GETTING THE DEAL THROUGH

Product Recall

in 26 jurisdictions worldwide

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Canada

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General product obligations

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

Canada has a complex legal framework at both the federal and provincial levels that governs the safety requirements for products sold in Canada. The Canada Consumer Product Safety Act (CCPSA) is a broad federal statute that addresses consumer product safety, testing, incident reporting, record-keeping, inspection and product recall.

Some products sold in Canada are subject to other specific federal and provincial safety related legal requirements, such as:

- foods;
- drugs;
- natural health products;
- cosmetics;
- medical devices;
- agricultural products (seeds, feeds, meats, fruits and vegetables);
- upholstered and stuffed articles;
- textiles;
- tobacco;
- alcohol;
- motor vehicles;
- electronics;
- precious metals or jewellery;
- pest control products; and
- consumer chemicals and containers.

Issues with respect to motor vehicles or child restraint systems, for example, are subject to potential investigation by Transport Canada's Defect Investigations Group. There are also several areas including electrical safety and fuel safety that are administered at the provincial level by agencies such as Ontario's Electrical Safety Authority or the Technical Standards and Safety Authority.

Most products sold to consumers in Canada will be subject to provincial consumer protection as well as Sale of Goods legislation, which typically contains implied warranty type provisions that consumer products will be 'fit for the purpose intended' and 'of merchantable quality'. The Consumer Protection Acts in some provinces provide that warranties that negate or vary these fundamental terms will be considered void.

Canada Consumer Product Safety Act

The Canada Consumer Product Safety Act (CCPSA) came into force in 2011. The CCPSA replaced part I and schedule I of the Hazardous Products Act. For the purposes of this chapter, we have elected to focus on the CCPSA, which applies to:

- consumer products;
- anything used in the manufacturing, importation, packaging, storing, advertising, selling, labelling, testing or transportation of a consumer product; or
- a document that is related to any of those activities or a consumer product.

The CCPSA prohibits the manufacture, sale, importation, or advertisement of products that are:

- a danger to human health or safety;
- subject to a recall order or a voluntary recall; and
- subject to a measure or order imposed under the act that has not been complied with.

The CCPSA also prohibits labelling or packaging that is misleading in respect of a product's danger or safety certification.

The CCPSA is administered and enforced by Health Canada, a federal agency. The CCPSA received Royal Assent on 15 December 2010 and its provisions took effect when the act came into force on 20 June 2011.

Under the CCPSA, a 'consumer product' is defined as a product, including its components, parts or accessories, that may reasonably be expected to be obtained by an individual to be used for non-commercial purposes, including for domestic, recreational and sports purposes, and includes its packaging.

The CCPSA and its supporting regulations also set out the requirements for a number of specific consumer products, including asbestos, candles, glass containers for carbonated beverages, carriages and strollers (pushchairs), children's jewellery, children's sleepwear, consumer chemicals and containers, consumer products containing lead, corded window coverings, cribs and cradles, expansion gates and expandable enclosures, face protectors and helmets for hockey and lacrosse, glass doors and enclosures, glazed ceramics, carpets, cellulose insulation, charcoal, infant feeding bottle nipples, kettles, matches, mattresses, pacifiers, tents, lighters, phthalates, playpens, residential detectors, motor vehicle restraint systems and booster seats, science education kits, surface-coating materials, textiles and toys. The CCPSA does not apply to products that are covered under other legislation such as food, cosmetics, medical devices, drugs, natural health products, pest control products, tobacco products, fertilisers and vehicles.

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

The CCPSA's mandatory document retention requirements ensure the traceability of consumer products through the supply chain in the event of a recall. The act specifies that manufacturers, importers, advertisers and retailers must prepare and maintain documents indicating the name and address of the person from whom they obtained a consumer product and the name and address of the person to whom they sold the product. Retailers must keep documents with the name and address of the person from whom they obtained a consumer product and the location where they sold the product.

Documents must be retained for six years after the end of the year to which they relate. A proposal has been put forward that may exempt charities from having to keep records of donated consumer goods with the exception of donations from a company or bulk items, in which case charities may still be required to keep records of these types of donations.

Whether records are stored in paper or electronic format, it is expected that they will be physically located in Canada or easily accessible on a computer terminal in Canada. This is to ensure that they will be readily available to Health Canada officials for effective product recalls as well as routine inspections. In cases where it is not possible to maintain records in Canada it is possible to apply for an exemption from this requirement. An exemption will be granted in cases where the minister of health considers it unnecessary or impractical for records to be kept at a place of business in Canada.

In case of drug or natural health product recalls, Health Canada expects the company undertaking the recall to be able to produce satisfactory evidence that all consignees (anyone who received or purchased the affected product) were contacted. According to Health Canada, for Type I hazards the recalling company should contact consignees within 24 hours of initiation of the recall strategy. For Type II hazards the initial contact with consignees should be made within 72 hours and for Type III risks the initial contact should be made within five working days.

In the case of food recalls, companies should be able to create a distribution list that is product and lot code-specific. Some products are subject to legislated coding system requirements. For products that fall outside these requirements, food companies may create their own coding/lot number system using a combination of letters, figures or both, by which any food can be traced in manufacture and identified in distribution. This coding system should be designed so that the company can also link raw ingredient lot numbers to finished product lot numbers. The Canadian Food Inspection Agency expects that food companies will keep accurate distribution records that will allow them to limit their food recalls to the specific accounts that received the product being recalled.

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

In general, it is an offence to contravene a provision of the act. Criminal sentences for the most serious offences may include a fine of up to C$5 million and imprisonment of up to two years. If a corporation commits an offence, the directors, officers and agents are deemed to be parties to the offence and are liable to punishment.

The CCPSA establishes an administrative monetary penalty (AMP) system for enforcement of the act and its regulations. An AMP system assigns a monetary penalty for contravention of certain provisions of the act. An AMP may be issued in response to non-compliance with orders made under sections 31 or 32 of the act, or orders reviewed under section 35 (these orders are written notices that direct a person to take specific actions). Contravention of these orders can constitute either a violation or an offence. Contravention of an order made under the CCPSA, for example, may lead to the issuance of a notice of violation (NoV). A NoV will provide the monetary penalty to be paid by the company. The amount of the penalty depends on the risk associated with the product (low, medium, high) and the company's history of violations. The penalties set out in the proposed regulations range from C$1,000 to C$25,000 per violation for which an NoV was issued. Early payment may reduce the amount of the penalty.

A person can also request the opportunity to enter into a compliance agreement with the minister of health. This may result in a reduction of the penalty. The compliance agreement may contain any terms and conditions, including a requirement to give security as a guarantee.

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?

A person who manufactures, imports, or sells a consumer product in Canada, who receives information respecting an event, must report the event if it is 'related' to a consumer product and it constitutes an 'incident'. The report must be provided to Health Canada and to the person from whom they received the consumer product.

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

There is essentially a two-step inquiry for determining whether an event is reportable:

- Is the event 'related' to a consumer product that the company manufactures, imports or sells in Canada?
- Does the event meet one of the criteria comprising an incident?

Health Canada has indicated that if a recall has been initiated in another country on a product that contains the same component part as the product sold in Canada, this may constitute an event 'related' to the latter product notwithstanding that the two products may not be the same.

Information regarding an incident that may be considered a reportable incident can come from a variety of sources, including but not limited to:

- consumer complaints or product liability lawsuits or claims;
- notification by government (including Health Canada) or standards bodies;
- notification from the person they obtained the product from or to whom they sold the product;
- notification by a non-government organisation; and
- receipt of reports from experts, test reports, scientific or epidemiological studies or other relevant information.

In determining whether there is a 'reportable incident', the following questions should be asked:

- Does the event relate to a consumer product that is sold, manufactured or imported into Canada (including its components, parts or accessories or packaging)?
- Does it meet the criteria of an incident in any one of paragraphs 14(1) (a) to (d) of the CCPSA?
  - (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) recall or other measure that was initiated for human health or safety reasons by another jurisdiction (including foreign entity).
- Does it indicate an unreasonable hazard posed by the normal or foreseeable use of the product or the foreseeable misuse of the product?

A related event may involve a consumer product that shares a component, accessory or part with a product involved in an incident.

Manufacturers, importers and sellers of consumer products must report 'information within their knowledge' to both Health Canada

and the person from whom they received the product within two calendar days of becoming aware of an incident. If a reporting date falls on a holiday or Sunday, the report will be due by midnight in the local time zone on the next non-holiday. Health Canada has indicated that the two-day mandatory reporting period is subject to some interpretation with regard to the length of time it may take to investigate and determine that there is a reportable incident.

Within 10 days, the manufacturer or importer must submit a further report about the incident, the product involved, any other products that could be involved in similar incidents, and any proposed response to Health Canada.

Health Canada expects that manufacturers/importers will first do an investigation and evaluation of reported events in order to determine whether this is a CCPSA 'incident' that should be reported to Health Canada. There is no timeline per se for these investigations or evaluations. However, if Health Canada learns of an incident before it is reported by the manufacturer, importer or seller, this may trigger compliance issues.

On the other hand, if someone else in the supply chain reports an incident to Health Canada, it is possible that the manufacturer, importer or seller may determine that it is not a reportable incident.

The online reporting form is the same for both the two-day and the 10-day reporting requirement. Health Canada expects that the reporter may leave some areas blank when making the two-day report, but will have completed all sections of the document when making the 10-day report.

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

Health Canada has web-based incident report forms for industry and consumers, which can be submitted directly to Health Canada online. Health Canada, however, does not act as a single window for other federal and provincial reporting bodies and their regulatory requirements. A report to Health Canada does not constitute a report to any other regulatory authority. Depending on the type of product, there may be several levels of government and government departments that regulate product recalls. Because of this overlap in the regulatory scheme, the manufacturer, importer or seller may need to notify several regulatory bodies of product incidents and recalls within short time frames. For example, the provincial (Ontario) Electrical Safety Authority (ESA) and Health Canada continue to discuss the scope of their overlapping responsibility with respect to incident reporting pertaining to electrical consumer products. At present, an incident report related to electrical consumer products needs to be made to both Health Canada and ESA.

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

The mandatory report must be delivered to Health Canada within two days after the day following awareness of the incident and must include:

- information about the incident;
- information about the product involved in the incident;
- information about any products that they manufacture or import, as the case may be, that to their knowledge could be involved in a similar incident; and,
- any measures they propose to be taken with respect to those products.

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

A subsequent more detailed report is due within 10 days following the initial report.

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

Health Canada has undertaken a risk-based approach to compliance and enforcement. As noted above, there is a range of penalties for violation of the CCPSA.

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

While confidential business information (CBI) submitted to Health Canada under the CCPSA is subject to the confidentiality provisions of the CCPSA, Health Canada may disclose personal information or CBI without consent where it is deemed necessary to address a serious and imminent danger. In these circumstances, it is open to manufacturers, importers and retailers looking to keep information confidential to seek to obtain a sealing order to protect against disclosure. Typically, a sealing order will keep documents out of the publicly available court record. It should be noted that it is difficult to obtain a sealing order unless there is a broad public interest in maintaining confidentiality.

If a person who manufactures, imports or sells a consumer product in Canada believes that information provided to Health Canada falls within the definition of CBI under the CCPSA, they should clearly indicate this to Health Canada at the time they provide the information.

To be considered CBI under the CCPSA, information respecting a person's business or affairs must meet all of the following criteria:

- it is not publicly available;
- it is information in respect to which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available; and
- it has actual or potential economic value to the person or their competitors because it is not publicly available and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors.

Pursuant to section 16, the minister may disclose CBI in relation to a consumer product without the consent of, or notice to, the person whose business or affairs the information relates if the disclosure is made to a person or government that carries out functions relating to the protection of human health or safety or the environment; and the person or government to whom the information is to be provided agrees in writing to maintain its confidentiality and to use it only for the purpose of carrying out functions relating to the protection of human health or safety or the environment.

Under section 17, the minister may disclose CBI in relation to a consumer product without the consent of the person to whose business or affairs the information relates and without notifying that person beforehand if the consumer product is a serious and imminent danger to human health or safety or the environment, and if the disclosure of the information is essential to address the danger. Subsection 17(2) requires that notification of the disclosure be provided to the person to whose business or affairs the information relates no later than the next business day following the disclosure.

The Access to Information Act (ATIA) allows Canadians access to federal government records. Such records may be made available through the ATIA in response to an access request. While provisions of the act specify what can be disclosed or exempt from disclosure, exceptions to this right of access are to be limited and specific. If a request is made under the ATIA, information will be dealt with in accordance with the act, including in section 20 which addresses third-party information.

The Privacy Act and section 15 of the CCPSA govern the collection, use and disclosure of personal information and the ATIA applies to the disclosure of CBI if a request for access to the information is made.

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

Information that is voluntarily disclosed to Health Canada as part of the reporting procedures or incident notification procedures under the CCPSA may be disclosed to prosecutors as evidence in prosecutions under the act. Disclosures made under regulatory schemes are deemed to be voluntary, and do not count as self-incrimination so long as the purpose of the disclosure is a legitimate regulatory objective. An individual may be convicted of a regulatory offence on the basis of a record or return that he or she is required to submit as one of the terms and conditions of his or her participation in the regulatory sphere.

Information that a manufacturer or importer is ordered to provide by written notice from the minister under section 12 of the CCPSA may not be used to incriminate a person in a proceeding against them under the act. This keeps the CCPSA in line with the constitutional protection from self-incrimination.

Product recall requirements

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

A person who manufactures, imports, or sells a consumer product in Canada and receives information respecting an event is required to report the event if it is 'related' to a consumer product, and if it constitutes an 'incident' as set out in the CCPSA.

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?

A consumer product may be recalled on a voluntary basis or may be ordered to be recalled by Health Canada.

The CCPSA grants Health Canada powers to order a person to take certain measures including but not limited to:

- stopping the manufacturing, importation, packaging, storing, advertising, selling, labelling, testing or transport of consumer goods;
- carrying out testing or studies; and
- any measure that Health Canada considers necessary to remedy non-compliance with the CCPSA, including any measure to address or prevent a danger to human health or safety.

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

Health Canada has not yet issued guidelines for the content of voluntary recall notices.

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

Health Canada has not specified what media must be used to communicate recalls to users or suppliers.

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

The CCPSA does not provide guidance with respect to the period of time after which a recall is deemed to be satisfactory. Inspectors work with the person recalling the products to ensure the products are removed from the market in a timely fashion. Historically, Health Canada has required the party recalling a product to prepare a report that identifies the parties notified of the recall, method of notification, number of recalled units, and a summary of the actions taken to return, repair or destroy the recalled products.

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

The mandatory incident report must include a range of measures to address the cause of the incident with respect to the consumer product; however, there are no mandatory remedial measures specified by the CCPSA.

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

Penalties under the CCPSA include fines as well as other more serious penalties where it can be proved that the contravention was done knowingly or recklessly.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

The CCPSA is enforced by Health Canada inspectors. Inspectors have broad search and seizure powers under the act. They may enter any place or conveyance where consumer products or related documents are stored, manufactured, sold, imported, packaged, advertised, labelled, tested, or transported and seize, photograph, open, move, test, and examine items. They do not require consent or a warrant to enter any place except for dwelling houses.

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

The types of consumer product safety alerts published by Health Canada include:

- Consumer Product Recall;
- Health Canada Public Advisory; and
- Health Canada Information Update.

Health Canada also posts a number of industry risk communications:

- Health Product Recall Notice – these notify health professionals when a product has been recalled by the manufacturer and include an explanation of why the recall has occurred.
- Industry-Issued Public Communication – intended for the general public, these communicate new health safety information to the public regarding marketed health products.

Health Canada issues a number of risk communication documents for marketed health products, food, pesticides and consumer products:

- Health Canada Public Advisory – Public Advisories provide information regarding products that may pose a health risk.
- Health Canada Information Update – Information Updates are used when the nature of the communication is less urgent than for an Advisory.
- Health Canada Foreign Product Alert – these online messages provide general warnings about health products originating in other countries that have been found by other regulators to pose a risk to health.
- It's Your Health Bulletin – these bulletins are fact sheets advising Canadians about the benefits and risks of products, procedures and substances.

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

Under subsection 31(1) of the CCPSA, the minister has the authority to order a recall if he or she 'believes on reasonable grounds that a consumer product is a danger to human health or safety'. An order

for recall must be issued in writing and must include a statement of the reasons for the recall and the time and manner in which the recall is to be carried out.

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

The CCPSA does not provide a mechanism for recovery of costs incurred by government authorities in relation to product safety or recalls.

23 How may decisions of the authorities be challenged?

A person who has been ordered to recall a consumer product or take another measure may request in writing to have the order reviewed. The request must specify the grounds for review and include evidence in support of the request. The recall order remains in force pending review of the order. The review process can result in the order being confirmed, amended or terminated.

A prosecution is subject to the rules of court in a criminal or regulatory matter and may be subject to appeal or judicial review in certain circumstances.

It goes without saying that consumer product recalls can spawn product liability claims. Product recall notices are a source of information for plaintiffs' counsel to monitor and investigate potential lawsuits.

Most Canadian jurisdictions have not adopted US principles of strict liability. Jury trials are relatively rare in product liability cases in Canada. In Ontario, for example, product liability law is governed by the common law of the tort of negligence. In general terms, this means that the plaintiff must prove on a balance of probabilities that the defendant's product is defective and that the defendant failed to meet the standard of reasonable care in preventing the defect. This can be a manufacturing defect, a design defect or a warning defect. In Canada, liability does not flow from the fact that there was a defect in the manufacture of the product alone. The court must also find that the manufacturer failed to take all reasonable steps to guard against the product being manufactured with that defect.

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?

Where a manufacturer shows that a product recall was reasonable in the circumstances, it has an ongoing obligation to warn consumers of any remaining risks. The main issues in Canadian product liability cases are:

- manufacturing defect;
- design defect; and
- breach of duty to warn.

On the latter point, the Ontario Court of Appeal has set out the following general principles applicable to the determination of a manufacturer's duty to warn:

- a manufacturer of a product has a duty to warn consumers of the dangers inherent in the use of its product of which it knows or has reason to know;
- once a duty to warn is recognised, it is manifest that the warning must be adequate;
- the warning should be communicated clearly and understandably in a manner calculated to inform the user of the nature of the risk and the extent of the danger; it should be in terms commensurate with the gravity of the potential hazard and it should not be neutralised or negated by collateral efforts on the part of the manufacturer;
- the nature and extent of the warning depends on what is reasonable having regard to the facts and circumstances relevant to the product in question; and
- generally, the warning must be addressed directly to the person likely to be injured.

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

In Canadian litigation, disclosure must be made of every record relevant to any matter in issue in an action that is or has been in the possession, control or power of a party subject to claims of privilege.

Update and trends

The relationship between product recalls and class actions is well established by case law. The CCPSA has created an environment ripe for cross-border class action lawsuits. Canadian courts appear willing to certify classes extending beyond Canadian borders despite the existence of parallel proceedings.

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