Recent Regulatory Reform Runs Rampant

By Kenneth Ross*

In 2009, there have been many changes and proposed changes in product safety regulatory schemes enacted by governments around the world. This article will discuss some of the current changes being considered by the Canadian and Australian governments as well as current regulatory activity by the U.S. Consumer Product Safety Commission ("CPSC").

Canada

In January 2009, the Canadian government introduced legislation that would be called the Canadian Consumer Product Safety Act ("Act"). The Act was passed by the Canadian House of Commons this past summer and was just enacted, with amendments, by the Canadian Senate. As a result of the amendments, the Act will be sent back to the House of Commons for reconsideration in late January 2010.

The Act is a revision to the Hazardous Products Act which prohibits and restricts the advertising, sale or importation of a consumer product that is or is likely to be a danger to the health or safety of the public by reason of its design, construction or contents. The Canadian government felt a need to revise this legislation in order to close gaps with other jurisdictions such as the United States, address unregulated products, provide for the early detection of safety issues, and give them more power to require corrective actions.

The Act says that no manufacturer or importer shall manufacture, import, advertise, or sell a consumer product that is a "danger to human health or safety." The definition says that such a danger is an unreasonable hazard, existing or potential, during or resulting from normal or foreseeable use that may reasonably be expected to cause the death of an individual exposed to it or have an adverse effect on that individual's health.

The key requirement, as it has been over the years with the CPSC, is an enhanced mandatory reporting system that creates a post-market surveillance system that will result in an early detection of consumer product safety issues. All parties in the supply chain will be responsible for ensuring that their products do not present an unreasonable danger to human health or safety.

The mandatory reporting process is triggered when there is an "incident" involving:

> (*a*) an occurrence in Canada or elsewhere that resulted or may reasonably have been expected to result in an individual's death or in serious adverse effects on their health, including a serious injury;

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(*b*) a defect or characteristic that may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury;

(*c*) incorrect or insufficient information on a label or in instructions — or the lack of a label or instructions — that may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury; or

(*d*) a recall or measure that is initiated for human health or safety reasons by a foreign entity or other Canadian entities.

And a manufacturer, seller, or importer must report to Health Canada within two days after someone in the supply chain becomes aware of the "incident" and must file a written report within ten days.

If this Act passes, Health Canada will issue interpretations of the legislation to provide better notice of what the Act means and what is required. However, Health Canada has already stated what they think these provisions mean during a presentation in October 2009 to the International Consumer Product Health and Safety Organization ("ICPHSO").

In connection with the definition of "incident," Health Canada stated at this conference that the term "serious adverse effect" in (a) above means a serious injury that requires hospitalization or urgent care treatment or can constitute a non-fatal threat to breathing. In addition, a serious adverse effect can occur if there is a permanent impairment of a body function or permanent damage to a body structure. And last, Health Canada also included loss or damage to another object as a result of using a consumer product as a "serious adverse effect" thus requiring a report.

In the same presentation, Health Canada defined a "defect or characteristic" in (b) as a "fault, flaw, or irregularity that causes weakness, failure or inadequacy in form or function that poses a danger to human health or safety." And they also said that the definition of defect includes products that (1) do not comply with performance requirements of the regulations, (2) do not meet certification requirements, (3) do not meet accepted standards related to health or safety, (4) contain manufacturing or production errors, or (5) contain defects in the product's design or materials.

Further defining the terms "incorrect or insufficient information" in (c), Health Canada said it includes (1) information that lacks precautionary or warning statements or labeling required by regulations, (2) information for assembly or use that allows the product to pose a danger to human health or safety, or (3) pictures or instructions that show or encourage unsafe use.

And last, in (d) above, Health Canada said a report is necessary if there is a recall or "other measure" (undefined) involving a product that is available in Canada and that poses a danger to human health or safety.

There have been and will continue to be situations where reporting to a government agency is triggered in one country and not another. Certainly, these safety agencies intend for manufacturers and importers to report to them if they have undertaken a recall in another country. Therefore, it will be harder to justify recalling your product in one country and not recalling in another country. And, inconsistent corrective actions can be used against the manufacturer in any litigation involving those recalled products.

A recent recall involving a baby stroller resulted in different corrective actions depending on where the product was sold. The CPSC required the manufacturer to repair the product. Health Canada said that, when used according to the manufacturer's instructions, the strollers are safe and comply with Canadian stroller regulations. Also, the stroller manufacturer did not recall the strollers in Europe, where a lower number of incidents had been reported but subsequently, under pressure, made the repair kit available to consumers anywhere in the world.

In addition, a recent corrective action issued by a baby hammock manufacturer in the United States offered a repair kit as a corrective action. Health Canada did not believe that this product was safe even if repaired and instead unilaterally issued an advisory to Canadian customers requesting that they throw the product away.

Additional features of the Act are that Health Canada will now be able to (1) require manufacturers to perform tests and studies to verify compliance or prevent noncompliance, (2) require record-keeping to allow traceability in the event of a recall, (3) order a recall or corrective action if the company refuses, and (4) assess increased fines and penalties.

The amendments approved by the Canadian Senate on December 15, 2009 minimized the power of Health Canada inspectors to conduct random safety checks at home-based offices and made it easier for toy companies and other distributors of consumer goods to avoid fines for violating Canada's safety standards if they engaged in due diligence. The amendments also limit Health Canada's ability to share incident reports with international agencies as part of joint safety investigations.

The expectation is that some version of this Act will pass in early 2010, most likely with some or all of the amendments approved by the Canadian Senate. Therefore, the enhanced reporting responsibilities and stronger power of the Canadian government to order recalls will still be in place.

Any company selling into Canada should become aware of these new requirements and start to think about how to mesh compliance with these requirements with those imposed by the CPSC and other agencies around the world.

Australia

The Australian government issued a report in 2006 on the consumer product safety system in Australia. This lengthy report studied product safety regulatory schemes in Australia and around the world and made various recommendations concerning safety standards and government involvement in enhancing safety in Australia.

In November 2009, the government released a consultation paper for comment that included draft amendments to product safety laws in Australia based on the 2006 report. Comments from stakeholders were received by the end of November and meetings have been held in December concerning possible reforms to be introduced into Parliament next year.

The legislation that will be introduced in early 2010 will include the framework for a new national product safety regulatory framework. The specific recommendations in this consultation paper include:

- Governments should amend consumer product safety provisions in all jurisdictions to cover services related to the supply, installation and maintenance of consumer products.

- The threshold test for bans and recalls should cover all goods of a kind which, under normal or reasonably foreseeable conditions of use, will or may cause injury to any person. The Minister would have the power to ban or recall goods which are assessed as unsafe in the course of their intended use or 'reasonably foreseeable use.' Such circumstances may arise if a consumer uses a product in a manner which, while not the primary or normal use of the product, should nevertheless have been foreseen, and the product causes an injury as a result.

- Governments should require suppliers to report to the appropriate regulator, products which have been associated with serious injury or death. There would be no requirement on the supplier to substantiate the report or to admit that their product was either at fault or even a contributing factor. The product need not be the direct cause of the serious injury or death or indeed the only cause; it is only necessary for the product to be 'associated' with the injury or death to trigger the reporting requirement. Consumer behavior and/or environmental factors are often contributing elements to product related deaths or injuries.

- Governments should have the power to undertake a recall directly where no supplier can be found to undertake such a recall.

This reporting responsibility clearly would be far more onerous than that existing for reporting to the CPSC and a bit more onerous than the Canadian requirements. For the CPSC, there needs to be a defect that could cause a substantial product hazard or an unreasonable risk of future serious injury or death. In the Australian recommendation, causation is not an issue nor is evidence of a defect.

In addition, the manufacturer or product seller must consider "use and misuse" if it is reasonably foreseeable. This is not much different than what is required under U.S. product liability law or CPSC regulations. Therefore, a report and recall could be appropriate even if the consumer is misusing the product.

One other development reported to me by the Australian Director of Product Safety Compliance is that they are working on a new guide for recall effectiveness and that it will be presented at the February 2010 meeting of ICPHSO (see www.ichpso.org).

Consumer Product Safety Commission

There have been innumerable articles on the new Consumer Product Safety Improvement Act ("CPSIA") published in this column and by DRI in For The Defense. I just want to highlight a few recent developments concerning CPSIA and other recent activities of the CPSC.

- Enforcement of most of the new testing and certification requirements that were to be effective February 10, 2009 but were stayed until February 10, 2010, have been stayed again until February 2011. While enforcement is stayed, the requirement to comply has not been stayed since the original effective date. While the commission's decision on December 18, 2009 means that manufacturers or importers of most products won't have to produce compliance certificates and perform third-party testing starting next February, many are already providing such certificates and doing testing as required by their retailer customers. See the CPSC's press release which describes the new dates for various products (http://www.cpsc.gov/cpscpub/prerel/prhtml10/10083.html).

- In addition, the commission also voted to allow manufacturers and importers to rely on testing from suppliers of buttons, paint, zippers and other parts that might be used in a toy, clothing or other product for a child. Therefore, they will not have any further duty to test.

- The CPSC held a workshop on December 10 and 11, 2009 on testing. You can access video of the presentations on http://www.cpsc.gov/about/cpsia/cpsiatesting.html.

- Establishment of a searchable consumer product safety incident database has made some progress. The CPSC issued an implementation proposal to Congress, held a hearing and received comments. See http://www.cpsc.gov/about/cpsia/sect212.html for information on all of these events. The CPSC will next hold a two-day workshop on January 11 and 12, 2010 on this subject.

- According to a December 15, 2009 article in the Wall Street Journal, Congressman Henry Waxman, the chairman of the House Energy and Commerce Committee and architect of the CPSIA, has finally decided to help businesses avoid some of the unintended consequences of the legislation. He is proposing an amendment to the CPSIA that would make it easier for certain children's manufacturers to get exemptions from new lead-limit rules. In addition, the amendments reportedly would exempt "ordinary books" from the lead limits. As of this writing, it is unclear

whether this proposed amendment has already been made and when it can be expected to be considered by the House of Representatives.

- There have been huge numbers of recalls in the U.S. and Canada, just in December. A few of the notable ones include: many millions of Roman shades and roll-up blinds; 447,000 infant car seat/carriers; 700,000 packages of cold medicine; 142,000 children's books; 53,800 blenders; and smaller numbers of many other products. In November, the most notable announcements involved 2.1 million drop-side cribs; 665,000 gas grills; 641,000 pacifiers; 282,000 playsets and 1.1 million strollers. If anyone thought products were getting safer, these statistics ought to get your attention. While not all of these recalled products resulted in serious injuries or deaths, there was enough potential risk so that the manufacturer agreed to the CPSC's demand for some corrective action program.

- The vast majority of penalty cases announced during the 2009 fiscal year dealt with failures to report drawstrings in children's outerwear and selling children's products that violated the federal lead paint ban. By far, the largest fine was $2.3 million for selling products in violation of the lead paint regulations. There appears to be very little additional activity concerning other violations of the reporting responsibilities. Time will tell whether the CPSIA will create significant new reporting penalties, especially given the continuing stay on enforcing some portions of the new testing and certification issues.

Conclusion

It will continue to be difficult to manage post-sale duties for products sold in many countries. The triggers for reporting differ from country to country. And there may be different corrective actions imposed on the manufacturer or product seller by the various governments.

These differences might require a manufacturer to be more conservative and recall more products than is really necessary. And if the manufacturer takes a different approach in different countries or regions, it may have to explain the inconsistency in a U.S. court as it defends a product liability case involving that recalled product.

Taking a global approach to post-sale monitoring and regulatory compliance is imperative now and in the future. Governments will continue to enhance the reporting and recall responsibilities and they will expand their cross-border communications on safety issues involving products sold outside of the U.S.

The better plaintiff's attorneys will be informed about these new laws and duties and will try to use the failure to comply as evidence of a negligent company that possibly can be viewed as disregarding public safety here or abroad.