in furtherance of this primary objective, the Minister would be required to:

- support sustainable development, designed to enable the needs of the present to be met without compromising the ability of future generations to meet their own needs;
- seek to minimize health and environmental risks posed by pest control products and encourage the development and implementation of innovative, sustainable pest management strategies by facilitating access to pest control products that pose lower risks and by other appropriate measures;
- encourage public awareness in relation to pest control products by informing the public, facilitating public access to relevant information and public participation in the decision-making process; and
- ensure that only those pest control products that are determined to be of acceptable value are approved for use in Canada (defined in clause 2, "value" means the product's actual or potential contribution to pest management, taking into account its conditions or proposed

conditions of registration, and includes the product's: efficacy; effect on host organisms with which it is intended to be used; and health, safety and environmental benefits and social and economic impacts).

Clause 4.1 is an interpretive clause. It specifies that, for greater certainty, the protection and consideration afforded children in the Act shall also extend to future generations.

5. Advisory Council: Clause 5

Clause 5 authorizes the establishment of an advisory council to assist the Minister in carrying out his or her duties under the Act. The Minister may specify the Council's functions and the means by which they would be performed. The Council would be required to submit its reports to the Minister, who would be required to place them in the Register created under clause 42.

6. Prohibitions: Clause 6

Clause 6 sets out a number of specific prohibitions regarding the manufacture, importation, exportation, handling, use, storage, advertising, etc., of pest control products unless it is done in accordance with the provisions of the Act and the regulations. It also sets out several defences. Offences under this clause are punishable:

- on summary conviction, by a maximum fine of $200,000 or imprisonment for up to six months, or both; or
- on conviction on indictment, by a maximum fine of $500,000 or imprisonment for up to three years, or both.

Comparable offences under the current Act are punishable:

- on summary conviction, by a maximum fine of $50,000 or imprisonment for up to six months, or both; or
- on conviction on indictment, by a maximum fine of $250,000 or imprisonment for up to two years, or both.

It should be noted that the penalties prescribed under clause 6 are only in relation to the offences set out under that clause. Additional offences and violations, as well as the related penalties, are scattered throughout the legislation (e.g., clauses 29 to 33, 40, 41, 43, 44, 46, 47, 50, 53, 57, 59, etc.). The general offences and punishment provisions are set out in

clauses 68 to 80. Clause 68(4) prescribes the severest monetary penalty in the bill. Anyone who, while contravening the Act or regulations, wilfully or recklessly causes a risk of imminent death or serious bodily harm to another person, a risk of substantial harm to the environment or actual harm to the environment, is punishable:

- on summary conviction, by a maximum fine of $300,000 or imprisonment for up to six months, or both; or
- on conviction on indictment, by a maximum fine of $1,000,000 or imprisonment for up to three years, or both.

7. The Registration of Pest Control Products: Clauses 7 and 8

Under clause 7(1) an application to register a pest control product or to amend an existing registration must be submitted to the Minister in the specified form and manner. Once satisfied that the application meets the prescribed requirements, the Minister is required by clause 7(3) to conduct any evaluations considered necessary in relation to the product's:

- health risks;
- environmental risks; and
- value (clause 2 defines "value" to mean the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's: efficacy; effect on host organisms with which it is intended to be used; and health, safety and environmental benefits and social and economic impacts).

The Minister must expedite the evaluation of reduced-risk products. In specified cases, he or she must also carry out consultations with the public and with federal and provincial departments and agencies whose interests and concerns are affected by the federal regulatory system. (clause 7(3))

In order to approve an application, the Minister must be satisfied that the product's health and environmental risks and value are "acceptable." (clause 8(1)) As mentioned earlier, pursuant to clause 2(2), the health and environmental risks of a product are "acceptable" if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.

In making a determination as to the acceptability of a product's risks, the Minister must apply a "scientifically based" approach. In addition, in evaluating the health risks (but not the environmental risks) of selected products, the Minister must also:

- consider available information on aggregate exposure to the product and cumulative effects of the product with other products having a common mechanism of toxicity;
- apply an appropriate margin of safety to take into account, among other factors, the use of animal experimentation data and the different sensitivities to pest control products of major identifiable subgroups (including pregnant women, infants, children, women and seniors); and
- apply an additional margin of safety that is ten times the "appropriate" margin of safety if the product is being proposed for use in or around homes, although this tenfold safety margin could be increased or decreased if, on the basis of reliable scientific evidence, it is found that a different safety margin would be appropriate.

As indicated above, the foregoing requirements apply only to selected products. These are products that, pursuant to clause 28, involve one of the following decisions to be made:

- a decision to register a product involving a new active ingredient;
- a decision to register or amend the registration of a product that, if allowed, may result in significantly increased health or environmental risks; or
- a decision about the product's registration following a re-evaluation or special review. (clause 7(7))

With regard to the evaluation of a product, other noteworthy requirements or provisions include the following:

- the applicant has the burden of persuading the Minister that the health and environmental risks and the value of a product are acceptable; (clause 7(6)(a))
- in evaluating these factors, the Minister must give effect to applicable government policy; (clause 7(8)) and
- comparative risk assessments may be made by taking into account the risks and value of other products that are registered for the same use. (clause 7(9))

After completion of the requisite evaluations and consultations, the Minister must (*shall*) register the product or amend its registration, if he or she considers that the product's health and environmental risks and value are acceptable. (clause 8(1)) Conversely, where one or more of these criteria is considered unacceptable, the Minister must turn down the application. (clause 8(4))

Where an application is approved, the Minister must specify the conditions under which the product may be manufactured, handled, stored, transported, imported, exported, packaged, distributed, used or disposed, as well as the conditions regarding its composition and labelling. (clause 8(1)) In accordance with any applicable regulations, the Minister must also specify that product safety information, including a material safety data sheet, must be provided to workplaces where the product is used or manufactured. (clause 8(3)) A registrant must also provide the Minister with sales data regarding the registered product. (clause 8(5))

A registration or amended registration is valid for the period of time specified by the Minister, which may be either "finite" or "indefinite." (clause 8(1))

8. Maximum Residue Limits: Clauses 9 to 11

Where necessary, the Minister would continue his or her current function of setting maximum residue limits (MRLs; i.e., the maximum limits of pesticide residues allowed on food). (clauses 9 and 10) In selected cases, however, the Minister would be required to:

- apply an additional margin of safety that is ten times greater than the appropriate margin of safety; and
- consider, based on available information:
  - the product's aggregate exposure (i.e., dietary exposure and exposure from other non-occupational sources, such as drinking water and use around homes and schools);
  - the cumulative effects of the product and other pest control products having a common mechanism of toxicity; and
  - the different sensitivities to pest control products of major identifiable subgroups, including pregnant women, infants, children, women and seniors. (clause 11)

Similarly to clause 7(7), which deals with the initial registration of a product or an amendment to the registration, the foregoing requirements for evaluating the health risks of a

product for the purposes of establishing the MRLs apply only to products involving a so-called "major" decision, namely:

- a decision to register a product consisting of or containing an unregistered active ingredient;
- a decision regarding the registration (or amendment) of a product that, if allowed, may result in significantly increased health or environmental risks; or
- a decision about the registration of a product following a re-evaluation or special review.

9. Additional Information and Mandatory Reporting: Clauses 12 to 15

A registrant could be required to compile additional information on the product, conduct tests and monitor experience with the product, and to submit the related report(s) to the Minister. (clause 12)

Registrants and persons applying to register a product or to have maximum residue limits specified would in turn have to report, on a mandatory basis, any information prescribed by regulation relating to the health or environmental risks of a product, or to its value. (clause 13) After considering the information, the Minister would be required to determine whether to initiate a special review. (clause 14) The Minister's conclusions regarding this information would also have to be placed in the Register and made public if the Minister concluded that the product posed a significant health or environmental risk or that it was in the public interest to do so. (clause 15)

10. Re-evaluations and Special Reviews: Clauses 16 to 21

The Minister may initiate a re-evaluation of a registered pest control product where there has been a change in the information required, or in the procedures used, to evaluate the health or environmental risks or value. (clause 16(1)) Where a product involved a so-called "major" decision, it would have to be re-evaluated on a mandatory basis. Specifically, the re-evaluation of an older product (i.e., registered before 1 April 1995) would have to be initiated, on a mandatory basis, no later than 1 April 2005 or the 16th year following the last date upon which one of the foregoing decisions was made, whichever date is the later. The re-evaluation of newer products (i.e., registered on or after 1 April 1995) would in turn have to be initiated no later than the 16th year after the last decision of that type was made. (clause 16(2)) Note that although this

clause requires the re-evaluation to be initiated within the specified time, there is no timeline regarding its completion.

In addition to re-evaluations, the bill also calls for products to undergo a special review in specified instances, namely:

- where the Minister has reasonable grounds to believe that a product's health or environmental risks or value are unacceptable;
- a member country of the Organisation for Economic Co-operation and Development (OECD) has prohibited, for health or environmental reasons, all uses of an active ingredient contained in a product; or
- a federal or provincial government department or agency has provided the Minister with information about a product's health or environmental risks or value, which leads the Minister to believe that the product's health or environmental risks or value are unacceptable. (clause 17(1) to (3))

Any person may also request a special review of the registration of a pest control product by making a request to the Minister. Within a reasonable time after receiving such a request, the Minister must decide whether to go ahead and must provide the applicant with written reasons for the decision. (clause 17(4) and (5))

Clauses 16, 18 and 19 set out the steps to be taken and the matters to be considered in carrying out a special review or a re-evaluation. Public consultations may be required in some, but not all, instances.

Clause 20 provides that during a re-evaluation or special review, the registration of a product may be cancelled or amended if the registrant fails to provide the requisite information, or where the Minister believes that such action is necessary to deal with a situation that endangers human health or safety or the environment, taking into account the precautionary principle. The precautionary principle, set out in clause 20(2), states that "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent adverse health impact or environmental degradation." This is the only reference in the bill to the precautionary principle.

Where, in turn, the requisite evaluations and consultations have been completed, the Minister must either confirm, cancel or amend the registration of the product in question. However, the effective date of the Minister's decision may be delayed on specified grounds, for

example, where an alternative is not available and the Minister considers that the product's health and environmental risks and value are acceptable until the effective date. (clause 21)

11. Other Grounds for Cancelling or Amending the Registration: Clauses 22 to 27

Clauses 22 to 27 specify additional grounds for cancelling or amending a product's registration. These include:

- where the registrant intends to discontinue the sale of a product for one or more uses for which the product was registered; (clause 22)
- where the registrant has failed to pay a fee, fine, penalty, charge or cost for which he or she is liable under the Act, but the registrant must be afforded an opportunity to make representations on the proposed action before it is taken; (clause 23)
- where the registrant fails to comply with the conditions of registration; (clause 25)
- where there has been a contravention of the Act; (clause 26) and
- where it is necessary to implement an international agreement. (clause 27)

The Minister may also amend the registration of a pest control product for the purpose of reducing its health or environmental risks or of increasing its value, but the registrant's written consent would be required. (clause 24)

12. Public Consultation: Clause 28

The Minister must consult the public as well as federal and provincial departments and agencies whose interests and concerns are affected by the federal regulatory system, but only in relation to selected decisions, namely decisions regarding:

- an application to register a pest control product involving an unregistered active ingredient;
- an application to register (or amend the registration of) a pest control product that might result in significantly increased health or environmental risks;
- the action to be taken following a re-evaluation or special review; or
- any other matter that the Minister considers is in the public interest. (clause 28(1))

Public consultations are initiated by making public a "consultation statement" containing specified information (e.g., summary of relevant reports, proposed decision and any confidential test data considered necessary in the public interest) and by inviting written comments, which the Minister must consider before making a decision. Following the decision, a "decision statement" must in turn be made public, containing specified information (e.g., reasons for the decision, summary of the comments made, and any confidential test data considered necessary in the public interest).

13. Export Controls: Clauses 33 and 34

Clauses 33 and 34 call for the establishment by the Governor in Council of a Pest Control Products Export Control List and prohibits anyone from exporting the products contained in the list unless duly authorized to do so.

Similar, albeit more detailed provisions, are contained in sections 100 to 103 of the *Canadian Environmental Protection Act, 1999* (CEPA, 1999). These provisions allow implementation of the 1998 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (the PIC Convention).

14. Reconsideration of Decisions: Clauses 35 to 40

Clause 35 allows a notice of objection to be filed in relation to specified decisions (e.g., decisions regarding the export of a pest control product or decisions regarding the registration of: a product involving an unregistered active ingredient; a product that might result in significantly increased health and environmental risks; or a product that underwent a re-evaluation or special review).

Following receipt of the notice of objection, the Minister may establish a review panel, whose role is advisory only. However, the Minister would have to make public the review panel's recommendations, as well as his or decision, the reasons for it, and a summary of the information considered, including any confidential test data deemed necessary in the public interest. (clause 39)

15. Authorization to Use an Unregistered Pest Control Product: Clause 41

The Minister could authorize the use of an unregistered product for a specified purpose, subject to the regulations and any conditions that he or she specified. The Minister

would have to do so (*shall*) where he or she considered that the specified purpose, if carried out in accordance with the conditions that were prescribed, would not pose unacceptable health or environmental risks.

16. Access to Information: Clauses 42 to 44

Clause 42(1) calls for the establishment of a Register of Pest Control Products which, subject to the applicable regulations, would contain information on pest control products, including information regarding applications, registrations, re-evaluations and special reviews. The Register would be required to contain the information specified in clause 42(2).

The public, however, would not necessarily have access to the information contained in the Register. It would have access to (and could copy) only information that was not confidential test data or confidential business information, unless disclosure, in the latter case, was otherwise authorized under the regulations. (clause 42(4)) However, confidential test data and confidential business information could be disclosed in the circumstances specified in clauses 43 and 44. For example, confidential test data in the Register could be inspected by a person who, after submitting the requisite application and an affidavit, was authorized to do so where the Minister was satisfied that the applicant would not use the data to register a product (or amend the registration) or supply the data to another person for such a purpose. (clause 43(2)) Subject to the regulations, confidential test data and confidential business information could also be released to specified parties for specified purposes, such as to medical professionals who request the data to make a diagnosis or provide medical treatment, or to a federal or provincial government that requests the information in order to respond to an emergency. (clause 44)

In addition to the establishment of the Register, which would have limited public access, clause 42(7) calls for the establishment of an "electronic public registry." This registry would have to contain any information contained in the Register, a copy of which could be obtained by the public under the Act or the regulations. It would also have to contain other specified information, including intergovernmental memoranda of understanding and reports on international harmonization activities regarding the regulation of pest control products.

Clause 42.1 requires the public to be consulted about policies, guidelines and codes of practice developed in relation to the regulation of pest control products.

17. Whistleblower Protection: Clause 47

Clause 47 would protect whistleblowers who reported an actual or potential contravention of the Act or the regulations to an inspector. Their anonymity would be maintained, if requested. They would also be protected in the workplace against dismissal, harassment, suspension, etc.

This workplace protection would also apply to persons who refused (or stated an intention to refuse) to do anything that he or she reasonably believed was or could be a contravention under the Act or who did (or stated an intention of doing) anything that he or she reasonably believed was required to be done under the Act.

18. Enforcement: Clauses 45 to 61

Clause 45 calls for the appointment of inspectors and analysts. Clauses 48 to 56 set out the provisions governing inspections, searches and seizures and the disposal of seized material. Because these are fairly standard enforcement measures, they will not be considered further.

Under clause 57, an inspector who believes on reasonable grounds that a person has contravened the Act or the regulations, may issue a stop or shut down order in relation to the offending activity. Such orders are subject to review in accordance with the provisions of clause 60. This clause also allows the review of other selected enforcement actions.

19. Fees, Charges and Costs: Clauses 63 and 64

Clause 63 allows the government to recover any fee or charge related to the administration of the Act or regulations. Clause 64, in turn, allows the government to recover, from specified parties, any charges under the Act or any costs incurred by the government in administering the Act or regulations, including those incurred in relation to specified actions (e.g., inspections, testing, seizures, forfeitures, disposals, risk-control measures, etc.).

20. Compensation for Use of Information: Clause 66

Clause 66 authorizes the Minister to determine the terms and conditions of agreements regarding the payment of compensation by an applicant for the right to use or rely on information provided to the Minister by registrants under the Act. Such agreements would have

to be made in accordance with the regulations and would have to provide for the determination of compensation payable through negotiation and binding arbitration. Selected sections of the *Commercial Arbitration Act* would govern the arbitration in question, unless the parties agreed otherwise.

21. Regulation-Making Powers: Clause 67

Clause 67 confers broad regulation-making powers on the Governor in Council. Regulations could be made in relation to 32 separate matters under clause 67(1). Regulations could also be developed to implement selected articles under the North American Free Trade Agreement (NAFTA) and the Agreement on Trade-related Aspects of Intellectual Property Rights (known as TRIPS) of the World Trade Organization Agreement. These articles deal with restrictions on the disclosure of trade secrets (NAFTA only) and of safety and effectiveness data submitted in support of an application to register an agricultural chemical product (both agreements).

22. Offences and Punishment: Clauses 68 to 79

As mentioned under clause 6, specific offences and related penalties are scattered throughout the bill. Clauses 68 to 69 set out additional offences and penalties, whereas clause 70 deals with corporate liability issues.

The remaining clauses deal with a variety of matters, including evidentiary and sentencing matters. For example:

- an offender is liable to be convicted for a separate offence for each day the offence occurs; (clause 72)

- in addition to any sentence imposed, the court may require an offender to take one or more of the 11 actions specified in clause 77 (e.g., compensate the victim, publish the facts of the offence, together with an apology, community service, etc.);
- in addition to any other fine imposed, the court may require an offender to pay a fine equal to three times the amount the court estimates was made by committing the offence; (clause 78) and

- in order to encourage voluntary compliance, the Minister may publish information about any contravention of the Act and regulations, including a contravention designated as a violation under the *Agriculture and Agri-Food Administrative Monetary Penalties Act*.

23. Report to Parliament: Clause 80

The Minister would be required to table an annual report in Parliament regarding the administration and enforcement of the Act for that year, including:

- a status report on registrations, including the registration of reduced-risk products, and on any re-evaluations and special reviews carried out; and
- a report on any scientific developments regarding the evaluation of a product's health and environmental risks and value and the integration of these developments into the decision-making process.

24. Parliamentary Review

Clause 80.1 requires a parliamentary review of the legislation every seven years after the day on which clause 1 (short title) comes into force.

COMMENTARY

In the 1st session of the 37th Parliament, Bill C-8's predecessor, Bill C-53, was referred to the House of Commons Standing Committee on Health. The Committee heard from more than 40 groups and individuals, as well as from the Minister of Health and officials from the Pest Management Regulatory Agency (the PMRA). As Bill C-8 was deemed to have passed all stages in the House of Commons on 9 October 2002, the following commentary will generally centre on the activities surrounding Bill C-53, including any amendments and House of Commons debates.

In general terms, the witnesses expressed support for the bill, which was viewed as an improvement over the existing thirty-year-old legislation. It was widely felt, however, that the bill could be strengthened in a number of respects, but there was no consensus on which changes should be made. For example, opinion differed on whether the bill should provide more or less protection for confidential business information.

The bill's failure to implement a phase-out or ban on the use of pesticides for cosmetic purposes was one of the main areas of concern. Witness after witness, primarily from the health and environmental sectors, emphasized the need for a Canada-wide approach, pointing out that initiatives at the municipal level, although welcome, failed to protect *all* Canadians from the harmful effects of pesticides.

Many members of the Committee were sympathetic to these concerns, but they decided against enacting a federal ban, due in large measure to the position of the federal government that regulating the use of pesticide products, post-registration, was an area of provincial and territorial jurisdiction.

A further area of concern was the lack of definition in the bill of the terms "acceptable risk" and "unacceptable risk." It was felt that these terms, which represent the standard by which products are approved or disapproved for registration, were too fundamental to the legislation to be left undefined. Several definitions were proposed, but the government's definition of "acceptable risk," as amended by the Committee to include a reference to "future generations," was accepted in the end. It essentially calls for "reasonable certainty of no harm" (clause 2(2)).

The bill's single reference to the precautionary principle in clause 20[(2)] also came under fire. Many witnesses felt that this principle (or a reworded version of it) should be enshrined in the preamble and "operationalized" in other parts of the legislation. The government officials responded that there was no need to do so because the bill already takes a precautionary approach. Notably, the bill authorizes the registration of only those products that pose an "acceptable risk." The bill also requires appropriate safety margins to be applied in evaluating risk. All amendments proposed in relation to the precautionary principle were accordingly defeated.

One important amendment that was made concerns the evaluation of aggregate exposure and cumulative effects. Initially, Bill C-53 required consideration of these factors only in the evaluation of health risks for the purpose of setting the maximum (pesticide) residue levels (MRLs) on foodstuffs (clause 11(2)(a)). Responding to concerns from health and environmental groups that these factors should be considered in *all* product evaluations (e.g., product registrations, re-evaluations or special reviews), the government introduced an amendment to clause 7(7), which requires that aggregate exposure and cumulative effects be considered in evaluating the health risks of products undergoing an initial evaluation for registration or a registration amendment.

---

(2) Clause 20(1)(b) enables corrective action to be taken (e.g., cancellation of a product's registration) where, during a re-evaluation or special review, the Minister believes that it is necessary to do so to deal with a situation that endangers human health or safety or the environment, taking into account the precautionary principle.

The amendment that was passed, however, requires consideration of these factors only in relation to "selected" products, namely, products involving one of the following so-called "major" decisions:

- a decision to register a product involving a new active ingredient;
- a decision to register or amend the registration of a product that, if allowed, may result in significantly increased health or environmental risks; or
- a decision about the product's registration following a re-evaluation or special review.

Furthermore, because of the specific way in which the amendment was framed, the pre-existing requirements in clause 7(7) to apply safety margins in evaluating health risks were also made subject to the "selected" products limitation. No such limitation had been prescribed in the original bill. It is, therefore, an open question whether clause 7(7), as amended, constitutes a step forward because it calls for consideration of aggregate exposure and cumulative effects, or a step backward because all of the factors to be considered and the safety margins to be applied in evaluating health risks are now limited to "selected" products, that is, those involving a "major" decision.

A concomitant amendment requiring consideration of aggregate exposure and cumulative effects was also made in relation to the evaluation of health risks in the course of a re-evaluation or special review of a product under clause 19(2).

One amendment that was urged by the witnesses was the enactment of a fast-track mechanism for the registration of reduced-risk products. Clause 7 was accordingly amended to require the Minister to expedite the evaluation of products that may reasonably be expected to pose lower health or environmental risks (clause 7(3)(b)).

A further amendment that was made, primarily in response to concerns raised by the agricultural sector, relates to "minor use" products. Minor use products are products that are not available in Canada because the market for them is too small and there is therefore insufficient economic incentive for their manufacturers to seek and maintain registration in this country. Several detailed amendments were proposed to promote and facilitate the registration of minor use products, but these were ruled out of order as falling outside the scope of the bill. The government's much simpler amendment was accepted. It amends the bill's regulatory

powers in clause 67 to expressly authorize the Governor in Council to make regulations respecting minor uses (clause 67(1)(*f*.1)).

A final noteworthy amendment concerns the periodic review of the legislation by Parliament. The original bill did not call for such a review. Because of the legislation's complexity and importance, it was widely felt that there should be a periodic review by Parliament, although there was disagreement on the appropriate timing for such reviews. Most proposed amendments called for a parliamentary review every five years, whereas the government amendment called for one every ten years. In the spirit of compromise, agreement was reached on a parliamentary review every seven years, which was added under new clause 80.1 of the bill.

In the 1st session of the 37th Parliament, approximately 200 amendments were proposed in relation to Bill C-53 during its consideration by the House Committee. Of these, only 18 were adopted, some of which were purely technical in nature. Many groups and individuals may, therefore, feel that the bill requires further improvement. It is unclear, however, whether they would prefer to see the bill passed as currently amended or to insist that additional amendments be made first, thereby delaying its passage, possibly for some time to come.