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Articles

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The Canada Consumer Product Safety Act is now in force: do your clients understand their reporting obligations?

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On 20 June 2011, the Canada Consumer Product Safety Act (CCPSA) came into force, introducing a comprehensive new regulatory regime for consumer product safety in Canada. Among the sweeping changes imposed by the CCPSA is a mandatory incident-reporting requirement for all members of the consumer product supply chain. Manufacturers, importers and sellers of consumer products will now have an obligation to report 'incidents' (as defined in the Act) to Health Canada upon 'becoming aware' of them.

Health Canada has released *Guidance on Mandatory Incident Reporting* ('MIR Guidance') and *Guidance on Preparing and Maintaining Documents*, which address some of the interpretation issues raised by the new legislation. These documents can both be found on Health Canada's website.

Identifying an incident

The MIR Guidance suggests that the following three-step analysis will help determine whether an 'event' rises to the level of a reportable incident:

1. Do you manufacture, import or sell a consumer product that is connected to the event?
2. Does the event meet the criteria of an incident?
3. Does the event indicate an unreasonable hazard posed by the normal or foreseeable use of the product or the foreseeable misuse of the product?

At the first step, Health Canada recommends a broad interpretation in determining whether a product is 'connected' to an event. For example, if a recall has been initiated in another country for a product that shares a component part with a product sold in Canada, this may constitute an event connected to the product in Canada.

At the second step, a company is required to determine whether the event falls within the definition of an 'Incident' as set out in the CCPSA. An Incident includes any of the following – an occurrence in Canada or elsewhere, a defect or characteristic, or incorrect or insufficient information on a label or instructions – that resulted, or may reasonably be expected to result, in death or serious adverse effects on health. An Incident also includes a recall initiated anywhere for health or safety reasons. The MIR Guidance provides examples of types of events that might fall into each Incident category.

At the third step, Health Canada has added an element that does not appear in the legislation. While early indications were that Health Canada wanted broad reporting of all events that met the statutory definition of an Incident for 'early warning' purposes, the introduction in the MIR Guidance of 'unreasonable hazard' as an element of a reportable Incident suggests that they are now taking a narrower view. This will come as welcome news to industry stakeholders who were pushing for harmonisation with US requirements. However, it is important to note that the legislation itself does not require that there be an 'unreasonable hazard' to trigger a reporting obligation and the MIR Guidance is clear that if there is any discrepancy between it and the legislation, the legislation will prevail. That said, the risk of attracting any penalty for doing what the MIR Guidance recommends is likely to be extremely low.

Becoming aware

Health Canada has clarified that a company doesn't 'become aware' of an Incident, thus triggering a duty to report, until reasonable consideration of all three questions listed above gives rise to information from which one may reasonably conclude the event is a reportable Incident. Health Canada has acknowledged

that manufacturers, importers and sellers may have to investigate before they can reasonably come to any conclusion. Only once the investigation 'indicates' an affirmative answer to all three questions will a company be deemed to have become aware of an Incident. It is at that point that statutory timelines for Incident reporting will begin to run.

Timeline for reporting

Manufacturers, importers and sellers of consumer products must report information within their knowledge to both Health Canada and the person from whom they received the product within two days of becoming aware of an Incident. A manufacturer or, if they are outside Canada, the importer must also provide a more detailed report within ten days of becoming aware of an Incident. The latter report must address, among other things, whether a corrective action plan is required and, if so, the proposed elements of the plan.

The two-day and the ten-day reporting timelines are concurrent. So the manufacturer or importer's ten-day report is due eight days after its two-day report. Each day counts for the purpose of counting days, including holidays and weekends. If a reporting date falls directly on a holiday or Sunday, the report is due by midnight in the local time zone on the next non-holiday.

How to report

Health Canada has developed an online form for the purposes of submitting the two-day and ten-day reports which can be accessed from their website. While the same online form will be used at both stages of reporting, an increased level of detail will be required in the second report. Health Canada has advised that use of the form is not mandatory and the required information can be alternatively submitted by fax or mail.

Concurrent reporting to other agencies

Health Canada has confirmed that even if an event is reportable to another regulatory body – such as Ontario's Electrical Safety Authority for electrical consumer products – reporting to Health Canada will still be required. Reporting to only one agency will not suffice. There are indications that intra-regulatory agency agreements currently being discussed may eliminate this need in the future.

Retroactivity

Health Canada has confirmed that the mandatory reporting provisions are not retroactive. What matters is the date a company was notified of a potential Incident. If the company first became aware of an Incident on or after 20 June 2011, it is reportable to Health Canada, even if the Incident occurred prior to the CCPSA taking effect.

Conclusion

The mandatory reporting obligations imposed by the CCPSA represent a radical change to the regulatory regime for consumer product safety in Canada. Manufacturers, importers, and sellers of consumer products now have significant obligations to report all consumer product safety Incidents to both Health Canada and the person from whom they received the product. While the MIR Guidance released by Health Canada clarifies some of the ambiguities in the legislation, there are still many unaddressed interpretation issues that are likely to generate additional 'Guidance'. Health Canada recommends that its website be consulted from time to time for updates to the MIR Guidance.