

THUNDER IN THE NORTH: BILL C-51

By Scott C. Tips

The buzz of the Internet, Canadian Bill C-51 has stirred up a hornets' nest of resistance by Canadian health-food and health-freedom organizations. Currently tabled by the ruling Conservative government in Ottawa, Bill C-51 is a set of proposed amendments ostensibly intended to modernize the existing Canadian Food & Drugs Act. The last significant revisions to the Food & Drugs Act took place more than half a century ago.

C-51's General Provisions

Affecting manufacturers, importers, distributors and retailers of foods, drugs, natural health products, veterinary drugs, cosmetics and medical devices in Canada, Bill C-51 would – in broad strokes – (1) define natural health products under the overarching category of “therapeutic products” (*i.e.*, drugs, natural health products, medical devices, cells, tissues and organs, and veterinary drugs); (2) increase governmental inspection and enforcement powers as well as the penalties for violations of the Food & Drugs Act and regulations; and (3) provide for licensing and/or registration of food-related activities and prescribing certain foods.

Evidently, Bill C-51 is intended to provide the overarching legislation for the Canadian *Food Regulations*, *Drug Regulations*, *Natural Health Products Regulations*, *Cosmetic Regulations* and *Medical Devices Regulations*. In fact, many of the Bill's provisions simply enact into statutory law certain existing regulations that the government has been using for years (*e.g.*, the “third” category as well as product and establishment licensing for natural health products).

C-51's “Extra” Provisions

Unfortunately, the Bill also goes beyond its “legislative enshrinement” goals; it would grant significant, added powers to the Canadian Health Minister, who could, among other things, arbitrarily demand information well beyond anything currently required under Canadian health regulations. This alarms many in the industry, including the Canadian Health Food Association (CHFA). CHFA, for example, is worried that under proposed Section 18.7(3), “*The Minister may issue the market authorization subject to the additional terms and conditions that he or she considers appropriate,*” while under Section 19.2(3) “*The Minister may issue the establishment license subject to the additional terms and conditions that he or she considers appropriate.*” These are whimsical, arbitrary powers,

far too dangerous and harmful to be entrusted to any government official, elected or not. Do Canadians really want any one person to be able to impose “extra terms and conditions” in order to do business? Are any politicians such angels that they may be freely granted such powers to decide the fates of others?

But it goes even further than that. Among other things, C-51 would authorize government agents to:

- Enter private property without a warrant (Section 23(4));
- Confiscate your property at their discretion, but at your cost (Sec. 23.3a);
- Dispose of your property at their discretion, but at your cost (Sec. 23.3c);
- Seize your bank accounts without even a showing of a warrant (Sec. 23(2)(d));
- Charge you for the shipping and storage of your seized property (Sec. 23.3a-b);
- Retain your property indefinitely without paying you damages (Sec. 23(2)(d)); and
- Levy punitively-high fines of up to \$5 million *and* throw you in prison for two years for each and every offense (Section 31.1).

It gets worse still. Imagine a law that would permit a government agent to issue to you a “stop order” based upon that agent's *belief* that you had a noncompliant product and if you did not stop selling the product, then you will have violated the law even if it turns out that you were right and the agent was wrong! In addition, there is no recourse for a business to challenge an Inspector's orders. Again, these are arbitrary powers that may be exercised at the Napoleonic whim of a novice or unprofessional inspector who may simply not like the way you parted your hair. That is the monster into which C-51 would breathe life.

Lewis Retik, a well-known and respected Canadian food-and-drug lawyer practicing in Ottawa, has reviewed the proposed legislation in depth and is very familiar with it. He points out an additional concern with the Bill, “Prison terms and fines are already enforcement tools available to the Health Minister. The problem here is that the fines that may be imposed are being radically increased from the existing \$5,000 fine to \$5,000,000. A fine of that size could put someone out of business and is too extreme for average noncompliance.”

First Bills Rarely Reflect Final Versions

Canadian Parliamentary procedure requires three readings of any bill before it can be voted upon and enacted into law. This procedure allows highly-biased entities (including the Government itself) to draft and offer for first reading in Parliament bills that will have had zero input from anyone other than their small cadre of drafters. Because of this, initial versions of a controversial bill – such as C-51 – rarely resemble their final versions because the “first reading” bill has not yet been subjected to any outside comments or debate. Once those comments and criticisms are made and incorporated into the bill, then this “second reading” bill can be radically different from its predecessor version. And the third, and final, reading bill can be even more different still.

So far, Bill C-51 is no exception. The “first reading” version of the Bill has been ridiculously one-sided and ignorant of industry and consumer needs and freedoms. Fortunately, thousands of Canadians expressed their outrage at the initial version of C-51. The furor was strong and sustained, and many parliamentary representatives asked pointed and persistent questions of the government spokesman for the Bill. Some were even calling for the resignation of Health Minister Tony Clement who had taken part in promoting this law affecting Canadian health rights. Others were calling for engagement through direct contact with the Minister to effect beneficial changes in the Bill.

Regardless, the debate at the second reading of the Bill in May and June 2008 has resulted in verbal concessions being made by the government spokesman, thanks to the persistent voices of Canadians to their representative members in Parliament, who in turn have pressured the government. Whether these changes will be sufficient to save the Bill remains to be seen.

The “Third” Category

Interestingly enough, the CHFA, for its part, sees C-51 as its perfect vehicle for creating a separate definition for natural health products within the Food & Drugs Act, citing the 1998 Standing Committee on Health recommendations in its report, *Natural Health Products: A New Vision* (www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/53_recommend_nhp-cps_tc-tm_e.html). So, the trade organization wants its members to work towards amending C-51 while admitting in its website that, “Currently natural health products are defined as “drugs” under the *Food & Drugs Act*. As such, stakeholders are finding that the interpretation and implementation of the *Natural Health Products Regulations* is more in line with a pharmaceutical approach

rather than one consistent with the low risk nature of natural health products. Further entrenching NHPs under the overarching definition of a *therapeutic product* (together with drugs, veterinary drugs, medical devices and organs, tissues and cells) perpetuates the idea that natural health products are pharmaceutical high risk products and should be evaluated as such.” (See www.chfa.ca.)

CHFA says that it expects that the creation of a separate category for natural health products will enable them to be treated as unique and distinct from drugs and foods and regulated by the government with the idea in mind that they are generally low risk and have a long history of safe use. This would be hoped for, of course; but third categories for natural health products have always led to a level of regulation considerably higher than that for foods, even though foods regularly cause more deaths per annum than natural health products!

The Codex “Trojan” Horse

Not surprisingly, Bill C-51 contains as one of its clauses a provision that “*regulations may incorporate by reference documents produced by a person or body – other than the Minister or Canadian Food Inspection Agency – including (a) an organization established for the purpose of writing standards Standards Council of Canada (b) an industrial or trade organization or (c) a government.*” This clause would allow the Canadian government to adopt into its laws and regulations those Codex standards and guidelines that have been “gazetted” in the *Canada Gazette*, the official government publication for new regulations (similar to the U.S. *Federal Register*). This is a real danger and interestingly enough tracks what has occurred in wording found in all U.S. “free” trade agreements.

Others, such as Canadian government spokesman Goodyear, find some solace in hiding natural health products in a third category that is neither foods nor drugs. As Mr. Goodyear noted in the Parliamentary debates on Bill C-51 recently, “*We have also heard great concern that in defining NHPs [Natural Health Products] care should be taken to avoid lumping them, as I am sure NDP members will continue to say, into the regulatory standards for foods. Foods are outlined in Codex Alimentarius. We agree with that. Therefore, it is the government’s view that our proposed approach to defining NHPs separate from drugs, but within an overall umbrella of therapeutic products, will prevent the application of Codex to NHPs.*”

My own view is to question the inclusion of a clause incorporating Codex standards. Why have the language of incorporation by reference for Codex if you are also want-

ing to protect natural health products from harsh Codex food standards? One could argue that the incorporation-by-reference language might apply only to standards affecting drugs and foods and not to natural health products, but that would seem to be wishful thinking at best. Regardless, with rapidly-deteriorating economic conditions of unprecedented proportions now confronting us, my years-old prediction that Codex might not survive beyond the second decade of the 21st Century seems increasingly likely.

Where To From Here?

The Canadian system for regulating the marketing and sale of natural health products offers less freedom than in the United States. Products must be licensed for sale; and at present, Health Canada – the Canadian version of the U.S. Food and Drug Administration – is rejecting as many natural health products for licensing (which they must be in Canada) as are being licensed. There is an enforcement policy in place whereby the government graciously *allows* these products to be sold if they have a submission number and do not pose a health hazard to the consumer, but that will last only until 2010. Nevertheless, the Canadian system offers one of the most open natural health products markets in the World today, probably second only to that of the United States. That market, though, is threatened by legislation such as C-51.

That is why many see C-51 in a different light than CHFA, as yet one more step down the road to Euro-style strangulation of the natural health products markets. The collective voices of these individuals, more than any other, have thrown Bill C-51 off track and alerted fellow citizens to the potential danger posed by companion Bill C-52, which is yet another story. The CHFA, through its policy of engagement with the government, is taking a compromise position and simply trying to minimize any harm that would flow from the Bill. The NHF and others see the Bill as a more direct threat.

Contrary to what some have said, C-51 is not definitively dead. Rather, Parliament has gone into recess and uncertainty reigns as the Canadian national elections loom large. These elections will occur prior to the U.S. elections, and the Conservatives are favored to win. Most likely, C-51 will be considered again – whether as this particular Bill, as a renumbered Bill, or as a newly-drafted Bill with similar, but somewhat different provisions. It is also possible that Canadians' determined opposition to C-51 has scared the politicians enough that they will now back away from this, at least for a while.

Stay tuned, as this will affect all of us in one way or another. Your health freedoms are at stake. 

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