World-wide Government Safety Reporting Requirements: A Comparison
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A number of governments around the world have adopted or are considering adopting reporting requirements for manufacturers, importers and product sellers when products have some sort of safety problem. The thresholds for reporting as established by these governments are wildly different, thus resulting in inconsistent duties for products sold in the U.S. and internationally.

This creates a dilemma when there is a duty to report in one or more countries but not in others where the product has been sold. Many of you may remember the problems created when Ford recalled Explorers with Bridgestone tires in Venezuela and Saudi Arabia, but not in the U.S. This resulted in changes in U.S. law requiring reports to the U.S. government when products are recalled in foreign countries.

In addition, there is an interesting question as to the admissibility of evidence concerning reports and recalls in foreign countries in U.S. litigation. Of course, such evidence is discoverable, but it may not be relevant. My conclusion as a non-litigator is that evidence of foreign safety activities, especially those after sale, stands a good chance of at least being used by a plaintiff's expert as a basis for their opinion.

Lastly, it is possible that corrective actions required by these various government agencies will differ. I advised on a recall earlier this year where the Consumer Product Safety Commission ("CPSC") allowed the product to be fixed in the U.S. but Health Canada requested Canadian consumers to throw the product away.

I have served as a defense expert witness on recall adequacy for a number of years and foreign activities have been a part of a good percentage of the cases I have worked on. In many situations, these activities are not helpful and hard to explain.

So, let's examine the reporting requirements for consumer products in the U.S. and elsewhere and see where there are similarities and differences.

U.S. CPSC Reporting Requirements

The Consumer Product Safety Act, Section 15(b) (also referred to as Section 2064(b)), independently requires manufacturers, importers, distributors and retailers to notify the Commission immediately if it obtains information which 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 which

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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 both a defect and the possibility of a substantial product hazard. The regulations to the CPSA provide some guidance on how to analyze the need to report. The first question is whether there is a defect. Under this subsection, a product without a defect is not necessarily subject to the reporting requirements even if injuries occur. Many products are reasonably safe and not defective and people still get hurt.

To help a company decide whether they have a defect, the Commission's regulations say:

> At 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. **** 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 CFR §1115.6.*

The Commission distinguishes products that hurt people but aren't defective by saying, "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." *CPSC Recall Handbook.*

The Commission encourages manufacturers to report even when in doubt about whether the product is defective. They say:

> 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. *CPSC Recall Handbook.*

The next question to be answered is whether this "defect" could create a "substantial product hazard." The Commission starts this analysis by saying:

> Generally, 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. *CPSC Recall Handbook.*

Then the regulations provide factors a manufacturer must consider in determining if there is a substantial product hazard: pattern of defect, number of defective products in commerce, severity of risk, and likelihood of injury. On these factors, in the *CPSC Recall Handbook*, the CPSC has said:

- **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.

There is an additional reporting responsibility that applies even if there is no defect. Section 15(b)(3) requires a report if there is 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 CFR §1115.6*

And, the U.S. Court of Appeals has confirmed that this subsection does not require that a defect exist in the product for there to be a reporting requirement. See *United States v. Mirama Enterprises,. Inc.,* 387 F.3d 983 (9th Cir. 2004)

Lastly, if there is the threshold for reporting, either under Section 15(b)(2) or (3), 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). *CPSC Recall Handbook.*

In order to encourage manufacturers to report even when they aren't sure if they are required to do so, the Commission has said:

> 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. *CPSC Recall Handbook.*

In November 2001, the CPSC finalized revisions to its interpretative rule concerning reporting regulations to make it clear that manufacturers and product sellers must consider information generated from sources outside the U.S. when deciding whether to report. It had previously taken this position, but the Ford-Bridgestone tire recall focused attention on the relevance of such information and demonstrated that manufacturers may not consider it relevant.

The CPSC clarified its position that information a manufacturer must evaluate to determine if a reporting responsibility has arisen includes information that a firm 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.

Given all of the above, manufacturers and others in the chain of production and distribution need to make some critical decisions so they can meet their statutory obligations and avoid being charged with violating these reporting requirements.

European Union

The most significant recent European effort to address post-sale duties is implementation of the General Product Safety Directive ("the Directive") throughout the European Union ("EU"). The Directive obligates EU member countries to impose upon consumer product manufacturers a general requirement to place only safe products on the market. The 2004 Directive substantially expands manufacturers' and governments' post-sale responsibilities.

The Directive also increases responsibilities for manufacturers and distributors. Distributors will have to monitor the safety of products placed on the market, especially by passing on information on product risks, keeping and providing documentation necessary for tracing the origin of products, and cooperating in actions taken by manufacturers and government agencies to avoid the risks. Both manufacturers and distributors have a duty to immediately notify government agencies when they know or ought to know that a product they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement of the Directive.

The Directive defines a "safe product" as one that "does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons…."

This threshold for reporting appears to be much lower than under any U.S. statute or regulation and therefore should result in more reports and presumably more recalls. The result has been a significant increase in the number of reports to EU member countries. However, these reports are complex as there is no EU safety agency to report to. Each country where the product has been sold must be notified. And the required corrective action may differ from country to country.

This multitude of reports and potentially different corrective actions are difficult to reconcile, especially when considering appropriate actions in the U.S. And the plaintiffs will try to use any inconsistencies between these actions against the manufacturer.

Canada

In January 2009, the Canadian government introduced legislation that, if enacted, will be called the Canadian Consumer Product Safety Act ("Act"). The Act was not completed

before Parliament was dissolved in 2009 and therefore was reintroduced in June of 2010. This year, it is referred to as C-36 and is similar to last year's Act which I described in more detail in my article, *Recent Regulatory Reform Runs Rampant,* which appeared in the Winter 2010 issue of *Strictly Speaking.*

The key requirement, as it has been over the years with the CPSC, is enhanced mandatory reporting 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;
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> (*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 then must file a more complete written report within ten days.

Health Canada issued a draft *Consultation on the Mandatory Reporting Policy for the Proposed Canada Consumer Product Safety Act* which included Health Canada's interpretation of the reporting requirements. Comments were accepted from July 19, 2010 until October 29, 2010. In part, it said:

> Companies are to report incidents whether or not an actual injury or other health effect has occurred or whether or not the actual injury or other health effect was itself serious. The potential for injury (often referred to as a "near-miss" incident) may be an indicator that the product is a danger to health and safety and is therefore reportable.

In addition, the consultation describes in detail the situations in which a company is deemed to have received sufficient information of a reportable incident. This is

important since so much information comes into companies through various means, including email and the Internet, and many times does not get to the safety personnel for analysis. In that connection, the consultation said:

> Companies should establish policies, processes and procedures to ensure that a responsible person receives and assesses information that comes to the company regarding the product(s) they supply in Canada and other products that could reasonably be expected to be involved in similar incidents. This person may determine if it is a reportable incident and what corrective measure, if any, may be required to address the hazard.

It is uncertain whether the Act will be passed during this session of Parliament. However, if not, I am sure it will be reintroduced and will ultimately be enacted.

Australia

Australia's new product safety law takes effect on January 1, 2011. The Australian Competition and Consumer Commission will administer the new law. Concerning reporting, the Commission said:

> Another important legal change will be the introduction of a mandatory reporting requirement. Under the new legislation, suppliers will be required by law to advise the ACCC when they become aware that a good or product related service they have supplied has caused, or may have caused death or serious injury or illness to any person. They are also required to report if another person (e.g. a customer) considers that the death, injury or illness was or may have been caused by using the good or product related service.

Like Health Canada, the Commission issued "*A guide to the mandatory reporting law in relation to consumer goods, or product related services, associated with death or serious injury or illness"* in August 2010. This consultation draft accepted comments until October 20, 2010. Concerning reporting, the draft says:

> 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;
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> - 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.

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 of foreseeable misuse of the consumer goods.

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. The reporting requirement applies regardless of whether or not the consumer goods were being used before or at the time the death, serious injury or illness occurred. The requirement also applies regardless of the country in which the death, serious injury or illness occurred.

These criteria are fairly complex and require a great deal of investigation and analysis. It remains to be seen how companies will respond to these new requirements. It should be pointed out that a reporting requirement can arise even if the death, serious injury, or illness did not occur in Australia.

South Africa

South Africa enacted a comprehensive Consumer Protection Bill in May of 2008. It is to become effective in March of 2011. In addition to adopting strict liability, the legislation contains extensive new safety requirements. The legislation requires companies to adopt safety monitoring systems to analyze "previously undetected or unrecognized potential risk" and to notify consumers and recall the products if they are unsafe.

The government is in the process of setting up a National Consumer Commission which will, similar to other consumer product safety agencies, establish guidelines or regulations for reporting. Reports from those individuals familiar with the legislation predict substantial increases in lawsuits and recalls resulting in huge new costs.

Japan

Japan adopted new legislation forming a Consumer Affairs Agency (CAA) which commenced operation on September 1, 2009. This agency has expanded recall responsibilities and powers and is working on a revision to a manual concerning recalls in Japan. In addition, the Ministry of Economy, Trade and Industry (METI) continues to be involved with product safety matters.

According to the latest version of Japan's consumer product safety act, a product seller must report to the government as follows:

> Any person engaging in the manufacture or import of consumer products who comes to know that serious product accidents have originated with the consumer products that he/she manufactured or imported, shall report to the competent minister the name and type of the consumer products, a detailed account of the accidents, and the quantity of said consumer products manufactured or imported, as well as the quantity sold.

In addition, the minister can order a product recalled and even order a Japanese-based company to establish a system to monitor and investigate accidents involving their products.

This reporting requirement focuses on "serious accidents" and has no requirement that there be a defect in the product and does not have an exception for products that have been misused.

Conclusion

This proliferation of product safety reporting requirements will continue to expand. And those countries that have adopted such requirements may choose to become more aggressive. While it hasn't happened yet, we can expect that at sometime in the future, a country in the EU will fine a company for not complying with the General Product Safety Directive. And governments in other regions may, likewise, decide to send a similar strong message about the necessity for companies to proactively deal with safety issues.

Given the significant increase in the potential for fines and the potentially devastating effect such fines can have on a company's reputation, it is clear that manufacturers and others in the chain of distribution should be sure that their post-sale monitoring systems can deal with these increased reporting responsibilities. In addition, the company must be sure that the reports and subsequent corrective actions are performed in a way that will be defensible in the event of lawsuits involving such recalled products.