BILL C-51: AN ACT TO AMEND THE FOOD AND DRUGS ACT AND TO MAKE CONSEQUENTIAL AMENDMENTS TO OTHER ACTS

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LEGISLATIVE HISTORY OF BILL C-51

HOUSE OF COMMONS			SENATE	
Bill Stage	Date	ı	Bill Stage	Date
First Reading:	8 April 2008		First Reading:	
Second Reading:			Second Reading:	
Committee Report:			Committee Report:	
Report Stage:			Report Stage:	
Third Reading:			Third Reading:	

Royal Assent:

Statutes of Canada

This bill did not become law before the 39th Parliament ended on 7 September 2008.

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

Legislative history by Michel Bédard

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BILL C-51: AN ACT TO AMEND THE FOOD AND DRUGS ACT AND TO MAKE CONSEQUENTIAL AMENDMENTS TO OTHER ACTS*

Bill C-51, An Act to amend the Food and Drugs Act and to make consequential amendments to other Acts, was introduced in the House of Commons on 8 April 2008. Among other things, the bill creates new offences relating to food, therapeutic products (a new term used in the bill that includes drugs) and cosmetics, requires licences for importing food and for interprovincial trade in food, and makes amendments to the licensing of therapeutic products.

BACKGROUND AND CONTEXT

This bill responds to a perceived weakness in the federal health law regime and stems from a reform initiative that has been under consideration for a decade.

A. Health Protection Legislative Renewal

Developing a new *Food and Drugs Act* was initially part of Health Canada's health protection legislative renewal exercise, which was started in 1998 to address "shortcomings in Health Canada's legislative basis for health protection." Initially, it was thought that the legislative renewal would culminate in a new Canada Health Protection Act, which, in addition to an amended *Food and Drugs Act*, would have incorporated an updated *Quarantine Act*, *Hazardous Products Act*, and *Radiation Emitting Devices Act*. Consultations on a legislative proposal were carried out in 2003. (2) Quarantine-related provisions were separated out of the

^{*} 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⁾ Health Canada, Report on Plans and Priorities, 2006–2007, p. 24.

⁽²⁾ Health Canada, "Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food," October 2006, Annex 3, Legislative Renewal, http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/blueprint-plan/blueprint-plan ann3 e.html.

health protection legislative renewal package when Bill C-12, the *Quarantine Act*, was introduced in 2004. (3)

The purpose of the Canada Health Protection Act⁽⁴⁾ would have been "to protect the health of the people of Canada."⁽⁵⁾ It would have included principles relating to both assessing and addressing risks to health: principles "based on science, weighing risk against potential advantages, the concept of precaution, allowing for informed choice by consumers, considering health determinants, and sustainable development."⁽⁶⁾ The Act would have created a product tampering offence as well as a deception offence, which would prohibit "deceiv[ing] consumers regarding the health and safety benefits of a product."⁽⁷⁾ It also would have "describe[d] the respective responsibilities of the various participants in the supply chain, including the responsibility of the manufacturer to monitor adverse health effects after a product has been sold and to take corrective action when necessary."⁽⁸⁾

B. Blueprint for Renewal

In October 2006, Health Canada's Health Products and Food Branch released a consultation document, "Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food." This document promoted an "adaptable and sustainable regulatory system," which had the following objectives:

• developing a "life cycle" regulatory approach to health products that would "encompass all stages of product development and use" (part of progressive licensing); (10)

⁽³⁾ Replacing the *Quarantine Act* became a priority when reports released after the 2003 severe acute respiratory syndrome (SARS) outbreak stressed the need for improved measures to address public health threats both at Canada's borders and within Canada.

⁽⁴⁾ The last explicit reference to a Canada Health Protection Act in Health Canada's "Report on Plans and Priorities" (RPP) was in 2004–2005. Health Canada's 2006–2007 RPP noted that as part of the Health Protection Legislative Renewal exercise, "the Department [was] ... engaged in reviewing the proposed legislation to determine whether to proceed with a single piece of legislation or to continue with a phased approach as started by the expediting of the new *Quarantine Act* (2005)," p. 25. In its RPP for the following year, Health Canada noted that it would continue with a phased approach to legislative renewal, which suggests that the concept of a broader Canada Health Protection Act has been put aside.

⁽⁵⁾ Health Canada, "Health Protection Legislative Renewal: the Proposal in 7 Pages," 4 June 2003.

⁽⁶⁾ Health Canada, "Legislative Renewal."

⁽⁷⁾ Health Canada (2003), "Health Protection Legislative Renewal."

⁽⁸⁾ Ibid.

⁽⁹⁾ Health Canada (2006), "Blueprint for Renewal," p. 3.

⁽¹⁰⁾ A progressive licensing project has been undertaken by the Health Products and Food Branch as part of the Blueprint for Renewal exercise. For information on the progressive licensing project, see the project website at: http://www.hc-sc.gc.ca/dhp-mps/homologation-licensing/index_e.html.

- developing a more transparent and consistent system of categorizing products and assessing their risks;
- designing and implementing a more responsive food regulatory framework "that protects and promotes human health, responds to emerging food safety and nutrition challenges, and minimizes unnecessary delays in bringing safe food and food products to the Canadian marketplace" (11);
- moving away from a reactive "waiting for events" regulatory system and developing a more proactive approach;
- "better generat[ing], disseminat[ing] and respond[ing] to safety and effectiveness data for health products and food" (12) and develop[ing] a "more proactive, post-market evaluation strategy";

(cont'd)

"Blueprint for Renewal II", cited below, describes progressive licensing as follows:

The central concept of progressive licensing is that, over time, there is a progression in knowledge about a product and that this increase in knowledge can allow for the benefits of a drug to be maximized and its risks minimized.

The framework supports evidence-based decision making. Not only will the key regulatory decisions throughout the product life cycle be based on evidence, but so will the policy choices for the framework, including evaluating how the framework is achieving its objectives.

Good planning will be another key feature of the framework. Planning at every step of the regulatory process will be introduced to allow a proactive approach to managing expected and unexpected issues. From the very beginning of the regulatory cycle, Health Canada can make best use of its science and regulatory resources, for example, by agreeing with a manufacturer on when a regulatory filing will be made and what data it will include. Early planning and assessment of clinical trial methods and protocols could reduce the number of trials that yield inconclusive or irrelevant results from a regulatory point of view. Planning for post-market activities – including studies, effectiveness monitoring, safety surveillance and risk management – at the pre-market filing stage would ensure that expectations for identifying and managing drug benefits and risks are established before a drug is marketed. Similarly, planning for changes in manufacturing to take advantage of a pre-approved range of parameters would reduce unnecessary filings and ensure that a drug remains of high manufacturing quality over its life cycle.

Accountability is incorporated into all aspects of the framework and reflects the ongoing requirement of Health Canada and drug manufacturers to justify the marketing of a product. The mechanisms for accountability in the framework include Health Canada's ability to set conditions when issuing an initial market license, so that, for example, certain field reporting commitments or further studies are required.

Health Canada, Health Products and Food Branch, "Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Food," 2007, p. 9, http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/hpfb-dgpsa/blueprint-plan_II_e.pdf.

- (11) Health Canada (2006), "Blueprint for Renewal," p. 3.
- (12) Ibid.

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- strengthening leadership on a range of health and safety issues affecting specific populations;
- promoting a more open and transparent regulatory system; and
- "better synchroniz[ing] the regulatory system with the objectives, policies and practices of the health care and innovation systems."

Consultations on the Blueprint document were carried out between October and December 2006, and these consultations were reported on in 2007 in "Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Food." The consultation process led to the inclusion of two additional objectives:

- putting in place better legislative, regulatory and policy tools to better support compliance and enforcement; and
- "work[ing] with partners in the health care system to make available more and better information about health products and food to enable Canadians to make informed decisions about their health." (14)

C. The "Food and Consumer Safety Action Plan"

In December 2007, Prime Minister Stephen Harper announced Canada's Food and Consumer Safety Action Plan, which would "modernize and strengthen Canada's safety system for food, health and consumer products and ... better support the collective responsibilities that government, industry and consumers have for product safety." (15)

Amendments to the *Food and Drugs Act* relating to food that were contemplated at that time included "clearly describing food not permitted for importation into or sale in Canada," establishing registration and licences relating to food importing, and prohibiting tampering with or threatening to tamper with food, food packaging or food labels.⁽¹⁶⁾

For health products, progressive licensing would be established, which would "shift the focus from pre-market review to one that continuously assesses a product's risks and

⁽¹³⁾ Health Canada (2007), "Blueprint for Renewal II."

⁽¹⁴⁾ Ibid., p. 7.

⁽¹⁵⁾ Government of Canada, "Strengthening and Modernizing Canada's Safety System for Food, Health and Consumer Products: A Discussion Paper on Canada's Food and Consumer Safety Action Plan," 10 January 2008, http://www.healthycanadians.gc.ca/pr-rp/dpaper-papier e.html.

⁽¹⁶⁾ Ibid.

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benefits both before and after it reaches the market." A progressive licensing framework would involve new obligations on the part of manufacturers, which could include active postmarket surveillance and reporting, and issuing risk information to the public. (18)

Other initiatives proposed in the Action Plan related to new industry reporting requirements, improved compliance and enforcement powers, an increase in fines and penalties, improved import safety and improved information for consumers and decision-makers. (19)

DESCRIPTION AND ANALYSIS

Bill C-51 contains a preamble and 75 clauses. The bill essentially overhauls the existing *Food and Drugs Act* by restructuring its format and replacing pages of existing text with new text that does not necessarily relate in any way to the existing text. In addition to technical and consequential amendments, and the inclusion of new definitions, new regulation-making powers, transitional provisions and consequential amendments, the bill:

- creates new offences relating to food, therapeutic products (a new term used in the bill that includes drugs) and cosmetics;
- requires licences for importing food and for interprovincial trade in food;
- makes amendments to the rapeutic product licensing;
- expands the powers of inspectors;
- adds new "Administration and Enforcement" measures, including mandatory recalls of therapeutic products and cosmetics;
- substantially increases the penalties relating to offences; and
- provides for the disclosure of confidential business information in certain circumstances.

The following section provides a summary overview of selected clauses contained in the ${\rm bill.}^{(20)}$

⁽¹⁷⁾ Ibid.

⁽¹⁸⁾ Ibid.

⁽¹⁹⁾ Ibid.

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A. Preamble

The nine-paragraph preamble notes, among other things, the need for a continued commitment to public health and safety and the need for ongoing assessments of information about therapeutic products. It also notes that regulated persons are responsible for ensuring that products meet legislative requirements, and highlights the importance of openness and transparency in the regulatory decision-making process.

B. Title and Definitions (Clauses 1–3)

Clause 1 of the bill changes the long title of the *Food and Drugs Act* to "An Act respecting foods, therapeutic products and cosmetics." "Therapeutic products" include drugs, devices, and cells, tissues or organs that are distributed or represented for use in certain circumstances (clause 3(6)).

C. Purpose (Clause 4)

Clause 4 replaces sections 3⁽²¹⁾ and 4 of the existing *Food and Drugs Act*. New section 2.3 indicates the purpose of the bill as protecting and promoting public health and safety and encouraging accurate and consistent product representation by prohibiting and regulating certain activities related to food, therapeutic products and cosmetics. The *Food and Drugs Act* does not currently include a "purpose" section.

D. Prohibitions (Clauses 4–18)

1. New prohibitions

Clause 4 also adds a new "Prohibitions" heading, grouping together prohibitions set out in the existing *Food and Drugs Act* under that heading as well as adding the following prohibited activities: knowingly providing the Minister with false or misleading information in relation to a matter under the bill (new section 3), tampering with a food, therapeutic product or

(cont'd)

⁽²⁰⁾ For reasons of clarity, discussion relating to the clauses of the bill will also refer to the particular sections of the Act referred to in a particular clause, as the majority of clauses in the bill amend or replace several different sections of the existing *Food and Drugs Act*.

⁽²¹⁾ Section 3 of the existing Act prohibits the advertising of a food, drug, cosmetic or device as a treatment or cure to "diseases, disorders or abnormal physical states" listed in Schedule A of the Act.

cosmetic (including tampering with its label or package) to either render it injurious to human health (new subsection 3.1(1)(a)) or to cause a reasonable apprehension that it is injurious to human health (new paragraph 3.1(1)(b)), selling or importing an aforementioned product that was tampered with to render it injurious to human health (new subsection 3.1(2)), or threatening to tamper with such a product (new subsection 3.1.(3)). Clause 4 also prohibits communicating or causing to be communicated information known to be false or "reckless as to its truth" for the purpose of causing a reasonable apprehension that a product has been rendered injurious to human health (new section 3.2).

The existing section 4, which prohibits the sale of food in certain listed circumstances, is amended to also prohibit the importing of food in those same circumstances, and the circumstances that prevent the sale (and now the importing) of food that "consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance" is replaced with prohibiting the sale or importing of food that is "injurious to human health" (paragraph 4(c)).

2. The Importing of and Interprovincial Trade in Foods

Clause 6 relates to the importing and interprovincial trade in prescribed foods, and prohibits the importing of or sending to another province a prescribed food without a registration or licence (new subsections 5.1 and 5.2). Ministerial authorization for such registrations and licences are established in the new section 18.2.

3. Therapeutic Products

Clause 8 replaces all of sections 7 to 21 of the existing Act, which currently prohibit the sale and manufacture of drugs (sections 8 to 15), cosmetics (sections 16 to 18) and devices (sections 19 to 21) in specific circumstances. The new sections 8 to 18 relate to therapeutic products; this is indicated by the addition of a new "Therapeutic Products" heading. New sections 18.1 to 20.3 relate to authorizations and licences.

The substance of the majority of the existing provisions relating to the sale and manufacture of drugs, cosmetics and devices is still contained in the new provisions, along with the addition of provisions relating to clinical trials and establishment licences. There are

currently no explicit references to either clinical trials or establishment licences in the *Food and Drugs Act*; they are provided for only in the *Food and Drugs Regulations*. (22)

These new provisions establish a framework for the licensing and marketing of therapeutic products and, to a lesser extent, food. The framework is similar in many ways to the framework that exists under the *Food and Drug Regulations*, but also goes beyond that by incorporating a "progressive licencing" framework.

The bill requires persons (defined to include individuals or organizations as defined in section 2 of the *Criminal Code*) to:

- obtain a clinical trial authorization before conducting clinical trials on therapeutic products that do not have a market authorization (new section 10), and to conduct clinical trials in accordance with the regulations (new section 11). (The procedures relating to obtaining, amending, suspending or revoking clinical trial authorizations are set out in new sections 18.2 to 18.6, and regulations relating to clinical trials can be made under new paragraphs 30(1)(w) to 30(1)(z.1).);
- obtain a market authorization before advertising, selling or importing for sale a therapeutic product (new subsection 12(1)). (The procedures relating to obtaining, amending, suspending and revoking market authorizations are set out in new sections 18.7 to 19.1.); and
- obtain an establishment licence before carrying out a controlled activity (i.e., before manufacturing, collecting, processing, preserving, labelling, packaging, importing for sale, distributing, wholesaling or testing a therapeutic product) (new section 13). (The procedures relating to obtaining, amending, suspending and revoking establishment licences are set out in new sections 19.2 to 19.7.)

It is within the Minister's discretion to grant a clinical trial authorization, a market authorization, or an establishment licence, and the terms and conditions to which all of these are subject can be established in the regulations (new paragraph 30(1)(s)). In all cases, the issuance of the authorization or licence will be subject to regulations, and the authorization or licence can be suspended or revoked in certain circumstances (and subject to regulations), including immediate suspension where "necessary to respond to a serious and imminent risk of injury" to health (new subsections 18.5(2), 19(2), and 19.6(2)).

E. Powers of the Minister (Clause 8, New Sections 19.8–20.3)

⁽²²⁾ Regulations relating to clinical trials are established in Part C, Division 5 of the *Food and Drug Regulations*, C.R.C., c. 870; establishment licences are provided for in Part C, Division 1A of those regulations.

Many of the powers listed in this section reflect a progressive licensing approach. For example, subject to the regulations, the Minister can compel the holder of a clinical trial authorization, market authorization or establishment licence to provide any information within their control that is considered necessary for the administration of the bill (new section 19.8). The Minister can also, subject to the regulations, require the holder of a market authorization or establishment licence in order to "compile information, conduct tests or studies or monitor experience" to obtain additional information about a therapeutic product's effects on health or safety (new paragraph 19.9(a)), or report such information to the Minister (new paragraph 19.9(b)).

Subject to the regulations, the Minister can also require labels of therapeutics to be revised to reflect information necessary to prevent injury to health (new section 20.1), require the holder of a market authorization to conduct a reassessment of a therapeutic product within a specific timeframe (new section 20.2), and publicly disclose information about the risks or benefits associated with a therapeutic product (new section 20.3).

F. General Provisions (Clause 8, new sections 20.4–21.2, and Clause 11, regulation-making authority)

Included under the "General Provisions" heading is the power of the Minister to compel a person to provide information relating to a food, therapeutic product or cosmetic that may present a serious risk to human health (new section 20.5). Prescribed classes of health care institutions are also required to provide adverse reaction information to the Minister (new section 20.7).

New sections 20.9 to 21.2 permit the Minister to disclose both personal information (new sections 20.9 and 21) and confidential business information (new sections 21.1 and 21.2) in certain circumstances. The circumstances in which business information ceases to be confidential business information, and the business information that is not confidential business information can be specified under the regulations (new paragraph 30(1)(c)). Regulations can also be made "respecting the collection, use or disclosure of personal business information or confidential business information by the Minister, including its disclosure to the public" (new paragraph 30(1)(z.7)).

G. Administration and Enforcement (Clauses 9–10)

The powers of inspectors under the existing *Food and Drugs Act* are amended in part to reflect changes in technology, e.g., examining documents contained within computers (new paragraph 23(2)(f)) and using copying equipment (new paragraph 23(2)(g)). The amendments also authorize an inspector to enter or pass through or over private property without being liable for doing so in carrying out their functions (new subsection 23(4)). New subsection 23.8(1) provides that if an inspector believes on reasonable grounds that there is a contravention of the Act or the regulations, he or she can direct a person to take a measure that is necessary to identify or respond to a risk of injury to health related to the contravening activity.

Of particular significance are the new sections 23.9 and 24. Section 23.9 authorizes an inspector to direct the person possessing a food, therapeutic product or cosmetic that was imported for sale, or its owner or importer, to remove it from Canada, at that person's expense, if there are reasonable grounds to believe that it either does not meet the requirements established under the Act or was imported for sale in contravention of a requirement established under the Act. New section 24 authorizes the Minister to direct a recall of a therapeutic product or cosmetic where the Minister is of the opinion that it presents a serious or imminent risk of injury to health (new subsection 24(1)). Regulations can be made requiring persons who sell or import for sale foods, therapeutic products or cosmetics to establish tracing systems to facilitate recalls (new paragraph 30(1)(f)), and new paragraph 30(1)(z.11) allows for other regulations to be made respecting recalls. The Minister can even authorize someone to sell a recalled product (new subsection 24(3)).

In addition to the power to compel a recall, the Minister can also apply to a court of competent jurisdiction for an injunction in certain circumstances (new subsection 24.1(1)).

H. Offences (Clauses 14–16)

The bill substantially increases the penalties for contravening the Act. The penalties for contravening a provision of the Act are increased from a maximum \$500 fine and/or three months' imprisonment (Food and Drugs Act, paragraph 31(a)) to a maximum \$250,000 fine and/or six months' imprisonment for a first summary conviction offence (new paragraph 31(1)(b)), and from a maximum \$5,000 fine and/or three years' imprisonment (Food and Drugs Act, paragraph 31(b)) to a maximum \$5,000,000 fine and/or two years' imprisonment (new paragraph 31(1)(a)) for an indictable offence.

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The bill also establishes penalties for wilfully or recklessly contravening the provisions of the Act: in the case of a summary conviction offence, the penalty for a first offence is a maximum \$500,000 fine and or a maximum of 18 months' imprisonment (new paragraph 31(3)(b)). In the case of an indictable offence under this section, the amount of the fine is within the court's discretion, and the offender can also be sentenced to five years' imprisonment (new paragraph 31(3)(a)).

I. Transitional Provisions, Consequential Amendments and Coming into Force

Clauses 18 to 28 include a number of complex transitional provisions governing various licensing decisions under the existing legislation and regulations and the timing of the coming into force of the bill. Clauses 29 to 74 contain a series of technical and consequential amendments. Clause 75 provides that, other than two coordinating amendments, the bill is to come into force on a day or days to be fixed by order of the Governor in Council.

COMMENTARY

In the weeks and months following Bill C-51's introduction, a number of concerns have been raised with respect to the scope and intent of the bill. The bill has been seen by some as an attempt to further regulate natural health products, which are currently governed by the *Natural Health Products Regulations* of the *Food and Drugs Act*. Among the concerns that have been raised are the beliefs that natural health products will be subject to the same licensing requirements as pharmaceutical drugs, that the search and seizure powers included in the bill are too broad, and that the increased penalties for violating the *Food and Drugs Act* or its associated regulations are excessive. In addition to the concerns raised by manufacturers and consumers of natural health products is the apprehension that removing section 3 of the *Food and Drugs Act* (which prohibits advertising foods, drugs, cosmetics or devices to the general public as a treatment, preventative or cure for diseases and conditions listed in Schedule A of the Act) will permit direct-to-consumer advertising in future.

⁽²³⁾ See for example: Carly Weeks, "Consumer Safety: Progressive Licensing; Experts sound alarm on drug-approval plan," *The Globe and Mail* [Toronto], Metro Edition, 9 April 2008; Karen Gram, "Natural health products unfairly hit, critics say," *Vancouver Sun*, 10 May 2008; Carly Weeks, "Bill C-51: Regulating herbs and vitamins," *The Globe and Mail* [Toronto], Metro Edition, 23 May 2008; Susan Zielinski, "Takin' it to the streets; Protesters oppose natural health products bill," *Red Deer Advocate*, 2 June 2008; André Picard, "Second Opinion; Bill C-51: Natural health products," *The Globe and Mail* [Toronto], Metro Edition, 12 June 2008; Stephanie Waddell, "Questions arise over Food and Drugs Act changes," *The Whitehorse Star*, 12 June 2008.

⁽²⁴⁾ The Canadian Press, "Critics say Ottawa is about to allow direct-to-consumer drug ads," 11 April 2008.

In response to the concerns raised with respect to the potential effect of Bill C-51 on the regulation of natural health products, the Government of Canada has posted information specific to Bill C-51 and natural health products on its "Healthy Canadians" website. The Government has also indicated that it will be proposing amendments to Bill C-51 once it has been referred to the House of Commons Standing Committee on Health. These amendments flow from "[e]xtensive stakeholder consultations [that] have been carried out to better understand [the] concerns [relating to the effect of Bill C-51 on natural health products] and to explain the underlying intent of the changes proposed in the Bill."

For example, the Government has indicated that it will propose an addition to the bill's preamble that would recognize: (1) the value of traditional knowledge and the history of the use of natural health products for benefit and risk assessment purposes; (2) that the information required to demonstrate that a therapeutic product's benefits outweigh its risks depends on the nature of the product and its intended use; and (3) that the "risk of injury to health is a factor relevant to the taking of administrative and enforcement measures." (28)

Other amendments that will be proposed include adding a definition of "natural health product" to the bill as well as including "natural health products" in the definition of "therapeutic product." With respect to search and seizure powers under the bill, amendments will be proposed to restrict the circumstances under which items seized in the course of verifying compliance or preventing non-compliance with the Act or regulations can be detained. Instead of articles or conveyances being detained "for any time that may be necessary" (proposed new paragraph 23(1)(d)), items will only be detained if "the inspector reasonably believes that the detention is necessary

(a) to prevent a risk of injury to health;

⁽²⁵⁾ Government of Canada, Healthy Canadians, "Bill C-51 and Natural Health Products: The Facts," http://www.healthycanadians.ca/pr-rp/billC-51_e.html; Government of Canada, Healthy Canadians, "Bill C-51 and the Regulation of Natural Health Products: Fast Facts," http://www.healthycanadians.ca/pr-rp/facts-c51-fiches-e.html.

⁽²⁶⁾ Government of Canada, Healthy Canadians, "Proposed Amendments to Bill C-51: Fact Sheet," http://www.healthycanadians.ca/pr-rp/fs-c51-fr_e.html.

⁽²⁷⁾ Ibid.

⁽²⁸⁾ Government of Canada, Healthy Canadians, "Proposed Bill C-51 Amendments," http://www.healthycanadians.ca/pr-rp/c51-amend-mod_e.html.

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- (b) to prevent inaccurate representations of the article, or an article in the receptacle, package or conveyance, as the case may be; or
- (c) to determine whether the article, or an article in the receptacle, package or conveyance, as the case may be, poses a risk of injury to health." $^{(29)}$