CONSUMER PRODUCT SAFETY REGULATION AND INCIDENT REPORTING IN CANADA

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THE *CANADA CONSUMER PRODUCT SAFETY ACT*

Health Canada is the Canadian federal agency that many U.S. and international manufacturers are most familiar with. Nevertheless, the scope of Health Canada's jurisdiction over consumer products was, until the coming into force of the *Canada Consumer Product Safety Act*, S.C. 2010, c. 21 (the "**CCPSA**"), relatively limited. Health Canada's power to regulate in this area was historically derived from the *Hazardous Products Act*, R.S.C. 1985, c. H.3 (the "**HPA**"). In general terms, the HPA set out certain classes of prohibited and controlled products, and accorded Health Canada the power to enforce those prohibitions and controls. Most germane for our purposes, Health Canada had no jurisdiction over electrically-powered consumer products. Even where a product fell under Health Canada's jurisdiction, it had no power to order a recall. That all changed with the introduction of the CCPSA on June 20, 2011.[1] The CCPSA ushered in a new regime under which Health Canada was accorded significantly expanded powers and responsibilities.

The Application and Scope of the CCPSA

The CCPSA applies to manufacturers, importers, distributors, and retailers alike. The Act and its regulations applies to consumer products, anything used in the manufacturing, importation, packaging, storing, advertising, selling, labelling, testing or transportation of a consumer product, and any document that is related to any of those activities or to a consumer product.[2] The Act broadly defines "**consumer product**" 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."[3] (emphasis added)

Prohibitions

The CCPSA contains a general prohibition against the manufacture, importation, advertising, or sale of a consumer product that fails to comply with the regulations made thereunder, or that is a danger to human health or safety.[4]

The Act defines "**danger to human health or safety**" as:

> …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."[5]

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[1] Bill C-36 was passed by the Senate on December 13, 2010, and received Royal Assent on December 15, 2010.[1]

[2] CCPSA, s. 2, "article".

[3] *Ibid.*, s. 2, "consumer product".

[4] *Ibid.*, sections 6-8. See also definition of "danger to human health or safety" in s. 2.

[5] *Ibid.*, s. 2, "danger to human health or safety".

The Act also includes a specific prohibition against advertising or selling a consumer product that is the subject of a mandatory recall ordered by the Minister of Health, or that is the subject of a voluntary recall that was undertaken because the product is a danger to human health or safety, or that is the subject of a corrective action that has been ordered, but not yet carried out.[6]

The CCPSA includes prohibitions against the labelling or advertising of consumer products in a manner that is false, misleading or deceptive or that may reasonably be expected to "…create an erroneous impression regarding the fact that it is not a danger to human health or safety, its certification related to its safety or its compliance with a safety standard or the regulations."[7]

Offences and Penalties

A contravention of the Act, or its regulations, exposes organizations and individuals to significant offences and monetary penalties. On conviction on indictment, a person who contravenes the Act (with the exception of sections 8, 10, 11 or 20) faces a fine of up to $5 million and/or imprisonment for not more than two years. On summary conviction, the maximum fine is $250,000 and/or no more than six months' imprisonment for a first offence, and up to $500,000 and/or not more than eighteen months' imprisonment for subsequent offences. Where the contravention is of section 8, 10, 11 or 20, or a wilful or reckless contravention of any other section of the Act, on indictment, the fine is in the discretion of the court, and the offender risks imprisonment for up to five years. On summary conviction for such contraventions, an offender faces a fine of up to $500,000, and/or eighteen months' imprisonment for a first offence, and up to $1 million and/or two years' imprisonment for subsequent offences.[8]

In essence, the Act creates two classes of offences. Section 41(1) creates the general offence for any contravention of the Act (other of sections 8, 10, 11, and 20), its regulations, or an order made under the Act. A due diligence defence is available to prosecution under this section. The plain language of the CCPSA suggests there is no due diligence defence available for, for example, the offence of selling or advertising a consumer product that is a danger to human health or safety found in section 8 of the CCPSA. That said, section 8 (and sections, 10, 11, and 20) expressly includes a knowledge or *mens rea* component.

Administrative Monetary Penalties

The Act also provides for administrative monetary penalties ("**AMP**") of up to $25,000 for breach of orders made by inspectors appointed under the CCPSA.[9] The AMP regime is set out in the Administrative Monetary Penalties (Consumer Products) Regulations, SOR/2013-101 (the "**AMP Regulations**"). An inspector may issue a notice of violation ("**NOV**") of a mandatory order made under sections 31, 32, or 35 of the Act. The administrative monetary penalties range from $10,000 to $25,000 depending on the "gravity factor" applicable to the violation.[10] Manufacturers should ensure that a process is in place to review and respond to any AMP. If paid within a prescribed time (15 days from the NOV), the entity against which the NOV is issued is able to discharge it by paying one-half of the original amount set out in the NOV.

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[6] *Ibid.*, s. 8.

[7] *Ibid.*, sections 9 and 10.

[8] *Ibid.*, s. 41. An offence that is committed or continued for more than one day constitutes a separate offence on each day that it is committed or continued: s. 44.

[9] *Ibid.*, s. 50.

[10] Administrative penalties for non-profit organizations range from $1,000 to $5,000.

The amount of the AMP depends on a variety of factors, including the section under which the order that was not complied with was made, and the prior history of non-compliance. The AMP Regulations also provide for a review of a NOV and administrative monetary penalty that exceeds $5,000 on limited grounds by the federal Minister of Health.

Directors' (and Others') Liability

The CCPSA holds individuals who participate or acquiesce in a corporation's contravention of the Act vicariously liable. This exposure is not limited to the corporation's directors or officers or other "directing minds". Rather, the Act provides:

> If a person other than an individual commits an offence under this Act, any of the person's directors, officers, agents or mandataries who directed, authorized, assented to, acquiesced in or participated in the commission of the offence is a party to the offence and is liable on conviction to the punishment provided for by this Act, even if the person is not prosecuted for the offence.[11]

Orders, Inspections, and Injunctions

The CCPSA empowers Health Canada to order that a manufacturer or importer conduct tests or studies to verify compliance or prevent non-compliance with the Act and its regulations.[12] Note that there is no requirement that the Minister have reasonable grounds to believe there has been a contravention of the CCPSA before ordering the manufacturer or importer to undertake testing, nor is the power tempered with any other "reasonableness" requirement. To our knowledge, the CPSC does not have the power to order that manufacturers conduct testing.

Inspectors appointed under the Act are accorded broad and sweeping powers to enter any place where a consumer product is being manufactured, imported, packaged, stored, advertised, labelled, tested, or transported, all without the necessity of a warrant.[13] Once inside, inspectors are empowered to, among other things, examine, test, take copies, access electronically stored information, and detain.

The CCPSA also provides for an application to the court for an injunction where it appears that a person is "…about to do or is likely to do an act or thing that constitutes or is directed toward the commission of an offence under this Act…".[14]

Mandatory Recalls and Corrective Actions

The CCPSA empowers the Minister to order that a consumer product be recalled by the importer, manufacturer or vendor of the consumer product,[15] if the Minister believes on reasonable grounds that a consumer product is a "danger to human health or safety."[16]

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[11] *Ibid.*, s. 42.

[12] *Ibid.*, s. 12.

[13] *Ibid.*, ss. 21(1). Where the place searched is a "dwelling house", the inspectors are not able to enter without the consent of the occupant or a warrant issued under the CCPSA: s. 22(1).

[14] *Ibid.*, s. 36.

[15] *Ibid.*, s. 31.

[16] *Ibid.*, s. 31.

If a manufacturer fails to comply with a mandatory recall order, Health Canada may, on its own initiative and at the manufacturer's expense, conduct the recall or other corrective action.[17] To our knowledge, the CPSC does not have the power to conduct, and charge-back, the expense of a recall.

Requests for Reviews of Recall Orders

A manufacturer (or other party) against whom a recall order is made can request an administrative review of the order by a review officer (basically, an inspector other than the one that made the order) on grounds that involve questions of fact alone, or law and fact.[18] A request for a review must be made within seven (7) days of the date on which the order was "provided", and unless the review officer decides otherwise, the order remains in force pending the outcome of the review, which must be completed no later than thirty (30) days after the review request is provided to the Minister. The review, which is conducted by a single inspector other than the one that made the order, is to be completed no later than 30 days after the day on which the request for review is made. The order remains in force during the review unless the review officer decides otherwise.[19]

Document Retention and Notice Requirements

Any person who manufactures, imports, advertises, sells, or tests a consumer product for commercial purposes is obliged to prepare and maintain (and retain for six years) certain prescribed documents including:[20]

(a) in the case of a retailer, the name and address of the person from whom they obtained the product and the location where, and the period during which, they sold the product; and

(b) in the case of any other person, the name and address of the person from whom they obtained the product and to whom they sold it, as the case may.[21]

Incident Reporting Requirements

Manufacturers are required to give the Minister notice of any "incident".[22] The definition of "incident" is broad, and includes:[23]

(a) an occurrence in Canada or elsewhere that resulted, or that may reasonably be expected to have resulted 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;

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[17] *Ibid*., s. 33.

[18] *Ibid*., s. 35

[19] *Ibid*., s. 35.

[20] *Ibid*., ss. 13(1).

[21] The types of documents that importers and others are obliged to create and maintain may be prescribed by regulation. The Act provides that importers of consumer products are obliged to provide the federal Minister (of Health) with the documents prescribed by regulation when (or before) the product is imported.

[22] The incident reporting obligation extends to importers, and sellers of consumer products.

[23] Act, ss. 14(1)

(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; and

(d) a recall initiated for human health or safety reasons by, among others, a foreign entity (which is currently undefined in the CCPSA but would, on its face, include CPSC-initiated recalls).

Note that the reporting obligation under the CCPSA extends to incidents in Canada and "elsewhere in the world." That said, incidents that take place outside of Canada that involve products not sold or imported in Canada should not, in our view, trigger a reporting requirement.[24]

The Act imposes a two-stage reporting regime that may be summarized as follows:[25]

(a) within two (2) days after the date on which the manufacturer becomes aware of the incident, manufacturers are required to provide the Minister with, "…all the information in their control regarding any incident..."; and

(b) within ten (10) days after the day on which the manufacturer becomes aware of the incident, or within such other period as the Minister may specify in writing, manufacturers are required to provide a report that includes:

> …information about the incident, the product involved in the incident, ***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 be taken with respect to those products… .[26] (emphasis added)

The Act does not define "serious adverse effects" on health. That said, Health Canada has offered some guidance as to the types of events that are reportable under the new regime. The guidance on mandatory reporting suggests that a manufacturer should apply the following considerations in determining whether an event constitutes a reportable "incident":

(a) did it manufacture the product at issue in the event or occurrence? If so;

(b) does the event meet the criteria for an "Incident", as set out in section 14(1) of the CCPSA (see Incident Reporting Requirements above); and

(c) does the event indicate an unreasonable hazard posed by the normal or foreseeable use of the product, or the foreseeable misuse of the product? Note that the unreasonable hazard aspect of the guidance document, though an apparent (and welcome) attempt to help harmonize the reporting regimes in the U.S. and Canada, is not derived from the Act or its regulations.

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[24] See the definitions of "import" and "sell" in s.2 of the Act. Note, however, that an incident involving a product that is not sold in Canada, but that is very similar in design and construction to one that is, may give rise to a duty to report.

[25] Act, ss. 14(2) and (3).

[26] *Ibid*., ss. 14(3).

Health Canada has also clarified that a company does not become "aware" of an "incident" until reasonable consideration of all three of these questions. Health Canada has acknowledged that manufacturers, importers, and sellers may have to conduct an investigation before they can reasonably come to a conclusion. The two and ten day timelines for the delivery of a report do not begin to run until that investigation is complete and the questions have been answered in the affirmative.

Manufacturers need to implement systems and processes to identify potentially reportable incidents, and to equip their organizations with the resources to make and respond to reports and regulators' inquiries in a timely, cogent, and consistent fashion. The effective management of these reporting requirements should be considered an essential element of the risk management plan of any company that makes, sells or distributes consumer products in Canada.

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Christopher advises and represents manufacturers, importers, and distributors and their captive insurers on products matters including the defence of product liability claims and products-related class proceedings, recalls and related regulatory matters. He advises and represents manufacturers and distributors in connection with reporting obligations imposed by Health Canada's *Canada Consumer Product Safety Act*, and in relation to related regulatory investigations.

He has acted in the defence of claims and in connection with recalls and corrective action plans involving a wide variety of products including major and small appliances, consumer electronics, HVAC systems, power tools, floor care products, industrial machinery, safety equipment, outdoor products, building and construction materials, and processed foods.

Mr. Diamond frequently works with manufacturers and their in-house and external counsel, claims managers, and product safety managers to co-ordinate incident reporting, the defence of products-related claims, and recalls of products that are distributed in both Canada and the United States.

He has acted as defence counsel in product liability class proceedings, including the defence of a multi-jurisdictional product liability class action brought against a major appliance manufacturer. He regularly defends product liability claims involving allegations of fire damage, working with local and international forensic engineers and fire investigators, and is familiar with NFPA 921.

Christopher is also retained to assist his clients in the negotiation, preparation and litigation of agreements relating to the sale and distribution of their products including vendor agreements, supplier agreements, indemnity claims, and distribution agreements. He is a member of, among others, the, American Bar Association, Defence Research Institute, International Consumer Product Health & Safety Organization, Advocates' Society, Canadian Bar Association, and Canadian Defence Lawyers' Association.