

## Canada Proposes Tough New Product Safety Laws

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The Canadian federal government recently introduced new legislation which, if enacted, will significantly change the regulatory regime for foods, therapeutic products (which includes drugs, natural health products and medical devices), cosmetics and other consumer products. Bill C-51, which will revamp the *Food and Drugs Act*, and Bill C-52, the new *Consumer Products Safety Act*, fulfil a promise made by the Conservative government in its 2007 Speech from the Throne to “introduce measures on food and product safety to ensure that families have confidence in the quality and safety of what they buy”. The “precautionary principle” stated as “a lack of full scientific certainty is not to be used as a reason for postponing measures that prevent adverse effects on human health if those effects could be serious or irreversible” is enshrined in the preamble to both bills.

If passed, the new legislation will have significant implications for pharmaceutical, medical device and other health product companies, food manufacturers, and anyone that manufactures, imports, advertises or sells consumer products. While these bills will likely be amended before they become law, and much of the detail will be contained in regulations not yet available, a review of some of the central features of this proposed legislation provides a preview of new regulatory requirements to come.

### Bill C-51 – Amendments to the Food and Drugs Act

Bill C-51 proposes significant amendments to the *Food and Drugs Act*. With respect to **food**, important amendments include:

- broadening the application of the Act to cover importation of food as well as its sale;
- expanding regulation-making authority to include: establishing food safety controls for preparation, packing and storage of high-risk foods; creating new record-keeping and reporting requirements for those involved in importing, processing, preparing or selling food; and requiring those who sell or import food to establish tracing systems;
- adding licensing and/or registration requirements for importation and interprovincial trade of food products and establishment registrations for sites conducting activities to be prescribed by regulation.

With respect to **health products**, such as pharmaceuticals and medical devices, two of the most significant changes announced by the federal government are: new powers to order a recall of products that pose “a serious or imminent health and safety risk”, and a move towards “progressive licensing” of therapeutic products, which will purportedly enable products to receive market authorization sooner, but with reporting and ongoing product assessment requirements through their life cycle. The bill would give the government power to order the holder of a therapeutic product market authorization to conduct a re-assessment and to report the results and to direct the holder of an establishment license or market authorization to conduct tests or

studies or monitor experience in respect of a therapeutic product for the purpose of obtaining additional information about its effects on health or safety. Details of these initiatives will be provided in regulations.

The lease of medical devices is to be treated the same as a sale of the medical device. Health care institutions specified by regulation will be required to report adverse reactions.

Other changes and features of Bill C-51 include:

- a broad new set of powers for the Minister of Health, including the power to order recalls of therapeutic products and cosmetics where, in the Minister's opinion, there is a serious or imminent risk of injury to health.
- increased fines and penalties for offences under the Act and/or non-compliance with orders made under the Act from the current maximum fine of C\$250,000 up to C\$5-million, or unlimited if the action was wilful or reckless;
- each day that an offence is committed or continued constitutes a separate offence;
- empowering Health Canada to make new regulations:
  - establishing pre-clearance or in-transit requirements for imported products;
  - establishing requirements for tracing systems, quality management programs, quality control programs, safety programs or other similar programs;
  - specifying the documents or classes of documents that are to be prepared, retained and/or provided to the government or an inspector under the Act; and
- new compliance and enforcement powers including the authority to order steps to be taken to reduce risks, such as stopping activities in contravention of the legislation, requiring measures to be taken to identify or respond to a risk of injury, or requiring imported products to be removed from Canada at the owner's or importer's expense.

### **Bill C-52 – Consumer Products Safety Act**

The proposed *Consumer Products Safety Act* contains a general prohibition on manufacturing, importing, selling or advertising any "consumer product" that poses a danger to human health or safety. "Consumer product" is broadly defined as "a product, including its components, parts or accessories, that can reasonably be expected to be obtained by an individual to be used for non-commercial purposes, including for domestic, recreational and sports purposes". The Act would not apply to certain products which are regulated under other legislation, such as food, drugs, devices and cosmetics under the *Food and Drugs Act*.

Significant features of the *Consumer Products Safety Act* include:

- the power to order recalls or other measures where products are found to pose a danger to health or safety;
- document and record preparation and maintenance requirements for all who manufacture, import, advertise, sell or test consumer products for commercial purposes, details of which will be provided in regulations;
- requirements to report, and provide all information regarding, "incidents" to Health Canada. This requirement will apply to any person who manufactures, imports or sells a consumer product for commercial purposes. An "incident" is defined as:

- (a) an occurrence in Canada or elsewhere that results, or could reasonably be expected to have resulted, in a death, serious adverse effect on health or serious injury;
  - (b) a defect or characteristic that may reasonably be expected to result in a death, serious injury or serious adverse effect on health;
  - (c) incorrect or insufficient information on a label or instructions that may reasonably be expected to result in a death, serious injury or serious adverse effect on health; or
  - (d) a recall initiated by a foreign entity, provincial government, public body or aboriginal government.
- powers to order anyone who manufactures or imports a consumer product for commercial purposes to conduct tests on the product and to compile any information Health Canada considers necessary to verify compliance with the legislation or regulations;
  - the power to order companies to undertake corrective measures such as issuing public advisories, stop manufacturing, importing or advertising, product labelling requirements or other measures deemed necessary to deal with a risk to health or safety; and
  - contravention of the Act or orders made under the Act are made offences subject to fines in an unlimited amount, if done wilfully or recklessly. Administrative monetary penalties are provided for “violations” (which are not offences) for breach of certain orders.

This new federal product safety regime will require increased record-keeping, reporting and testing requirements for a broad range of businesses. The full extent of any new regulatory requirements will not be known until the legislation is passed and regulations enacted, making C-51 and C-52 bills to watch closely over the coming months.

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