

# Health Canada Issues Guidance Clarifying Canada Consumer Product Safety Act Requirements

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On June 20, 2011, the Canada Consumer Product Safety Act ("CCPSA") became effective, imposing incident reporting, testing, recall, and recordkeeping requirements on entities that manufacture, import, or sell consumer products in Canada. As noted in Kelley Drye & Warren's January 5, 2011 [Client Advisory](#),<sup>1</sup> many of Canada's new requirements may be more stringent than current U.S. consumer product safety laws, especially with regard to reporting and recordkeeping requirements.

## Canada's Broad Consumer Reporting Requirements

As discussed in the January 5, 2011 Client Advisory, Canada's new regulations impose broad mandatory reporting requirements for incidents involving consumer products. Specifically, the new regulations require mandatory reporting of any incidents, in Canada or elsewhere, involving a consumer product where the product is associated with a serious injury or potential serious injury. In June 2011, Health Canada—one of Canada's consumer protection agencies—published guidance regarding the mandatory incident reporting requirements.<sup>2</sup> The guidance provides information regarding (1) the definition of consumer product under the CCPSA; (2) how entities should determine if an "incident" has occurred; (3) when incident information must be provided to Health Canada; and (4) what type of information must be provided under the CCPSA.

- **Definition of Consumer Product:** The CCPSA definition of consumer products includes products "that may reasonably be expected to be obtained by an individual to be used for non-commercial purposes." Certain categories of products are excluded from this definition, such as food, drugs, explosives, and natural health products.
- **Determining If an Incident Has Occurred:** Under the CCPSA, reporting requirements are triggered by an "incident" involving a consumer product, which the statute defines broadly to include situations involving "an occurrence . . . that resulted or may reasonably have been expected to result in an individual's death or in serious adverse effects on their health" or "a defect or characteristic that may reasonably be expected to result in an individual's death or in serious adverse effects on their health."

According to informal conversations with Health Canada and the recent guidance, it appears that Health Canada has attempted to harmonize the CCPSA regulations with the U.S. substantial product hazard or unreasonable risk of serious injury or death reporting standard by noting that, "[f]or an event to be an incident [under the CCPSA] it may be determined that the event indicates an

unreasonable hazard posed by the normal or foreseeable use of the product." The regulation still requires reporting if an event "may reasonably have been expected to result in [death or serious health effect]," despite "whether or not an actual injury or other health effect has occurred." For example, Health Canada states that an entity must report an event involving a consumer product that repeatedly sparks causing "the entire house [to catch] on fire," even if no deaths or serious adverse health effects occur, because "without prompt evacuation there would have been deaths or serious adverse effects on health."<sup>3</sup> But, the "unreasonable hazard" language in Health Canada's guidance indicates that an event, regardless of whether there is a death or serious adverse health effect, should indicate that a product is unreasonably dangerous before the reporting requirement is triggered; however, Given that this language is only found in the guidance, not the statute, it is still unclear exactly how Health Canada will enforce the reporting requirements.

Canada's new requirements also require reporting if "a recall or measure was initiated for human health or safety reasons" by an appropriate Canadian regulatory body or a foreign entity. The term "foreign entity" is defined to include a foreign corporation, as well as foreign governments and public bodies. Because a foreign entity includes a corporation, entities should report voluntary recalls to Health Canada that the entity initiates for human health or safety reasons. The reporting requirements only apply to incidents that occur on or after the CCPSA's effective date. For example, the reporting requirements do not apply to consumer recalls in the U.S. that were initiated prior to the CCPSA's effective date.

Further criteria for determining if an event is a reportable incident requires an entity to determine if the event is "related to a consumer product" that is manufactured, imported, or sold in Canada. According to Health Canada's guidance, this language is intended to require reporting for product incidents even where the product involved is not "exactly identical to the product the person manufactures, imports or sells in Canada." For example, if a product recall is initiated for human health and safety reasons in another country and the recalled product shares the same component as a product that is manufactured, imported, or sold in Canada, the foreign country recall "might be an event 'related to' the consumer product."

- **Providing Incident Information:** The CCPSA requires that manufacturers, importers, or sellers provide all the information in their control regarding an incident to both Health Canada and the person from whom they received the consumer product within two days of becoming aware of the incident. A manufacturer or importer, within ten days after becoming aware of an incident, must provide a written report regarding the incident that includes information about the incident, the specific product involved in the incident, any products manufactured or imported by the reporting entity that "could be involved in an [sic] similar incident," and any measures that the entity proposes taking with regard to the reported products. An entity is considered to be "aware" of the incident once "a person has information from which one may reasonably conclude that there is an incident related to a consumer product."

Health Canada's guidance also provides information regarding how reporting information should be provided to Health Canada, how Health Canada will treat the information (e.g., treatment of confidential business information), and penalties regarding the failure to provide required information.

## CCPSA Recordkeeping Requirements

In addition to reporting requirements, entities should be aware that the CCPSA requires that certain documents-such as documents regarding when a product was sold and, in some instances, to whom the product was sold-must be retained for six years at a Canadian business location. In June 2011,

Health Canada also issued final guidance regarding recordkeeping requirements.<sup>4</sup> The recordkeeping requirements apply to retailers, manufacturers, importers, advertisers, sellers, and testers of Canadian consumer products.

Entities are required to "keep the documents [discussed above] at their place of business in Canada;" however, according to Health Canada's guidance, records may be stored in electronic form on a server located outside of Canada, if those records are "easily and readily accessible on a computer terminal at the person's place of business in Canada." The CCPSA allows Health Canada to exempt entities from the requirement to keep records at a Canadian business location. Health Canada has not yet implemented rules or procedures to allow entities to request such an exemption; rather, it has stated that exemption requests "will be reviewed on a case-by-case basis." Further, though not discussed specifically in the statute or Health Canada's guidance, given that the statute does not require entities to maintain a Canadian business location, if an entity does not have a place of business in Canada, that entity would not be required to maintain the documents in Canada. Not having a Canadian business location, however, does not exempt entities from the requirements to "prepare and maintain" specific records.

## Recommendations

As recommended in the January 5, 2011 Client Advisory, entities that manufacture, import, or sell products in Canada should ensure that they have created policies and procedures for detecting, reporting, and maintaining records for consumer product safety issues that comply with Canadian laws. The implementation of new requirements since January 2011 under U.S., Canadian, and other countries' (e.g., Australia) consumer product safety laws makes it critical for entities to implement systems that will help them comply with the various new requirements and quickly implement corrective action plans.

## Kelley Drye & Warren LLP

Kelley Drye & Warren's Consumer Product Safety practice group is experienced in providing advice on the difficult issues of how and when potentially hazardous consumer products must be reported to the CPSC. If product recalls are necessary, we work with our clients and CPSC staff to quickly develop and implement cost-effective communications programs that satisfy product liability concerns and minimize potential penalties. When the CPSC threatens or brings enforcement actions, we advise our clients on appropriate strategies. For more information about this client advisory, please contact:

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<sup>1</sup>See Kelley Drye & Warren, "Broad Consumer Product Safety Laws Become Effective in Canada and Australia in 2011" (Jan. 5, 2011), available at, <http://www.kelleydrye.com/News-Events/Publications/Client-Advisories/Broad-Consumer-Product-Safety-Laws-Become-Effectiv>.

<sup>2</sup>Health Canada, Guidance on Mandatory Incident Reporting Under Canada Consumer Product Safety Act - Section 14 Duties in the Event of an Incident (June 2011), available at, [http://www.hc-sc.gc.ca/cps-spc/pubs/indust/2011ccpsa\\_incident-lcspc/index-eng.php](http://www.hc-sc.gc.ca/cps-spc/pubs/indust/2011ccpsa_incident-lcspc/index-eng.php).

<sup>3</sup>Health Canada's guidance also provides standards regarding "serious adverse health effects," indicating that an event causes a serious adverse health effect if an injury or illness requires medical attention, or a product causes a non-fatal threat to breathing, such as a choking, strangulation, or other respiratory impairment.

<sup>4</sup>Health Canada, Guidance on Preparing and Maintaining Documents under the Canada Consumer Product Safety Act (CCPSA) - Section 13 (June 2011), available at, [http://www.hc-sc.gc.ca/cps-spc/legislation/pol/doc\\_13-eng.php](http://www.hc-sc.gc.ca/cps-spc/legislation/pol/doc_13-eng.php).