



# Product Recall

in 20 jurisdictions worldwide

Contributing editor: Mark Tyler

# 2010



Published by  
*Getting The Deal Through*  
in association with:

Ajumogobia & Okeke

Anderson Mōri & Tomotsune

Barrocas Sarmento Neves

Brandi Advogados

Clayton Utz

EBA – Endrös Baum Associés

Gianni, Origoni, Grippo & Partners

McCague Peacock Borlack McInnis & Lloyd LLP

MMLC Group

Monereo Meyer Marine-Lo Abogados

Nörr Stiefenhofer Lutz

S Horowitz & Co

Shook, Hardy & Bacon LLP



## Product Recall 2010

**Contributing editor:** Mark Tyler  
Shook, Hardy & Bacon  
International LLP

**Business development manager**  
Joseph Samuel

### Marketing managers

Alan Lee  
Dan Brennan  
George Ingledew  
Edward Perugia  
Robyn Hetherington  
Dan White  
Tamzin Mahmoud  
Ellie Notley

### Subscriptions manager

Nadine Radcliffe  
Subscriptions@  
GettingTheDealThrough.com

### Assistant editor

Adam Myers

### Editorial assistant

Nick Drummond-Roe

### Senior production editor

Jonathan Cowie

### Chief subeditor

Jonathan Allen

### Senior subeditor

Kathryn Smuland

### Subeditors

Laura Zúñiga  
Ariana Frampton  
Sarah Dookhun

### Editor-in-chief

Callum Campbell

### Publisher

Richard Davey

### Product Recall 2010

Published by  
Law Business Research Ltd  
87 Lancaster Road  
London, W11 1QQ, UK  
Tel: +44 20 7908 1188  
Fax: +44 20 7229 6910  
© Law Business Research Ltd  
2009

ISSN: 2042-2040

No photocopying: copyright  
licences do not apply.

The information provided in this publication is general and may not apply in a specific situation. Legal advice should always be sought before taking any legal action based on the information provided. This information is not intended to create, nor does receipt of it constitute, a lawyer-client relationship. The publishers and authors accept no responsibility for any acts or omissions contained herein. Although the information provided is accurate as of September 2009, be advised that this is a developing area.

Printed and distributed by  
Encompass Print Solutions  
Tel: 0870 897 3239

**Law**

**Business**

**Research**

<b>Overview</b> Mark Tyler <i>Shook, Hardy &amp; Bacon International LLP</i>	<b>3</b>
<b>Australia</b> Colin Loveday and Richard Abraham <i>Clayton Utz</i>	<b>5</b>
<b>Brazil</b> Clarissa Borsoi, Joana Whately Pacheco e Silva and Patrícia Saggiomo Martins <i>Ferreira Brandi Advogados</i>	<b>10</b>
<b>Canada</b> Mark Mason and Jason Rabin <i>McCague Peacock Borlack McInnis &amp; Lloyd LLP</i>	<b>15</b>
<b>China</b> Yu Du and Ellen Wang <i>MMLC Group</i>	<b>21</b>
<b>Czech Republic</b> Philip Smitka and Jan Čížek <i>Nörr Stiefenhofer Lutz</i>	<b>28</b>
<b>France</b> Florian Endrös and Muriel Mazaud <i>EBA – Endrös Baum Associés</i>	<b>34</b>
<b>Germany</b> Michael Molitoris and Thomas Klindt <i>Nörr Stiefenhofer Lutz</i>	<b>39</b>
<b>Hungary</b> Bajorfi Ákos and Sieber-Fazakas Eszter <i>Nörr Stiefenhofer Lutz</i>	<b>45</b>
<b>Israel</b> Avi Ordo and Moran Katz <i>S Horowitz &amp; Co</i>	<b>51</b>
<b>Italy</b> Daniele Vecchi and Federico Busatta <i>Gianni, Origoni, Grippo &amp; Partners</i>	<b>57</b>
<b>Japan</b> Naoki Iguchi and Tomokazu Suwa <i>Anderson Mōri &amp; Tomotsune</i>	<b>63</b>
<b>Nigeria</b> Babatunde A Sodipo and Peju Lawal <i>Ajumogobia &amp; Okeke</i>	<b>67</b>
<b>Portugal</b> Margarida Barrocas <i>Barrocas Sarmiento Neves</i>	<b>71</b>
<b>Romania</b> Roxana Fercală, Diana Grigoroiu and Gabriel Popa <i>Nörr Stiefenhofer Lutz</i>	<b>75</b>
<b>Russia</b> Ekaterina Kalinina and Thomas Mundry <i>Nörr Stiefenhofer Lutz</i>	<b>79</b>
<b>Slovakia</b> Pavol Rak and Zuzana Meinecke <i>Fabry Nörr Stiefenhofer Lutz</i>	<b>83</b>
<b>Spain</b> Sönke Lund and Ramon Romeu Cònsul <i>Monereo Meyer Marinel-Lo Abogados</i>	<b>88</b>
<b>Ukraine</b> Oleg Dorofeev and Angelina Sums kaya <i>Nörr Stiefenhofer Lutz</i>	<b>94</b>
<b>United Kingdom</b> Mark Tyler and Alison Newstead <i>Shook, Hardy &amp; Bacon International LLP</i>	<b>99</b>
<b>United States</b> Gregory L Fowler, Harley V Ratliff and Jeffrey D Mitchell <i>Shook, Hardy &amp; Bacon LLP</i>	<b>104</b>

# Canada

**Mark Mason and Jason Rabin**

McCague Peacock Borlack McInnis & Lloyd LLP

---

## General product obligations

- 1 What are the basic laws governing the safety requirements that products must meet?

In Canada safety requirements for products (including consumer products) are governed by a constellation of federal statutes and supporting regulations. They dictate the manufacturing specifications for products, as well as how they may be packaged, labelled, advertised, and distributed.

The statutes and regulations are product-specific, and therefore there is no unified code governing general product safety. Moreover, Canada has no single regulatory agency for products. There are several federal regulatory agencies that administer Canada's product safety regime. There are also several areas, such as electrical safety and fuel safety, which are administered at the provincial level by provincial agencies such as Ontario's Technical Standards and Safety Authority and Electrical Safety Authority.

Some of the pertinent federal statutes are as follows:

- Agriculture and Agri-Food Administrative Monetary Penalties Act;
- Canada Agricultural Products Act;
- Canadian Food Inspection Agency Act;
- Consumer Packaging and Labelling Act;
- Explosives Act;
- Feeds Act;
- Fertilizers Act;
- Fish Inspection Act;
- Food and Drugs Act;
- Hazardous Products Act;
- Health of Animals Act;
- Meat Inspection Act;
- Motor Vehicle Safety Act;
- Nuclear Safety and Control Act;
- Pest Control Products Act;
- Plant Breeders' Rights Act;
- Plant Protection Act;
- Precious Metals Marketing Act;
- Seeds Act; and
- Tobacco Act.

The three key statutes that cover the most common types of consumer products are the Hazardous Products Act (HPA), the Food and Drugs Act (FDA) and the Motor Vehicle Safety Act (MVSA).

### Hazardous products

The HPA is the key statute regulating the advertising, packaging, distribution and labelling of consumer products in Canada. It is administered and enforced by various departments within the federal agency called Health Canada.

The HPA classifies products into two categories: those that are deemed 'prohibited' (part I of schedule I) and those that are deemed

'restricted' (part II of schedule I). The former category of products may not be advertised or sold in Canada or imported into Canada. With respect to the latter category, the products may be advertised, sold or imported, but only as authorised by the accompanying regulations to the HPA.

These regulations pertain to the following products: asbestos, carbonated beverage glass containers, carriages and strollers, children's jewellery, consumer chemicals, corded window coverings, cribs and cradles, glass doors and enclosures, booster cushions, carpets, cellulose insulation, charcoal, children's sleepwear, child restraint systems, crocidolite asbestos, expansion gates and expandable enclosures, infant feeding bottle nipples, kettles, matches, mattresses, dummies, tents, toys, lighters, playpens, science education sets and surface coating materials.

The HPA empowers the minister of health to appoint inspectors who may at any reasonable time enter any place where the inspector believes on reasonable grounds any hazardous product (ie, one that is restricted, controlled, or prohibited) is manufactured, prepared, preserved, processed, packaged, sold or stored for sale, processing or packaging and to examine products, or even seize them if necessary.

Inspectors may also examine books, computer files, and other documents if the information is relevant to the enforcement of the statute. Private residences, however, may only be entered or inspected with the consent of the owner, or with a warrant.

### Food and drugs

The FDA is the key statute for the regulation of advertising, packaging, distribution and labelling of products meant for consumption by humans and animals. The FDA is administered and enforced by two federal agencies called the Canadian Food Inspection Agency with respect to food and agricultural products, and also by various departments within Health Canada in respect of other products, such as medical devices and cosmetics.

The Canadian Food Inspection Agency is unique in Canada, insofar as it is the sole federal regulatory agency that has the authority to order mandatory product recalls with respect to those products coming under its jurisdiction. This authority is granted pursuant to the Canadian Food Inspection Agency Act (CFIAA).

The FDA, like the HPA, authorises the minister of health to appoint inspectors to enter, on reasonable grounds, any place where articles governed under the statute are manufactured, prepared, preserved, packaged or stored, and to inspect or even seize said articles in accordance with the statute. Similar rules apply with respect to the entering of private residences.

### Motor vehicles

The MVSA is the key statute for the regulation of manufacturing and importing of motor vehicles and other related equipment within Canada. The MVSA is administered by Transport Canada, through the Road Safety and Motor Vehicle Regulation Directorate.

The MVSA authorises the Minister of Transport to appoint inspectors to enter any location where it is believed that vehicles or vehicle components are located for which safety standards have been prescribed. The inspector may seize or detain any vehicle or component falling under the purview of the statute with respect to which it is believed that there has been a contravention.

**2** What requirements exist for the traceability of products to facilitate recalls?

There are no express traceability requirements with respect to product recalls in Canada. This is because, with the exception of mandatory recall orders under the CFIAA, product recalls in Canada are entirely voluntary.

There are no express traceability requirements built into even the CFIAA. However, the Canadian Food Inspection Agency does publish an Importer's Guide, which makes the following recommendations for limiting a recall to a specific product:

- link the products received to each supplier;
- link the products received to the accounts that the products have been distributed to;
- all products received should be identified with a specific lot code. A system should be in place that identifies and records the lot codes of each product received from each supplier; and
- for each supplier it should be documented:
  - the definition of a lot for each product;
  - the parts and interpretation of the codes (obtained from the supplier); and
  - a description of the system being used to link the lot codes from the supplier to the shipping records.

**3** What penalties may be imposed for non-compliance with these laws?

Penalties for contravention of the various statutes regulating product safety vary from statute to statute, and could include anything from a simple fine up to and including imprisonment.

The HPA, the FDA and the MVSA are the three key statutes with the broadest impact, and all three contain their own enforcement mechanisms with prescribed punishments.

Penalties under these statutes fall into two categories: summary conviction offences and indictable offences. The former type tend to be less serious in nature, carry lesser penalties, and have clearly defined limitation periods prescribed after which time no charges by regulatory authorities may be laid. Indictable offences are more serious in nature, require the authority to obtain arrest warrants, and carry much stiffer penalties.

Typically, penalties under these statutes may reach C\$100,000 and up to six months in jail for the less serious, summary conviction offences, and as high as C\$1 million or two years' imprisonment for the more serious indictable offences.

### Reporting requirements for defective products

**4** What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

There is no universal requirement to notify government authorities of defects discovered in products, or known incidents of personal injury or property damage. Each product type is governed pursuant to the applicable statute, which may or may not contain notification provisions.

**5** What criteria apply for determining when a matter requires notification and what are the time limits for notification?

Notification requirements vary depending on the product in question.

In the FDA, under the Natural Health Products Regulations and the Medical Devices Regulations, notification is contingent on the manufacturer or distributor instituting a recall.

In the realm of motor vehicles and related components, the MVSA requires notice to be provided with respect to any 'safety defects'. This term is not defined in the statute. However, the Guidelines on Enforcement and Compliance Policy (GECIP) issued by Transport Canada states, for example, that a defective product would be one which 'reasonable persons would not put on the market if they had knowledge of its harmful character'. A product must meet 'the reasonable expectations of the ordinary consumer as to safety'.

There is no time requirement built into the statute. However, the GECIP states that Transport Canada monitors compliance with this provision by investigating complaints alleging a safety defect. These complaints may come from the general public, police agencies, consumer agencies and many other sources.

**6** To which authority should notification be sent? Does this vary according to the product in question?

Notification should be sent to the authority governing the specific product at issue. A non-exhaustive list of contacts in this regard is as follows.

#### Consumer and children's products

National Capital Region Consumer Product Safety Office  
 Product Safety Programme  
 Health Canada  
 MacDonald Building  
 123 Slater Street, 4th Floor AL 3504D  
 Ottawa, Ontario  
 K1A 0K9  
 Tel: +1 613 952 1014

Toll-free: +1 866 662 0666 (calls will be routed to closest regional office)

#### Cosmetic or personal care products

Toll-free: +1 866 662 0666 (calls will be routed to closest regional office)

#### Microwave, tanning lamp, cell phone products

Consumer and Clinical Radiation Protection Bureau  
 Health Canada  
 775 Brookfield Road  
 AL 6302C  
 Ottawa, Ontario  
 K1A 1C1  
 Tel: +1 613 954 6699  
 E-mail: ccrpb-pcrpcc@hc-sc.gc.ca

#### Pesticide products:

Pest Management Regulatory Agency  
 Health Canada  
 2720 Riverside Drive  
 Ottawa, Ontario  
 K1A 0K9  
 Tel: +1 613 736 3799  
 Toll-free telephone: +1 800 267 6315  
 Fax: +1 613 736 3758  
 E-mail: pmra\_publications@hc-sc.gc.ca

#### Motor vehicle products

Nigel Mortimer, Head Recalls Systems Analysis and Evaluation Road Safety and Motor Vehicle Regulation Transport Canada  
 2780 Sheffield Rd  
 Ottawa, Ontario  
 K1B 3V9

Tel: +1 613 993 9542  
 Fax: +1 613 991 5802  
 E-mail: nigel.mortimer@tc.gc.ca

- 7 What product information and other data should be provided in the notification to the competent authority?

Not all statutes and regulations have built-in notification requirements or criteria. However, the agencies responsible for enforcement do publish guidelines in this regard on their respective websites.

#### Food products

The Canadian Food Inspection Agency advises that it should be provided with the following information on notification of suspicion that a party has sold, distributed, or imported a product that may pose a serious risk to consumers:

- a detailed description of the nature of the problem;
- the name, brand, size and lot codes affected;
- details of complaints received and any reported illnesses;
- the distribution of the product – local or national;
- when the product was distributed (specific dates);
- labels of the products that may be recalled;
- the total quantity of product imported and distributed;
- the name of the firm's contact with the Canadian Food Inspection Agency; and
- the name and telephone numbers of the firm's after-hours contact.

#### Consumer and children's products

Health Canada should be provided with the following information

- the province or territory where the incident occurred;
- a description of the injury or near miss and the event;
- the product's condition: used, new, borrowed or second-hand;
- the product name, brand or description; and
- the store name and location if purchased.

#### Motor vehicles

In the case of a motor vehicle-related notification, section 15 of the Regulations Respecting Safety for Motor Vehicles and Motor Vehicle Components states that the following information should be included in the initial information package:

- the name of the company giving such notice;
- the make, model, model year, vehicle identification number or serial number range of vehicles potentially affected: this number shall be the vehicle identification number (rather than any other serial number) and the period of manufacture of the vehicles potentially affected;
- the total number of vehicles in Canada affected, and the estimated percentage that may contain the defect;
- a description of the defect and consequences;
- a statement of the measures to be taken to repair the defect; and
- where the statute requires an evaluation of the safety risk related to the defect, this should be included in the description of the defect and should take the form of the probable consequences to the vehicle should the defect occur.

Once this initial information has been provided in the notice of defect, within 60 days the following additional information must be submitted in a report:

- the total number of vehicles affected by the notice of defect and the number of such vehicles in each identifying classification;
- a chronology of all principal events that led to the determination of the existence of the defect; and
- copies of all notices, bulletins and other circulars issued by the company in respect of the defect, including a detailed description of the nature and physical location of the defect with diagrams and other illustrations as necessary.

- 8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

The investigatory powers of the various agencies, particularly those prescribed by the HPA, the FDA and the MVSA are broad. To the extent that notification is required under the statute, there is an ongoing obligation to cooperate with investigators and to provide additional information as it becomes available.

In the case of the MVSA, once the mandatory notice obligations are triggered under section 10, the party is required to provide follow-up reports on a quarterly basis for two years after the day on which the notice was given, unless the regulator orders otherwise.

- 9 What are the penalties for failure to comply with reporting obligations?

Penalties for failure to comply with reporting obligations are covered under the general penalties described in question 3.

- 10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

Most of the product safety statutes have provisions pertaining to the disclosure of information obtained in the course of an investigation or on notification to the regulatory bodies.

For example, the HPA expressly provides that information obtained in the course of an investigation must be limited to use for the purpose of that investigation. Even where no express confidentiality provisions exist (such as under the MVSA) the regulator will generally keep commercially sensitive information confidential, unless given permission to release it.

- 11 May information notified to the authorities be used in a criminal prosecution?

Information and documentation given to the authorities may be used in a criminal prosecution.

#### Product recall requirements

- 12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

With the exception of food and agricultural products, which are subject to mandatory recall orders under section 19 of the CFIAA, product recalls in Canada are generally carried out on a voluntary basis.

With respect to food and agricultural products, which are regulated by the Canadian Food Inspection Agency, the criteria for a mandatory recall order is simply where a regulated product 'poses a risk to public, animal or plant health'.

Other agencies such as Health Canada may also request a product recall on a voluntary basis, typically when the party becomes aware of a defect that makes a product unsafe, an injury or death caused by an unsafe product, or where a product does not comply with legislative requirements.

- 13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

There are few express requirements built into the statutes requiring product recalls or even warnings directed at distributors and members of the public.

The major exceptions are those contained in the Motor Vehicle Safety Act and the CFIAA, discussed earlier.

**14** Are there requirements or guidelines for the content of recall notices?

Health Canada provides a series of guidelines for the content and proper procedure on recall notices, including templates and sample media releases. Most of this information can be found in its publication, 'Recalling Consumer Products, a Guide for Industry'. This lays out the following guidelines for a proper recall notice, which should be in both English and French and be distributed to all customers that have purchased the recalled products:

- 'Urgent – Product Recall' heading;
- date on which the recall notice is sent to accounts;
- product identity (includes brand, UPC, lot number, item number, description, etc and a picture if possible);
- reason for the recall, including a statement of the hazard and associated risk;
- request to immediately remove the product from sale;
- recall action to be completed by the account (remove from sale, instructions for arranging return, etc);
- request that a recall be initiated by any accounts who have further distributed the product;
- name and contact number at your company to call for more information;
- date that recall action is to be completed by the account; and
- statement that the recall will be monitored for compliance by Health Canada.

**15** What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

In respect of recall orders by the Canadian Food Inspection Agency, any recalls must be published in both English and French, and may be made through newspaper advertisements, display signs or point-of-sale posters to display in retail outlets where the recalled products were sold, and may also be posted on the company website. If sales were made directly to consumers and a customer database is available, customers may even be contacted directly.

The MVSA provides that where the name of the current owner of a vehicle subject to the mandatory notice requirements cannot be ascertained, the minister may order the party to give notice of the defect by publication for five consecutive days. This publication must be in two major newspapers in each of the six regions, namely Atlantic Canada, Quebec, Ontario, the Prairie Provinces, British Columbia and the Territories. This information may also be disseminated by an alternative means, if the minister deems it appropriate.

**16** Do laws, regulations or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

Health Canada recommends that the supplier report the number of recalled units identified by their accounts to a Health Canada product safety officer, and include a summary of the actions taken to return, repair, or destroy all of the recalled products.

The MVSA requires the following information in its quarterly reports, following a mandatory notice of defect:

- the number, title or other identification assigned by the company to the notice of defect;
- the number of vehicles affected by the notice of defect;
- the date that notices of defect were given to the current owners of the affected vehicles; and
- the total number or percentage of vehicles repaired, including vehicles requiring inspection only.

**17** Must a producer or other supplier repair or replace recalled products, or offer other compensation?

There are no express requirements that a company repair or replace a recalled product at its own expense.

However, many Canadian provinces have sale of goods legislation providing implied warranties of fitness for any consumer products sold in the province. If the manufacturing or design defect is serious enough to warrant a recall, then it is likely that the customer would be entitled to a replacement or repair pursuant to those implied warranties.

Even in the absence of an implied warranty of fitness, it would reflect very poorly on a company if it failed to offer a free replacement or repair for its defective products, particularly if a customer was subsequently injured by one of those products.

A civil court would likely hold this against the company as evidence of a lack of due diligence in terms of keeping defectively dangerous products off the market.

**18** What are the penalties for failure to undertake a recall or other corrective actions?

In the case of a contravention of a recall order made under the CFIAA, the penalty on summary conviction is a fine of up to C\$50,000 or imprisonment of up to six months, or both.

However, even where no precise penalty is prescribed in statute or regulation, failing to issue a recall or other corrective action may have consequences in terms of civil liability. For a more comprehensive discussion of the duty to warn, see question 24.

**Authorities' powers****19** Can the authorities impose recall action plans?

Some regulations, like the Health of Animals Regulations and the Regulations Respecting Food and Drugs, have built-in requirements to institute written procedures to facilitate effective recalls.

**20** Can the government authorities publish warnings or other information to users or suppliers?

Even though recalls are generally voluntary in Canada, many of the statutes and regulations require notification to the pertinent regulator of any recalls. Health Canada posts advisories, warnings and recalls from industry concerning consumer products.

**21** Can the government authority organise a product recall where a producer or other responsible party has not already done so?

Currently there are no provisions for government regulators to institute or organise product recalls. However, new amendments introduced under Bill C-6 are currently moving through the legislative process and promise to change all of this. For a more detailed discussion of Bill C-6, see 'Update and trends'.

**22** Are any costs incurred by the government authority in relation to product safety issues or product recalls recoverable from a producer or other responsible party?

Currently, apart from the fines and penalties established by the HPA, FDA and MVSA, costs incurred by government authorities are not recoverable.

**23** How may decisions of the authorities be challenged?

Criminal and quasi-criminal prosecutions under the HPA, the FDA and the MVSA are heard before the provincial or superior courts. These prosecutions are subject to the ordinary rules of evidence in criminal and regulatory matters, and may be appealed or be subject to judicial review in limited circumstances.

In the case of the HPA, where a product has been added to part I of schedule 1 (prohibited products) or to part II of schedule I

### Update and trends

Canada's current product safety enforcement regime consists of a grab-bag of intersecting federal statutes and regulations.

However, a simplified and comprehensive regime is currently in the works, and will soon dramatically change how product safety is dealt with in Canada. The latest incarnation of the Canada Consumer Product Safety Act (Bill C-6), introduced by the Canadian federal minister of health on 29 January 2009, is currently winding its way through the legislative process.

While Bill C-6 has yet to receive royal assent (the final step in the process of bringing the Bill into law) it is expected to happen soon, perhaps even before the end of 2009.

According to the Bill's preamble, it 'modernises the regulatory regime for consumer products in Canada'. It is designed to make it easier to identify dangerous consumer products and to buttress existing enforcement mechanisms.

Bill C-6 applies broadly to all manner of 'consumer products', which it defines as those that may reasonably be expected to be obtained by individuals for non-commercial purposes. This definition includes both the components as well as packaging.

Products exempt from Bill C-6 are listed in schedule 1 and include: explosives, cosmetics, medical devices, drugs, food, pest control products, motor vehicles and related components, feeds, fertilizers, seagoing vessels, firearms, ammunition, cartridge magazines, cross-bows, 'prohibited devices' under the Criminal Code, plants, seeds, controlled substances, aeronautical products and animals.

The substantive changes introduced in Bill C-6 are too numerous to list thoroughly here, but some of the key changes are as follows.

Inspectors would be authorised under section 30 to order parties to recall consumer products that pose a danger to health and safety. Any order in this regard must include a statement of the reasons for

the recall, together with the time and manner in which the recall is to be carried out. Inspectors are also authorised to enter any premises where they suspect a defective consumer product may be present without a warrant, except for residential premises.

Under section 32, if a party does not comply with a mandatory recall order, inspectors would be authorised to carry out the recall on their own initiative, and at the party's expense.

However, recall orders would also be subject to a prescribed review process under section 34, which permits a party to make a formal written request to have the order reviewed by a designated review officer.

Manufacturers and others marketing consumer products in Canada would be subject to mandatory reporting requirements under section 14. Any information within the party's control must be reported to the minister of health within two days of the party becoming aware of an 'incident' involving the product. A more detailed written report with respect to such 'incidents' must be provided within seven days or within a period specified by the minister of health.

'Incident' is defined broadly to include occurrences where someone has suffered an injury or death due to a consumer product; a defect has been identified that may lead to injury or death; there is incorrect or insufficient labelling on the product that could be expected to result in injury or death; or there has been a recall measure instituted by a government (foreign or otherwise), a public body established under the statute or by the legislature of a provincial government, or by certain prescribed non-governmental institutions.

Fines and penalties have been toughened over those prescribed by existing statutes such as the HPA. Under section 38, offenders may be subject to fines up to C\$5 million or imprisoned for up to two years, or both. Due diligence would be, however, a defence to a prosecution under the more serious provisions.

(restricted products) any manufacturer or distributor or seller of that product may, within 60 days of the minister of health's order, request him or her to refer the order to a board of review.

The board of review is then required to convene a hearing and give the requester a reasonable opportunity to present evidence and make representations. The board of review must then submit a report to the minister of health, who must publish the report within 60 days of receipt, unless the board recommends that it be kept confidential.

### Implications for product liability claims

**24** Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

In Canada, the general rule is that a manufacturer, distributor, or designer of a product may only be found liable for injuries or damages caused by that product if it can be shown that (i) the product at issue was defective, (ii) this defect caused the plaintiff's injury or loss and (iii) there was a failure to exercise reasonable care in regard to the manufacture, design, distribution, or inspection of the defective product in question. The duty to warn of dangers related to the product (whether arising out of a defect, or simply inherent to the nature of the product) is also a necessary component to the standard of care, as are the rules of foreseeability in negligence law.

Subject to certain limited exceptions, such as sale of goods legislation in many provinces, there is no strict liability in Canada, which means that the criterion of reasonable care is usually a necessary component to a finding of liability.

The publication of a safety warning or the institution of a product recall may very well have an impact in respect of all three of these above-listed criteria, but particularly (i) and (iii).

For example, if a car is recalled because the engine has a tendency to spontaneously catch fire, and the plaintiff was injured when her car's engine spontaneously ignited, the evidence of the recall or the warning would likely be conclusive of the fact that the car in question was indeed defective.

But even in that scenario, the plaintiff would still need to prove that the defect caused her injury. Causation is an entirely separate and distinct step in the process. It should be self-evident in the above scenario that if the plaintiff suffered orthopaedic injuries as a result of a vehicle rollover, it is of little assistance to her claim to introduce evidence that the engine was recalled due to a risk of spontaneous fire. Indeed, this latter evidence could very well be deemed inadmissible if its prejudicial effect was out of proportion to its probative value.

With respect to the third criterion, the evidence of the recall or warning with respect to that product may be key in demonstrating that the manufacturer exercised reasonable care and complied with the duty to warn. In Canada, courts have imposed a positive obligation on manufacturers to warn distributors and even end-users of defects in their products. This duty to warn exists even with respect to products that have already gone to market. In the case of motor vehicles, this duty has been enshrined in statute, under section 10 of the MVSA.

Failing to issue a warning or institute a recall where the manufacturer knows about a specific defect in the product may be used against the manufacturer as evidence of a failure to warn, or a lack of reasonable care and due diligence. Punitive damages may even be warranted if the information was deliberately withheld to save on costs or to avoid public embarrassment and legal liability.

**25** Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

The trend in Canada has been to favour broad and comprehensive disclosure at the discovery stage of the litigation. For example, in Ontario any document relevant to the issues in dispute in the litigation that is within the possession, power or control of a party to the action must be produced, in accordance with rule 30.02 of the Rules of Civil Procedure.

Subject to privilege, almost any internal report, memorandum, or e-mail must be produced, provided it meets the relevant requirements

of the rules in the province where the action is taking place. Even non-written information and recollections of verbal conversations could be compelled at the oral discovery stage.

It is, however, important to note that even where broad discovery rules favour full disclosure of such information or documentation, this does not automatically mean that said information or documentation will be admissible at trial before a jury.

In particular, post-incident remedial conduct is a subject of much controversy in Canadian courts. While the recent trend has been to favour the admissibility of relevant post-incident remedial conduct, courts have not always done so. Historically, the policy reason for not admitting such evidence was that doing so would discourage parties from taking remedial measures to improve safety out of fear

of having that used against them in ongoing and future civil actions. The trend in Canada has been to move away from this policy, toward one of full admissibility.

However, in cases where the evidence has very limited probative value and would result in significant prejudice before the jury, it may be deemed inadmissible at trial, notwithstanding the obligation to disclose it at the discovery stage of the litigation.

Another important point is the implied undertaking rule and the related deemed undertaking rule, which are enshrined in several Provincial civil procedure statutes. This rule states that information disclosed in the discovery process cannot be used for any purpose outside the civil proceeding in which it was obtained.

McCAGUE  
PEACOCK  
BORLACK  
MCINNIS  
LL&YD<sup>LLP</sup>

---

**Mark Mason**

**Jason Rabin**

**[mmason@mwpb.com](mailto:mmason@mwpb.com)**

**[jrabin@mwpb.com](mailto:jrabin@mwpb.com)**

---

Suite 2700, PO Box 136

The Exchange Tower

130 King Street West

Toronto, Ontario

M5X 1C7

Canada

Tel: +1 416 860 0001

Fax: +1 416 860 0003

[www.mwpb.com](http://www.mwpb.com)



**GETTING THE DEAL THROUGH®**

**Annual volumes published on:**

Air Transport	Merger Control
Anti-Corruption Regulation	Mergers & Acquisitions
Arbitration	Mining
Banking Regulation	Oil Regulation
Cartel Regulation	Patents
Construction	Pharmaceutical Antitrust
Copyright	Private Antitrust Litigation
Corporate Governance	Private Equity
Dispute Resolution	Product Liability
Dominance	Product Recall
e-Commerce	Project Finance
Electricity Regulation	Public Procurement
Environment	Real Estate
Franchise	Restructuring & Insolvency
Gas Regulation	Securities Finance
Insurance & Reinsurance	Shipping
Intellectual Property & Antitrust	Tax on Inbound Investment
Labour & Employment	Telecoms and Media
Licensing	Trademarks
	Vertical Agreements

**For more information or to  
purchase books, please visit:  
[www.GettingTheDealThrough.com](http://www.GettingTheDealThrough.com)**



Strategic research partners of  
the ABA International section



THE QUEEN'S AWARDS  
FOR ENTERPRISE  
2006



The Official Research Partner of  
the International Bar Association