International Reporting Requirements

By Kenneth Ross

New Safety Laws May Result in Significant New Liability

This year has seen an explosion of new product safety laws around the world. Australia, South Africa, and Canada have new safety laws in force, most creating new legal safety governmental reporting responsibilities for manufacturers. This will most likely result in more reports to more governments, more potential for fines for late reporting, and increased U.S. and foreign litigation based on product liability and warranty liability theories. In addition, these reports and subsequent corrective actions will most likely also result in more class actions and shareholder lawsuits in the United States and elsewhere.

The thresholds for reporting as established by these new laws are somewhat different, resulting in inconsistent duties for manufacturers selling products in the United States as opposed to selling products internationally. This creates a dilemma when a manufacturer has a duty to report in one or more countries but not in others. In addition, it is possible that corrective actions required or approved by these various government agencies will differ. Lastly, it is likely that plaintiffs' experts will try to use evidence of foreign safety activities, especially after-sale activities, in U.S. lawsuits as the bases for their opinions that the products were defective.

This article will focus on the reporting requirements for safety issues involving consumer products in the United States, Canada, and Australia.

Consumer Product Safety Commission Reporting Requirements

The Consumer Product Safety Act (CPSA), section 15(b), also referred to as "section 2064(b)," requires manufacturers, importers, distributors, and retailers to notify the Consumer Product Safety Commission immediately if they obtain information that reasonably supports the conclusion that a product distributed in commerce (1) fails to comply with a consumer product safety standard, rule regulation, or banning regulation; (2) contains a defect that could create a substantial product hazard to consumers; or (3) creates an unreasonable risk of serious injury or death.

The most important basis for reporting to the commission is section 15(b)(2), which requires reporting if there exists both a defect *and* the possibility of a substantial product hazard. The CPSA regulations provide some guidance on how to analyze the need to report. The first question is whether a product has a defect. Under section 15(b)(2), a product without a defect is not necessarily subject to the reporting requirements even if injuries occur. Many products are reasonably safe and are not defective and people still get hurt.

To help a company decide whether it has a defect requiring a report, the commission's regulations state that

> [a]t a minimum, defect includes the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function. A defect, for example, may be the result of a manufacturing or production error; that is, the consumer product as manufactured is not in the form intended by, or fails to perform in accordance with, its design. In addition, the design of and the materials used in a consumer product may also result in a defect.
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> …
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> A design defect may also be present if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended. A defect can also occur in a product's contents, construction, finish, packaging, warnings, and/or instructions. With respect to instructions, a consumer product may contain a defect if the instructions for assembly or use could allow the product, otherwise safely designed and manufactured, to present a risk of injury.

16 C.F.R. §1115.6.

The commission distinguishes products that hurt people but aren't defective from defective products: "Not all products that present a risk of injury are defective. A kitchen knife is one such example. The blade has to be sharp to allow the consumer to cut or slice food. The knife's cutting ability is not a product defect, even though some consumers may cut themselves while using the knife." U.S. Consumer Prod. Safety Comm'n Recall Handbook.

Despite that, the commission encourages manufacturers to file a report even when in doubt about whether a product is defective.

> If the information available to a company does not reasonably support the conclusion that a defect exists, the firm need not report to the Commission under the defect reporting provision of Section 15(b)(2). However, since a product may be defective even when it is designed, manufactured, and marketed exactly as intended, a company in doubt as to whether a defect exists should still report.

U.S. Consumer Prod. Safety Comm'n Recall Handbook.

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Manufacturers will have to consider this language along with reporting responsibilities in other countries since a plaintiff will always argue that by reporting to the commission, a manufacturer has admitted that its product was defective.

The next question is whether this "defect" could create a "substantial product hazard." According to the commission,

> [g]enerally, a product could create a substantial hazard when consumers are exposed to a significant number of units or if the possible injury is serious or is likely to occur. However, because a company ordinarily does not know the extent of public exposure or the likelihood or severity of potential injury when a product defect first comes to its attention, the company should report to the Commission even if it [sic] in doubt as to whether a substantial product hazard exists.

U.S. Consumer Prod. Safety Comm'n Recall Handbook.

To clarify further, the regulations provide factors that a manufacturer must consider in determining if a product may pose a substantial hazard: pattern of defect, number of defective products in commerce, severity of risk, and likelihood of injury. The commission explains these factors as follows:

- **Pattern of defect.** The defect may stem from the design, composition, content, construction, finish, or packaging of a product, or from warnings and/or instructions accompanying the product. The conditions under which the defect manifests itself must also be considered in determining whether the pattern creates a substantial product hazard.
- **Number of defective products distributed in commerce.** A single defective product could be the basis for a substantial product hazard determination if an injury is likely or could be serious. By contrast, defective products posing no risk of serious injury and having little chance of causing even minor injury ordinarily would not be considered to present a substantial product hazard.
- **Severity of risk.** A risk is considered severe if the injury that might occur is serious, and/or if the injury is likely to occur.
- **Likelihood of injury.** The likelihood is determined by considering the number of injuries that have occurred, *or that could occur*, the intended or reasonably foreseeable use or misuse of the product, and the population group (such as children, the elderly, or the disabled) exposed to the product.

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U.S. Consumer Prod. Safety Comm'n Recall Handbook.

A manufacturer has an additional reporting responsibility that applies even if a product does not have a defect. Section 15(b)(3) requires a manufacturer to file a report if a product creates an unreasonable risk of serious injury or death. The critical term is "unreasonable," which is defined as follows:

> The use of the term "unreasonable risk" suggests that the risk of injury presented by a product should be evaluated to determine if that risk is a reasonable one. In determining whether a product presents an unreasonable risk, the firm should examine the utility of the product, or the utility of the aspect of the product that causes the risk, the level of exposure of consumers to the risk, the nature and severity of the hazard presented, and the likelihood of resulting serious injury or death. In its analysis, the firm should also evaluate the state of the manufacturing or scientific art, the availability of alternative designs or products, and the feasibility of eliminating the risk. The Commission expects firms to report if a reasonable person could conclude given the information available that a product creates an unreasonable risk of serious injury or death.

16 C.F.R. §1115.6. The U.S. Court of Appeals for the Ninth Circuit has confirmed that under this subsection, a manufacturer must still file a report even if a product does not have a defect. *See United States v. Mirama Enterprises,. Inc.*, 387 F.3d 983 (9th Cir. 2004).

Lastly, a manufacturer or product seller must file a report if either obtains information that reasonably supports the conclusion that a product distributed in commerce fails to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the commission has relied.

Since the Consumer Product Safety Improvement Act of 2008 has established more standards, the potential for reporting under this subsection is even more likely than before. This reporting requirement is truly strict in that it requires a report without proof of defectiveness or proof of an elevated risk of harm.

A number of years ago, the commission revised its interpretative rule concerning reporting regulations to make it clear that manufacturers and product sellers must consider information generated from sources outside the United States when deciding whether to report. A manufacturer must evaluate information that it obtains, or reasonably should have obtained, about product use, experience, performance, design, or manufacture outside the United States and that is relevant to products sold or distributed in the United States. This applies to manufacturers that sell products outside the United States, and importers, distributors, and retailers that obtain or should have obtained information in a foreign country. This requirement makes it even more important that field experience and reporting responsibilities in each country in which the product is sold be considered at the same time.

If the threshold for reporting is met under section 15(b), the CPSA requires companies to report immediately. The commission defines this requirement as follows:

> A company *must* report to the Commission within 24 hours of obtaining reportable information. The Commission encourages companies to report *potential* substantial product hazards even

while their own investigations are continuing. However, if a company is uncertain whether information is reportable, the firm may spend a reasonable time investigating the matter. That investigation should not exceed ten working days unless the firm can demonstrate that a longer time is reasonable in the circumstances. (emphasis in original).

U.S. Consumer Prod. Safety Comm'n Recall Handbook.

To encourage manufacturers to report even when they aren't sure if they are required to do so, the commission has tried to reassure them:

> Reporting a product to the Commission under section 15 does not automatically mean that the Commission will conclude that the product creates a substantial product hazard or that corrective action is necessary. The CPSC staff works with the reporting firm to determine if corrective action is appropriate. Many of the reports received require no corrective action because the staff concludes that the reported product defect does not create a substantial product hazard.

U.S. Consumer Prod. Safety Comm'n Recall Handbook.

But the commission is not bound by the above-quoted language, and evidence indicates that the commission staff today are more likely to require a corrective action such as a recall even if a risk is remote. Manufacturers have been complaining, publicly and privately, that the commission has been requiring unnecessary corrective actions, but these complaints have mostly fallen on deaf ears.

Consumer-oriented commissioners now make up the majority of the Consumer Product Safety Commission, and this year it hired two former U.S. Department of Justice prosecutors, one to head the Office of Compliance and Field Operations, and the other to head administrative litigation in the Office of the General Counsel. The consequence is that it would not be surprising to see more recalls, faster recalls, and more civil penalties for failing to report to the commission in a timely fashion.

If the new law and regulations increase reports of incidents occurring outside of the United States to U.S. manufacturers, the commission may also receive more reports, which may, in turn, create potential problems for companies that fail to set up systems to receive worldwide safety information and to evaluate it centrally to decide whether reporting is necessary and, if so, to which government agency.

Figure 1

Canada

On June 20, 2011, Canada's new Consumer Product Safety Act went into force. This legislation, which is similar to most of the other safety laws around the world, establishes a reporting requirement to Health Canada.

The legislation requires mandatory reports for "incidents" 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;

(*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 Canadian entities.

Consumer Product Safety Act §14(1) (Can.).

A manufacturer, seller, or importer must report to Health Canada within two days of someone in the supply chain becoming aware of an "incident" and then must file a more complete written report within 10 days.

In June 2011, Health Canada issued the Guidance on Mandatory Incident Reporting Under the Canada Consumer Product Safety Act—Section 14 Duties in the Event of an Incident, which set forth Health Canada's interpretation of the reporting requirements. This Health Canada guidance does not substitute for, supersede, or limit the requirements under the act. Therefore, the actual legislation takes precedence.

Section 14(1)(a) of the legislation makes clear that potential future harm constitutes an "occurrence" requiring a report if it "may reasonably have been expected"

to result in death or serious injury. Consumer Product Safety Act §14(1)(a) (Can.). Section 14(1)(b) and the guidance make clear that even without an "occurrence," a report is required if "a defect or *characteristic* may reasonably be *expected* to result in an individual's death or serious injury." *Id.* at §14(1)(b) (emphasis added). And section 14(1)(d) and the guidance make clear that a recall anywhere in the world related to a product or a part sold in a product in Canada would require a report. *Id.* at §14 (1)(d). Health Canada's guidance does not clarify whether only recalls mandated by governments require reporting or if voluntary recalls initiated by manufacturers or product sellers also call for reporting.

After receiving comments from the manufacturing community about the low threshold for reporting, Health Canada inserted a new section in the guidance that poses a question that manufacturers and product sellers should ask and answer in deciding whether the Canadian legislation requires a report: "Does it [an incident or characteristic] indicate an unreasonable hazard posed by the normal or foreseeable use of the product or the foreseeable misuse of the product?" This provision decreases the reporting responsibility under all section 14 subsections by raising the harm standard to an "unreasonable hazard." However, section 14 of the Canadian act does not contain the word "unreasonable," and the Health Canada guidance does not define it. In addition, the Health Canada guidance states that "[w]hat constitutes normal or foreseeable use of a consumer product will depend on the particular product involved, and with the circumstances surrounding the event." Therefore, while it provides a way for companies not to report if they don't deem a hazard unreasonable, or they deem a product's use or misuse unforeseeable, it does not help them much in making these determinations. Also, since the reporting section doesn't contain the word "unreasonable," it isn't clear if the attempt by Health Canada to limit the reporting responsibility to more serious risks will withstand legal scrutiny. *See* Figure 1, page 20 for Health Canada's depiction of the reporting requirements as expressed in the guidance.

Other complicated reporting responsibility questions remain unanswered. Reporting responsibility belongs to a product manufacturer, importer, or seller. But what if a product manufacturer is based in the United States and becomes aware of an incident in the United States or elsewhere in the world that might require a report in Canada? That manufacturer is not a Canadian entity. Is it required to report to Health Canada, or is it required to tell a Canadian entity that the manufacturer sells the product to, *e.g.*, the importer, the retailer, or Canadian subsidiary or division? And what happens if the manufacturer doesn't? None of this is dealt with in the legislation or in the Health Canada guidance. Companies will need to make decisions about how they will interpret and comply with this requirement.

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One other issue to mention is that Canada has another safety agency to which companies have had responsibility to report safety issues involving consumer products for a number of years. The Electrical Safety Authority of Ontario (ESA) has jurisdiction over unsafe electrical products sold in Ontario. However, in accordance with a Memorandum of Understanding (MOU) dated September 2010, Health Canada has allowed the ESA to take the lead on nationwide safety issues involving electrical products. After June 20, 2011, Health Canada and ESA started to discuss revising the MOU to accommodate Health Canada's new responsibilities, however, at the moment, for electrical products, companies have to report to both Health Canada and ESA.

Australia

Australia's new product safety law, referred to as the Australia Consumer Law, took effect on January 1, 2011. The Australian Competition and Consumer Commission will administer the new law. As with Health Canada, the Australian commission issued a guidance, A Guide to the Mandatory Reporting Law in Relation to Consumer Goods, in December 2010. Concerning reporting, the Australian guide states the following:

> Individual suppliers are responsible for reporting incidents where consumer goods have been associated with a death or serious injury or illness of any person.
>
> Broadly there are *two* triggers to the reporting requirement for suppliers, both of which must be present before the supplier is required to report:
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> - The goods in question are consumer goods;
> - A supplier of such consumer goods, or services related to them, has become aware that a person has suffered death or serious injury or illness.
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> The second trigger, that the supplier has become aware of a death, serious injury or illness only triggers the reporting requirement if either:
>
> 1. The supplier considers that the death or serious injury or illness was caused, or may have been caused, by the use or foreseeable misuse of the consumer goods.
>
> OR
>
> 2. The supplier becomes aware that a person other than the supplier considers that the death or serious injury or illness was caused, or may have been caused, by the use or foreseeable misuse of the consumer goods.
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> Provided at least one of these two elements of the second trigger is met, along with the first trigger, a supplier is required to report the incident.

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Unlike Health Canada's guidance, the Australian guide elaborates on foreseeable use and misuse:

> This includes the use of consumer goods for their primary, normal or intended purpose; using the goods for an unintended purpose; or misusing the goods. Suppliers need to report deaths, serious injuries or illnesses believed to be caused by a consumer good however it might have been used and regardless of whether there were defects with the good or whether misuse of the good may have contributed to the cause of the incident.

Guide to Mandatory Reporting Law (Austl.), *supra*.

All participants in the supply chain are required to comply with the Australian reporting requirement within two days of becoming aware of an incident. This includes a retailer, a dealer, a distributor, an installer, a repairer, an importer, a manufacturer, and an exporter of the consumer good in question.

However, as in Canada, interesting questions remain about the responsibility of a foreign entity in the supply chain to inform Australian members of the supply chain about an incident occurring beyond Australia that may trigger the reporting duty. The Australian Competition and Consumer Commission does not have jurisdiction over a foreign entity, and the knowledge of a non-Australian parent will not be imputed to its Australian subsidiary, which is considered a separate legal "person." Last, the Australian commission has said that members of the Australian supply chain do not have obligations to take active steps to seek information regarding foreign incidents.

Despite these restrictions, non-Australian manufacturers will have to decide how to meet these reporting requirements under Australian law to minimize future risk of harm in Australia and elsewhere.

Conclusion

Product safety reporting requirements will continue to expand. And those countries that have adopted such requirements may choose to become more aggressive in enforcing compliance and sending similar, strong messages about the necessity of companies to deal proactively with safety issues.

Given the significant increase in the potential for fines and the potentially devastating effect such fines can have on reputations, it is clear that manufacturers and others in the chain of distribution should ensure that their post-sale monitoring systems can deal with these new reporting responsibilities. In addition, companies must make sure that the reports and subsequent corrective actions are performed in defensible ways in the event of lawsuits involving recalled products.

As evident from the descriptions above, the new reporting requirements are inconsistent. And incidents occurring anywhere in the world might trigger a reporting responsibility in one or more countries. A U.S. company will need to evaluate its worldwide approach to incident reporting and investigation and adapt it to comply with these new requirements, and both are difficult tasks. Given the vagueness of some of the requirements, a company will have to decide whether and how to exceed the new requirements so that it can identify emerging safety risks rapidly, make reports quickly, and take appropriate corrective actions swiftly.