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DEFECT REPORTING

CONSUMER PRODUCTS

The reporting by corporations of consumer product safety event information often differs from country to country, posing implications for the coordination of reporting, not only to avoid penalties, but to insure that different government agencies take consistent positions with respect to the same product, say attorneys Mark L. Austrian and Christie L. Grymes in this BNA Insight. The authors survey existing reporting requirements and information sources in the United States, Canada, Australia and Europe, with special attention to new product safety requirements.

Multinational Corporations Face Conflicting, Uncertain Reporting Standards

By Mark L. Austrian and Christie L. Grymes

Rapid changes worldwide in governmental regulation of product safety require multinational corporations to understand these rules and monitor incident reports worldwide. Unfortunately, reporting requirements differ from jurisdiction to jurisdiction. Reporting an incident or conducting a recall in one country may have implications in other jurisdictions. Thus, multinational corporations must implement procedures for coordinating their product safety and governmental reporting operations not only to avoid penalties but to insure that different government agencies take consistent positions with respect to the same product.

This article compares and contrasts new and existing reporting requirements and information sources in the United States, Canada, Australia and Europe, with special attention to the new product safety laws effective

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January 2011 in Canada and Australia. It examines these laws from the standpoint of the overall reporting standard, factors to be considered in the reporting determination, the methodology for integrating these factors, the time for investigation, the persons to be notified and the availability of the reports to other jurisdictions.

As will be discussed below, the approaches taken by individual jurisdictions are often quite different. Some countries may require the reporting of *all* serious incidents, others where a product *could cause* a serious injury, and still others where the product *does cause* a serious injury. Australia appears to require reporting if a *consumer* considers that the product caused the injury, even if the supplier disagrees. The European Union sets forth a unique methodology for aggregating the individual factors to determine reporting obligations, but no other jurisdiction does this.

Another problem for multinational corporations is how to aggregate product safety information from various external sources as well as from different business units operating within various jurisdictions. The new consumer complaint data system recently implemented by the United States Consumer Product Safety Commission attempts to aggregate information from voluntary on-line consumer reports but this system currently is unique to the United States. In 2011, the EU Parliament directed the European Commission to develop a public consumer safety information database. Privacy issues may inhibit governmental agencies from sharing consumer complaints with other jurisdictions. Nonetheless, it is incumbent upon multinational corporations to develop systems to monitor products sold worldwide and devise a system of grouping similar products for product safety analysis.

One of the more difficult issues in any reporting scheme is determining a ''triggering event.'' To illustrate the issues presented, consider the following hypothetical: A customer returns a hot water bottle to a retailer and asks for a refund. She states that, in her opinion, the hot water bottle burst, she received a second degree burn and required skin grafts. The manager believes that the purchaser put pressure on the bottle by putting it under her body. The company has no other incidents reported and has not been able to duplicate this scenario in testing. As discussed below: In the United States, the European Union and Canada this would probably not be reportable; in Australia it would be reportable.

Reporting Standard

1. The United States

The United States requires reporting to the CPSC where the company has information which reasonably supports that conclusion that there is a (1) ''defect'' which ''could create a substantial product hazard,'' or (2) the product contains ''an unreasonable risk of serious injury or death.'' 15 U.S.C. § 2064 (b); 16 C.F.R. §§ 1115.4, 1115.6. The CPSC's regulations identify sources which should be evaluated when determining whether to report. 16 C.F.R.§ 1115.12 (f). This includes complaints from consumers and claims for personal injury filed on incidents occurring within the United States, as well as from outside of the United States, that is ''relevant'' to products sold or distributed in the United States. *Id.* The CPSC also recommends certain factors to be considered when evaluating the hazard created: the pattern of defect; number of products in commerce; and severity of the risk. 16 C.F.R. § 1115.12 (g). The CPSC does not set forth a methodology for evaluating these factors together.

If the information is not ''clearly reportable,'' the firm is given the right to conduct a ''reasonably expeditious investigation,'' generally not to exceed 10 days, to determine if there is a reportable event and to report within 24 hours thereafter. 16 C.F.R. § 1115.14 (d). The regulations make it clear, however, that in filing the report a company does not need to admit that there is a substantial product hazard. 16 C.F.R.§ 1115.12 (a).

There is no requirement that a manufacturer, distributor or retailer submit the Section 15(b) Report to anyone other than the CPSC. Moreover, if a distributor or retailer receives information from a manufacturer that may be reportable, there is no need to file a separate Section 15(b) report if a Report has already been filed. 16 C.F.R. § 1115.13(b). The CPSC regulations encourage companies to file Section 15(b) reports even if the company does not believe that the filing is required or that any corrective action is necessary. This is often referred to as an ''informational'' Section 15(b) report. 16 C.F.R. § 1115.12.

It is unlikely that the water bottle incident would be reportable to the CPSC.

2. Canada

In December 2010, the Canadian Consumer Product Safety Act (the ''Canadian Act'') passed through the Canadian Legislature and subsequently received executive approval. The Canadian Act went into effect on June 20, 2011.[1] Section 8 of the Canadian Act states that ''No person shall advertise or sell a consumer product that they know: (a) is a danger to human health or safety.'' Section 2 of the Act provides that:

> 'danger to human health or safety' means any unreasonable hazard—existing or potential—that is posed by a consumer product during or as a result of its normal or foreseeable use and that may reasonably be expected to cause the death of an individual exposed to it or have an adverse effect on that individual's health—including an injury—whether or not the death or adverse effect occurs immediately after the exposure to the hazard, and includes any exposure to a consumer product that may reasonably be expected to have a chronic adverse effect on human health.

Section 14 of the Canadian Act takes a much more expansive approach to reporting and, in conjunction with proposed regulations, appeared to require reporting of all incidents, not just when the product presents a substantial hazard. The Act defines ''incident'' as:

> (*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

[1] *Available at* http://laws-lois.justice.gc.ca/eng/acts/C-1.68/index.html.

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> serious adverse effects on their health, including a serious injury.

The issue of what is an ''occurrence'' is not limited to an actual event where there is a serious injury. Proposed regulations make it clear that there may still be a reportable event (1) even if there was not an actual injury or (2) whether or not the injury was serious. The key requirement is whether the occurrence may reasonably have been expected to result in such harm.

The potential definition of ''occurrence'' to require reporting of all incidents regardless of whether the product was defective or unreasonably dangerous caused a huge outcry in the business community. As a result, on June 15, 2011, Health Canada issues a ''Guidance on Mandatory Incident Reporting which clarified the situation.[2] Section 5.3 of the Guidance document states that ''For an event to be an incident, under paragraphs 14(1)(a) to (c), it may be determined that the event indicates an unreasonable hazard posed by the normal or foreseeable use of the product.'' This would appear to be consistent with the CPSC standard that reporting is required where there is ''an unreasonable risk of serious injury or death.''

Section 14 mandates that the reporting must be made within two days (not ''business days''). There is no specified time for conducting an investigation. A supplemental report must be filed within 10 days and should include information about the incident, the product involved, products that could be involved in a similar incident and proposed corrective measures. Subsequently, there will be discussions between Health Canada and the importer/manufacturer as to what, if any, remedial measures should be taken.

This reporting requirement applies to each entity in the supply chain. There does not appear to be any exemption, as exists with the CPSC, if the company knows someone else has reported. Moreover, the reporting entity must, within the two-day period, notify the person from whom they received the product. The time begins to run when a ''responsible person'' (''a directing mind of the organization'') who, through the exercise of due diligence, should become aware of the incident. The statute refers to an occurrence in Canada ***or elsewhere.*** This means that there is a reporting obligation if the product is sold in Canada, but the incident occurred in the United States or anywhere else in the world.

It appears likely that under the current regulations the water bottle incident would not be reportable to Health Canada.

3. The Australian Legislation

Australia's new product safety law, the Competition and Consumer Act 2010 (the ''ACL''), became effective Jan. 1, 2011.[3] The Australian legislation, Part 3-3; Division 5; 131, permits manufacturers to determine whether the product raises a safety concern before a report is required, but it too has a two-day reporting period:

> (1) If:
>
> (a) a person (the *supplier*), in trade or commerce, supplies consumer goods; and
>
> (b) the supplier becomes aware of the death or serious injury or illness of any person and:
>
> (i) 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
>
> (ii) 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; the supplier must, within 2 days of becoming so aware, give the Commonwealth Minister a written notice that complies with subsection (5).

The Australian Competition & Consumer Commission, in its December 2010 guide (the ''Guide'')[4] states that suppliers should be very cautious about choosing not to report incidents. If there is doubt about whether to report an incident, it is appropriate to report it. However, there is very little guidance as to how the ''causation'' principle should be determined. The key question appears to be whether the supplier concludes that the product caused or may have caused the incident.

However, subsection (ii) as explained in the Guide may be more troublesome. The Guide suggests that if *a consumer* considers that the death or serious injury or illness was caused by the product, this becomes a reportable incident. In the Guide's Case Study, § 7, presented above, the bursting hot bottle is a reportable event despite the fact that the manager believes that the individual, rather than the product, caused the injury. The manager's evaluation is not, controlling and the incident is reportable:

> The hot water bottle is a consumer good and someone thinks it caused a serious injury so the reporting requirement is triggered.

p. 14.

The ACL specifically states that any filing will not be considered an admission of liability. Incident reports filed pursuant to the Australia legislation will not be added to any publicly available computer database. There are no specific requirements for reporting incidents which took place outside of Australia.

4. European Union

Article 5, 3 of the EU Directive 2001/95[5] (the ''General Product Safety Directive (GPSD)'') provides that:

> when producers and distributors know or ought to know that a product poses risks to the consumer that are incompatible with the general safety requirement, they must *immediately* inform the member states' authority of any action to prevent risks to the consumer. (Emphasis added)

The general safety requirement contained in Article 2 (a) states as follows:

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[2] *Available at* http://www.hc-sc.gc.ca/cps-spc/pubs/indust/2011ccpsa_incident-lcspc/index-eng.php.

[3] *Available at* http://www.austlii.edu.au/au/legis/cth/consol_act/caca2010265/.

[4] *Available at* http://www.treasury.gov.au/consumerlaw/content/downloads/Australian_Consumer_Law_A_Guide_to_Provisions_April_2010.pdf.

[5] *Available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0095:EN:NOT.

(b) 'safe product' shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation, maintenance requirements, does not present any risk or only the minimum risk 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. . . .

A ''dangerous product'' is defined in Article 2(d) as ''any product which does not meet the definition of ''safe product'' in (b). ''Serious risk'' means ''any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities. Article 5(3) requires producers, where they know that the product poses risks to the consumer that are incompatible with the general safety requirement, to immediately inform the competent authorities of the member states.

There are no specific factors which are specified in the Directive or supporting regulations to help determine whether a product is dangerous. However the Directive, under ''Whereas'' (28) states that there shall be guidelines for criteria for the application of the definition of ''serious risk.'' With this in mind, the European Commission set forth a series of ''Guidelines for the Notification of Dangerous Consumer Products'' which provides, in ANNEX, a ''Methodological framework for facilitating consistent risk estimation and evaluation.'' The analysis attempts to quantify some of the factors that should be employed to determine whether the incident is reportable: severity of injury, probability of health/safety damage, vulnerability of the individual, knowledge of the risk, possibility of precautions and is quantified as follows:

A. Severity of Injury

Slight	Serious	Very Serious
Less than 2% incapacity Usually reversible and not usually requiring hospital treatment.	**2 – 15% incapacity Usually irreversible requiring hospital treatment**	**More than 15% incapacity Irreversible requiring hospital treatment**
		Death
Minor cuts	Serious cuts	Serious injury to internal organs
Very minor fractures	Major fractures, loss of finger or toe	Loss of limbs
	Damage to sight	Loss if sight
	Damage to hearing	Loss of hearing
Minor burns	Moderate burns	Serious burns (more than 25%)
Sprains	Moderate disability	Severe permanent disability
		Serious mental disorder or prolonged coma

B. Probability of Injury

Overall Probability of Injury		Probability of product being defective		
		1%	10%	100%
Probability of injury per year from regular exposure to hazardous product	Hazard is always present and injury is likely to occur in regular normal use	Medium	High	Very High
	Hazard is present intermittently and injury is likely to occur	Low	Medium	High
	Hazard is present intermittently and injury is possible	Very Low	Low	Medium
	Hazard is present occasionally and/or injury is unlikely	Extremely Low	Very Low	Low

Once these are quantified than, they are combined in the following manner:

The above-example shows that where the severity of the risk is very serious but the probability of injury is very low, the level of risk is low.

The next step in the analysis is to grade the risk which includes the vulnerability of the individual, the knowledge of the risk and possibility of taking precautions:

Very vulnerable	Vulnerable
Blind	Partially sighted
Severely disabled	Partially disabled
Very old	Elderly
Very young (< 3 years)	Young (3 – 11 years)

Using the above analysis, consider the following example: A chain saw user has suffered a badly cut hand and it is found that the chain saw has an inadequately designed guard which allowed the user's hand to slip forward and touch the chain. The following factors could reasonably be analyzed:

- The assessment of probability is high because the hazard is present on all products and may occur under certain circumstances.

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Table A - Risk Estimation

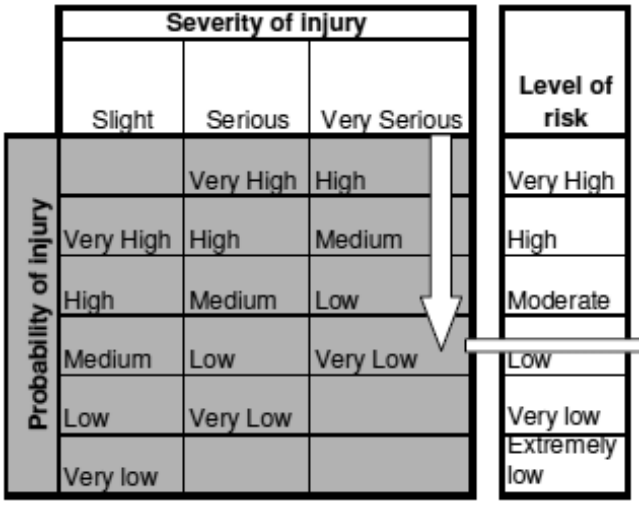
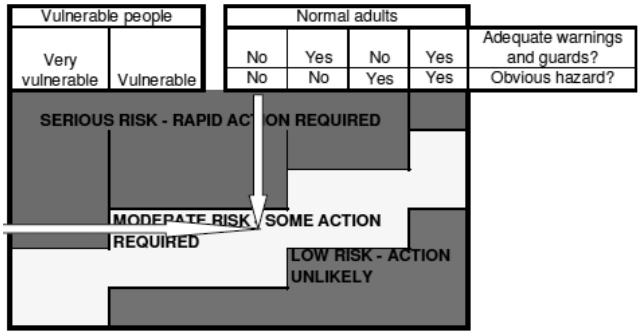


Table B - Risk Evaluation



- The assessment of severity is serious leading to an overall gravity rating of high.
- The chain saw is in use by non-vulnerable adults.
- It presents an obvious hazard but with inadequate guards

These events would likely require notification based upon the overall analysis shown above.

One of the problems with discussing the EU standards is that the actual reporting requirements are put into place by the EU members. For example, Part 2, § 8 of the *United Kingdom General Product Safety Regulations*, 2005, provides that a manufacturer must give notification to an enforcement authority if the product on the market ''poses risks to the consumer that are incompatible with the general safety requirement.'' The General Safety Requirement states that ''No producer shall place a product on the market unless the product is a safe product.'' A recall may be directed ''where an enforcement authority has reasonable grounds for believing that a product is a dangerous product. . . .'' 2005 General Product Safety Regulations, § 15.

Comparison of Standards

As can be seen from the chart below, the statutory requirements for reporting differ significantly, ranging from reporting every ''occurrence'' to ''minimal risk'' to ''causation'' to ''substantial product hazard'' or ''unreasonable risk.''

What is clear is that a report to one regulatory agency does not automatically require that a report be sent to the other agencies. However, prudence may require that a report in one jurisdiction be brought to the attention of another governmental agency.

Regulatory Exchange of Post-Market Surveillance Information

Regulatory agencies are making concerted efforts to collect and analyze as much post-marketing surveillance data as possible. This is being done through the mandatory reporting discussed above and, in the case of the CPSC, a consumer reporting database. In addition, the regulatory agencies in the United States, Canada, the EU and Australia have signed memoranda of understanding governing the exchange of information. The question arises as to what extent post-marketing surveillance information will be shared among the various regulatory agencies.

All of the regulatory agencies receive information from different sources. The CPSC, for example, receives information from the National Electronic Injury Surveillance System (''NEISS''), information from some retailers (the ''Retailers Reporting Model''), In-Depth Investigations (''IDIs'') and letters to the CPSC. Reports that are followed up by the CPSC through an IDI are sent to manufacturers for comment as are reports from The Retailers Reporting Model. In general, incident reports contained in a Section 15(b) filing are not publicly available but may be after the investigation is concluded under a Freedom of Information Act Request. 16 C.F.R. § 1115.15.

Pursuant to Section 212 of the Consumer Product Safety Improvement Act of 2008 (''CPSIA''), the CPSC has established a publicly available and searchable database for reports of harm from a consumer product. The database became operational in March 2011. While the database refers to reports submitted to the CPSC by ''consumers,'' ''government agencies,'' and ''public entities,'' the regulations define these terms broadly to include the actual users of consumer products as well as family members, friends, attorneys, investigators, consumer organizations, public safety officials, trade associations that have a public safety purpose, etc. These ''Submitters'' are not required to have first hand knowledge of the incident. Before reports are added to the da-

Canada	EU Directive	Australia	U.S.
Information regarding 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, including a serious injury.	A safe product *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. . . .	If a person. . . becomes aware of the death or serious injury or illness. . . and: (i) considers that the death or serious injury or illness *was caused, or may have been caused*, *by* the use or foreseeable misuse. . . .	Information which reasonably supports the conclusion that a product contains a defect which could create *a substantial product hazard* . . . or *creates an unreasonable risk* of serious injury or death.

tabase they are forwarded to individual manufacturers for comments or claims of material inaccuracy. However, the name of the submitter will not be forwarded to the manufacturer unless the submitter consents. This can make it very difficult for the manufacturer to confirm the accuracy of the information presented. No other country currently has this system of reporting.

The EU has in place its Rapid Exchange of Information System (RAPEX) established by the GPSD. This is a Community rapid alert system for dangerous non-food consumer products. It is intended to ensure that information about dangerous products withdrawn from the EU market and/or recalled from consumers is quickly circulated between Member States and the European Commission, with the aim of preventing or restricting the selling of these products on the market. This system, however, does not provide for the circulation of incident reports.

The presence of this large amount of information raises a number of issues for multinational corporations. Corporations must, of course, keep track of incident reports that it actually receives from any source, investigate the claims made and make a determination of whether a reportable event occurred. This would include incident reports contained in the CPSC database since these reports are submitted to the manufacturer. Whether such reports should be reported to other jurisdictions would depend upon their contents. This presumably would not apply where there is a claim that the product caused an injury but the manufacturer is not given the name of the submitter.

It would appear to be the goal of the regulatory agencies to share all available product safety information. In 2005, the United States and Canada signed a Memorandum of Understanding governing the exchange of information between the CPSC and the Canadian Department of Health.[6] Similar Memoranda of Understanding were entered into with the EU (2005) and Australia (2011). These agreements would most certainly include the exchange of information concerning product recalls or prohibited products sold in other jurisdictions and collaboration on standards. However, it is doubtful that this would include the exchange of reports filed by individuals. The Canadian Memorandum of Understanding, for example, makes clear that it does not supersede the confidentiality restrictions of either country, and the Australian Memorandum of Understanding refers to only publicly available information. This would appear to preclude the CPSC from receiving incident reports, other than through traditional means.

Practical Pointers

- Establish systems to organize and analyze product safety information worldwide.
- Centralize decision making authority for deciding when and where to report.
- Monitor product safety legislation in countries where similar products are sold.
- Open a dialogue with regulators to coordinate recall activity.

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[6] Memorandum of Understanding between the Consumer Product Safety Commission of the United States of America and the Healthy Environments and Consumer Safety Branch of the Department of Health of Canada Regarding Cooperation Related to the Safety of Consumer Products dated June 22, 2005.

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