Mini-Review **MR-149E**

HERB REGULATION IN CANADA: BACKGROUND AND ISSUES

Gérald Lafrenière
Law and Government Division

Nancy Miller Chenier
Political and Social Affairs Division

6 October 1997

Library of Parliament

Bibliothèque du Parlement

Parliamentary Research Branch

The Parliamentary Research Branch of the Library of Parliament works exclusively for Parliament, conducting research and providing information for Committees and Members of the Senate and the House of Commons. This service is extended without partisan bias in such forms as Reports, Background Papers and Issue Reviews. Research Officers in the Branch are also available for personal consultation in their respective fields of expertise.

CE DOCUMENT EST AUSSI PUBLIÉ EN FRANÇAIS

CANADA

LIBRARY OF PARLIAMENT
BIBLIOTHÈQUE DU PARLEMENT

HERB REGULATION IN CANADA: BACKGROUND AND ISSUES

Various actions by the federal government over the last decade have directed increased attention to herbs and botanical preparations and have intensified debate in Canada over their regulation. This paper establishes the context of the debate since the mid-1980s and outlines four different areas where federal action has been perceived as affecting herbal regulation. These actions include: the proposed Schedule 705 based on an assessment of herbs as foods; the *Controlled Drugs and Substances Act*, with its potential to restrict herbs as drugs; the U.N. Codex Committee on Nutrition and Foods, which aims for harmonized treatment of herbs; and the proposed cost recovery scheme of the federal government whereby licensing fees were to be applied to establishments that manufacture or distribute herbal medicines.

GENERAL BACKGROUND

- The term "herbs" is frequently used to apply to both the actual plant and to the products synthesized from plants. Although it is difficult to obtain exact figures, there is a reported increase in the sale and use of herbs in Canada. One estimate suggests that in North America herbal remedies constitute a $2-billion-a-year industry that is growing at a pace of 15% annually.

- Herbal products are generally regulated either as foods or as drugs under the *Food and Drugs Act*. The designation depends on the pharmacological activity of the ingredients, the intended purpose of the product, and the representations made regarding its use, including medicinal claims. Within Health Canada, responsibility for these products crosses the boundaries between the directorate responsible for food safety and the directorate responsible for drug

protection. Some products, such as cannabis and khat, are controlled substances pursuant to the *Controlled Drugs and Substances Act*, where different restrictions and regulations apply.

- Individuals and industry representatives argue that the *Food and Drugs Act* restrictions on selling and advertising the products and importing them for sale are too severe. These critics insist that the products are natural and, if used appropriately, do not cause harm to humans.

- Health Canada asserts that some of these products, sold as foods and claimed to be medicinal, are harmful. The regulations of the *Food and Drugs Act* require any marketed herbal product claiming to have medicinal properties to carry a drug identification (DIN) or general public (GP) number. These numbers indicate that there has been a review of the product's formulation, labelling and instructions for use, and are intended to provide assurance that any content and health claims are accurate.

- Health Canada has made several public attempts to address the issue of regulation of herbs. Over the last decade, at least two Expert Advisory Committees on Herbs and Botanical Preparations, one in 1986 and another in 1993, reviewed the issue of herbs that are available as foods. Most recently, in May 1997, the department established the Advisory Panel on Herbal Medicines to advise on the development of an appropriate framework for regulating herbal remedies. In addition, Health Canada has issued information letters, guidelines and policy statements.

- On 4 October 1997, Health Minister Allan Rock announced that the House of Commons Standing Committee on Health would be asked to conduct a review of herbal regulation.

SPECIFIC ISSUES

A. Schedule 705

- Recent public discussions date back to a 1986 report by an Expert Advisory Committee on Herbs and Botanical Preparations which was established by the federal health department. This Committee reviewed safety and regulatory control mechanisms for such substances when sold as foods. It identified four basic classifications of herbs and botanical preparations:

unacceptable for use in or as food; generally acceptable as foods; acceptable as foods under specified conditions; and generally used for medicinal purposes.

- In 1989, the Committee's assessment, combined with additional consultations, led to the publication of Schedule 705, which outlined those substances not permitted for use in or as food and those substances acceptable as foods under specified conditions. These proposed amendments to the Food and Drug Regulations were published in the *Canada Gazette, Part I*.

- In 1992, there were further proposed amendments to the Regulations, in response to which the department received over 2,000 letters and 5,000 petition signatures.

- The Expert Advisory Committee was reconstituted in 1993 to reconsider the concerns raised. The Committee recommended removal of seven herbs and botanical preparations from the "unacceptable as food" list in the proposed Schedule 705. Of these seven, five - Wormwood, Feverfew, Levant Wormseed, Mugwort, and St. John's Wort – would now be generally acceptable as food. The other two - Goldenseal Root and Oregon Grape Root – would now be acceptable as food under specified conditions.

- From 1994 to the present, the department used this 1993 Expert Advisory Committee report as a basis for consultation with representatives of industry and other interested individuals. The department recognizes that this is a complex issue crossing the boundaries between food and drugs.

- As part of its ongoing review, Health Canada considered other options than the regulatory one to be adopted in the proposed Schedule 705. The Advisory Panel on Herbal Medicines was established in May 1997 to advise on a framework for herbal remedies and is currently working on this issue.

B. Bill C-85/C-7/C-8, the *Controlled Drugs and Substances Act* (CDSA)

- This legislation aimed to consolidate and supplement the *Narcotic Control Act* and Parts III and IV of the *Food and Drugs Act*, as well as to harmonize Canada's narcotic, controlled and restricted drug regulations with those of other countries. The legislation originated in the 34th

Parliament as Bill C-85, the Psychoactive Substance Control Act, was introduced in the first session of the 35th Parliament as Bill C-7; and re-emerged as Bill C-8 in the second session of the 35th Parliament. This bill was passed in June 1996 and came into force in May 1997.

- After arguments had been made by natural product producers, retailers and consumers, Bill C-7 was amended to remove the definition of a controlled substance as one producing a stimulant, depressant or hallucinogenic effect. These critics continue to find fault with the expanded regulatory authority under the legislation, however, arguing that it could be used to further restrict herbs.

- According to Health Canada, the availability of herbs and herbal products is regulated under the statutory authority of the *Food and Drugs Act*, not under the *Controlled Drugs and Substances Act*. As noted earlier, however, some botanical preparations are already controlled and are specifically mentioned in schedules of the latter Act.

C. The UN Codex Alimentarius Commission

- The UN Codex Alimentarius Commission aims to harmonize international food standards to protect consumers against health hazards and fraud; to ensure safe practices in the food trade; and to facilitate international trade in food and food products.

- In 1997, the Codex Commission's Committee on Nutrition and Foods for Special Dietary Uses reviewed concerns over potentially harmful herbs and botanical products sold as foods. It stated that the toxicity of herbs is essentially a safety problem with no nutritional implications and recommended that national authorities establish lists of potentially harmful plants on a toxicological basis.

- As one of its 151 member countries, Canada is free to adopt or reject the standards, guidelines and recommendations the Commission develops. The herbal community is concerned that Canada will yield to international trade pressure but Health Canada stresses that the World Trade Organization does not have the authority to require countries to adopt and enforce a Codex finding.

D. Cost Recovery through Licensing Fees

- When Bill C-95, An Act to establish the Department of Health, was enacted in 1996, Health Canada was authorized to charge user fees for some services it provides to external users. In line with Treasury Board policy guidelines on cost recovery and user fees, the purpose is to recover, partly or totally, the cost of providing departmental services. The 1996 Act does not specify the types of service to which the fees could apply, nor does it identify the users who could eventually be charged.

- By July 1997, manufacturers, distributors and importers of herbal remedies were to pay an annual licensing fee to Health Canada to cover the cost of facility inspections. The aim was to ensure that these herbal products would be prepared following certain standards, called Good Manufacturing Practices (GMPs). These are uniform requirements applied to all facilities wishing to fabricate, package, import, distribute, or test drugs in Canada.

- Herbal industry participants claimed that this licence fee, estimated to be 1.5% of gross annual sales, would make their marginal operations unprofitable and drive them out of business.

- The Advisory Panel on Herbal Medicines recommended a temporary delay and further study before implementation of the licence fee.

- In late June, the Minister of Health accepted the advisory panel’s recommendation and delayed implementation of the licensing fee regulations until January 1998.

- In his 4 October 1997 announcement that the House of Commons Standing Committee on Health would be reviewing herbal regulation, Health Minister Rock stated that implementation of licensing fee regulations would now be halted for an indefinite period.