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QualityScan

One Flaw Can Trigger Worldwide Reporting Obligations

New consumer product regulations are not limited to the US Consumer Product Safety Improvement Act of 2008 (“CPSIA”) and its Publicly Available Consumer Product Safety Information Database (“Database”). Countries around the world are passing and enhancing regulations aimed at consumer product safety, including, among others, Canada, Australia, and the European Union. The end result to manufacturers is that an incident or recall involving one product in one country may now trigger reporting in another country, and another, as the domino effect continues. Consequently, manufacturers must understand the different regulations and assess their current policies and procedures to ensure a timely response to each regulation.

United States: For US manufacturers, the first domino is likely the CPSIA, which gives manufacturers 24 hours to report a consumer product that (1) fails to comply with an applicable consumer product safety rule, (2) contains a defect that could create a “substantial product hazard,” or (3) contains a defect that creates an unreasonable risk of serious injury or death. Separate from a manufacturer’s reporting requirement, virtually anyone has the ability to submit a report of harm on the new Database. Manufacturers generally have 10 business days to investigate and respond to a report before it and the manufacturer’s response are publicly posted on the Database. More importantly, reports posted on the Database—however vague and unsubstantiated—may trigger a reporting obligation under the CPSIA and elsewhere. That is when the first domino may fall.

Penalties in the United States carry maximum civil fines of \$100,000 per violation and \$15 million for a series of violations.

Canada: Health Canada requires two reports under Canada’s Consumer Product Safety Act (“CCPSA”), the first within two days’ notice of an incident or recall and a second more detailed report within 10 days. Canada may be the next domino, as the CCPSA requires reporting of incidents that occur not just in Canada, but elsewhere. It also requires reporting “near-misses,” rather than incidents involving physical harm required for reporting in the US and incidents involving medical treatment required for

reporting in Australia. The CCPSA requires reporting regardless of which government initiates a recall, even if the recall is based on the breach of a local standard or condition. It may require reporting a component in a product sold in Canada merely because the same component is used in another product sold elsewhere, even if the overall designs and applications are different.

Australia: The Australia Competition and Consumer Commission enforces the Australian Consumer Law (“ACL”), which gives manufacturers two days to report incidents. Australia may be the next domino as the ACL, like Canada, requires a report regardless of where the incident occurred and, like the US, notice may come second-hand from an industry or consumer organization, *e.g.*, the Database or Health Canada.

European Union: Unlike Canada and Australia, the European Union General Product Safety Directive of 2001 applies only to products in the European Union marketplace. But the European Union may be the next domino if an incident involved a commercial product that “migrated” to consumer use. If so, the manufacturer has 10 calendar days to report an unsafe product, reduced to three calendar days if the product poses a “serious risk.”

Penalties for Not Reporting

Penalties in the US carry maximum civil fines of \$100,000 per violation and \$15 million for a series of violations. Six- and seven-figure fines were not unusual in 2011, with a high of \$1.3 million. In Canada, criminal penalties up to \$250,000 and six months’ imprisonment for a first offense and \$5 million and two years’ imprisonment for repeat offenses are available.

Preparing for the First Incident or Recall

Manufacturers should: (1) review product lines to determine which products are subject to which regulations; (2) review contracts for risk and indemnity obligations potentially affected by the regulations; (3) establish or modify record keeping, record retention, and reporting policies; and (4) create an incident report form tailored to the company’s business.

Manufacturers would be wise to put processes in place now to stay ahead of future reporting obligations, instead of beating back civil penalties and reacting to claims and litigation. **ME**