McMillan Corporate Counsel CPD Series - Canada's Consumer Product Safety Act: Where Are We Now?

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Outline

- Health Canada's Experience in 2012
- Interpreting and Applying Key Provisions
  - Prohibitions
  - Record-keeping
  - Mandatory Reporting of Incidents
- Compliance and Enforcement Activities
- Anticipated CCPSA Developments in 2013
- Questions

Health Canada's Experience in 2012

- Emphasis remains on voluntary compliance and education – for now.
- Health Canada's key areas of activity:
  - "Active Prevention"
  - "Targeted Oversight"
  - "Rapid Response"
- Health Canada's main complaints – under-reporting; timing requirements not met; interpretation of "unreasonable hazard" too technical.

Prohibitions

The Expectation - Industry Awareness

- Ultimately, the supply chain must ensure that products brought into, made and sold in Canada are compliant with the CCPSA.
- Expectation of industry awareness of:
  - CCPSA recalls
  - CCSPA notifications
  - Amendments to product safety standards

Prohibited Products & Activities

- The CCPSA also prohibits the manufacture, importation, advertisement or sale of consumer products that are prohibited or do not meet requirements of product-specific regulations.
- Prohibited products are listed in CCPSA s. 5, Schedule 2) - new prohibition proposed for children's products made with polyurethane foam that contains tris (2-chloroethyl) phosphate).
- Products subject to regulation - regulatory non-compliance is not necessarily subject to mandatory reporting requirements – there must still be a serious injury or health risk

The General Prohibition

- Manufacturer and importers are prohibited from **manufacturing, importing, advertising or selling**; and
- **Any person** is prohibited from **knowingly advertising or selling**….

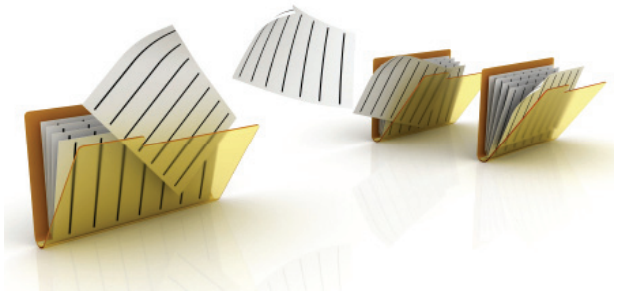
…a consumer product that:

- is a **danger to human health or safety**;
- is the subject of a recall order, or is the subject of a voluntary recall in Canada because the product is a danger to human health or safety; or
- is the subject of a measure that was ordered to be carried out, but wasn't.

Record-keeping in Practice

Production of Records

- Must produce “prescribed documents” at time of importation.
- Otherwise, must keep required records 6 years and be able to produce on written request by Health Canada within time requested.
- Records are focused on ensuring traceability to permit effective recalls



Common Questions

- What about personal information?
- What are the requirements for “prescribed documents”?
- Location of electronic records
- Authorization to store records outside of Canada

Update on Mandatory Reporting

The Basic Reporting Obligation

- CCPSA imposes mandatory incident reporting for manufacturers, importers and sellers.
- There are two separate reporting duties:
  - A two-day requirement for manufacturers, importers **and** sellers; and
  - A ten-day requirement for manufacturers **or importers**.
- Language of the mandatory reporting provision is broad, and guidelines do not have the force of law.

Interpretation Points - When Do You Become “Aware” of an “Incident”?

- Health Canada has taken the position that:
  - the CCPSA requires a person to determine (i) whether an event is "related" to a consumer product that they manufacture, import or sell in Canada and (ii) that the event is an Incident; and
  - it is only once a person has completed this determination and become "aware" of an incident that the 2 and 10 day timelines specified in the CCPSA commence.

Interpretation Points – “Awareness”

- Information about an Incident may come directly from consumers (reports, complaints or lawsuits).
- Per Health Canada, other possible sources include:
  - Information received from governments, standards bodies, suppliers, customers, NGOs;
  - reports from experts, test reports, studies;
  - any other direct notification with enough detail for evaluation.




Interpretation Points – "Incident"

– An "Incident" is…
  - an occurrence in Canada or elsewhere;
  - a defect or characteristic; or
  - incorrect or insufficient product information

  that resulted, or may reasonably have been expected to result, in death or in serious adverse effects on health, including serious injury.
– An Incident also includes…
  - a recall initiated (anywhere) for health or safety reasons.
– Incidents can include normal or foreseeable use **or misuse**.

Health Canada's Guidance:

What Level of Inquiry is Required?

- Little to no guidance on what is “reasonable inquiry”
- Duty to report not avoided by insufficient or inadequate inquiry to allow a company to reach conclusion
- Do you have time to investigate?
  - Yes! Investigation can be undertaken before timelines start to run
  - BUT no guidance on what amount of time is reasonable for investigation

Two-Day Reporting Requirement

- Within two days of awareness, an Incident must be reported.
- Retailers must report to…
  - Health Canada; and
  - the person from whom you got the product.
- **You must report even if the manufacturer or importer has already reported.** Health Canada expects multiple reports - the manufacturer, importer and seller all must report.

What and How to Report?

- All relevant information within one's control regarding the Incident must be reported.
- Health Canada industry on-line reporting form: **http://www.hc-sc.gc.ca/cps-spc/advisories-avis/incident/cpir-ricpc-i-eng.php**
- Or by email, fax or mail

Health Canada / Santé Canada

Your health and safety... our priority.

Consumer Product Incident Report: Form for Industry

Office use only:

Date Received	Form Identifier
	CPS-SPC-0003.03

1 Information about this report

Protected when completed and received by Health Canada
Treasury Board Secretariat Government Security Policy

Case Number:		Submission Number:	
Product Type:			
Report Type: *	New		

Purpose of report:

- ☐ 14(2) - Information regarding incident (Section 7 not required)
- ☐ 14(3) - Manufacturer/Importer report (Section 7 required)
- ☐ Notification - evaluated as not an incident

NOTE: If you have received this report from a customer, you will find your information in area 6. If you want to report to Health Canada with no changes to the content of the report, go to section 6 and click the Confirmation Report button.

2 Information about who is reporting

Business Name (Full legal name - no abbreviations):					
Address:					
City:			Province / Region:		
Country:		Postal Code:		Website:	

Who are you? *					
Name: *		Title:			
Email:		Telephone:		Fax:	

Claim of Confidentiality and Privacy Notice

Claim of Confidential Business Information. The person submitting this report claims that this report and all attachments are confidential business information on the basis of the definition under Section 2 of the CCPSA. *

Under the *Canada Consumer Product Safety Act* (CCPSA) manufacturers, importers and sellers of a consumer product for commercial purposes are required to provide information regarding any incident related to the product. Some of the information required may be personal information as that term is defined under the *Privacy Act*. The information is being collected for the purpose of assessing and mitigating risks to human health or safety from consumer products. Non-compliance with the provisions of the CCPSA may result in prosecution.

Personal information that you provide is protected under the provisions of the *Privacy Act*. Personal information will be stored in a Personal Information Bank entitled "Incidents, Complaints and Adverse Effects" (HCan PPU 088). The *Privacy Act* provides a right of access and to have incorrect information changed. Should you require clarification about this statement, contact our Privacy Coordinator (http://www.hc-sc.gc.ca/contact/ahc-asc/csb-dgsg/atip-aiprp-eng.php).

3 Information about the incident

If more than one person was affected, please report on the worst case

Date of the incident:		Number of people affected:		Sex:		Age (years)	
Incident Type: *	Pick worst case		Injury Type: *	Pick worst case			
Body Part:			Treatment: *				

Describe the incident: * Characters remaining: 4,000

* - denotes mandatory

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Canada

Consumer Product Incident Report: Form for Industry

4 Information about the product

Product Brand and Name: *			
Please include any of the information below that you can find on the product or packaging:			
Model Number:		Serial Numbers:	
Date Codes:		Universal Product Code / UPC / Bar Code:	
Certification / Standards: (e.g. CSA, ULC stickers)		Batch Number:	
Product Description: (for example: colour, packaging, warnings on the label) *			Characters remaining: 1,500

5 Information about the manufacturer from the product label or package

Business Name (Full legal name - no abbreviations):					
Address:					
City:			Province / Region:		
Country:		Postal Code:		Website:	
Email:		Telephone:		Fax:	

6 Information about where you got the product

If you are not the manufacturer or importer, you must notify the person from whom you received the product, of this incident, within 2 days. CCPSA 14(2).

When was the product acquired? (may be approximate)			From whom did you get the product?		
Business Name (Full legal name - no abbreviations):					
Address:					
City:			Province / Region:		
Country:		Postal Code:		Website:	
Contact Person:		Title:			
Email:		Telephone:		Fax:	

Quantity of Product involved:		Country of Origin:	
Production / Importation began:		Ended:	
Distribution began:		Ended:	
Retail Sale began:		Ended:	

Confirmation Report

* - denotes mandatory

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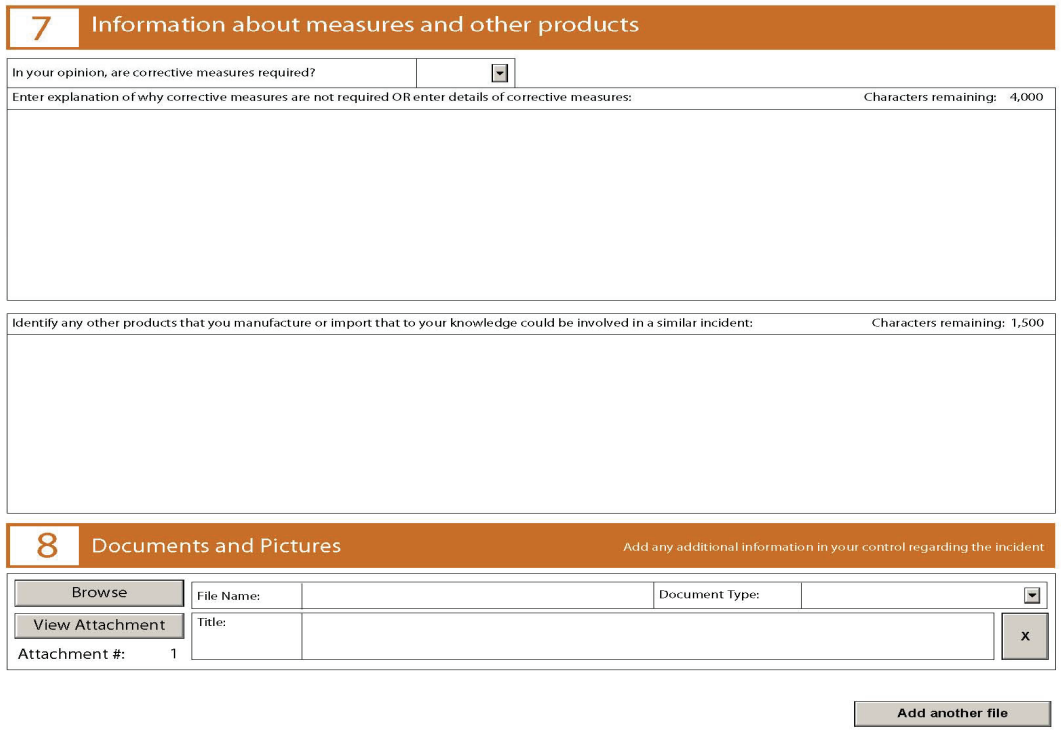
Consumer Product Incident Report: Form for Industry



* - denotes mandatory

Consumer Product Incident Report: Form for Industry

9 Administrative Information

Health Canada invites you to subscribe to our consumer product safety newsletter so you can receive the latest news and information.

How were you made aware of the incident?	

How to submit your incident report:

- ○ Save the report and submit it online.
- ○ Save the report, burn to CD/DVD and submit by post.
- ○ Save the report, print and submit by post.

Save | Print Form

* - denotes mandatory

The Ten-Day Requirement in Practice

- Within **ten days** of awareness of an Incident, manufacturers **or importers** must submit a written report (on-line form) to Health Canada.
- Same form (and HC case number) as Two-Day report, but must contain information about:
  - the Incident;
  - the product involved;
  - other products that could be involved in a similar incident; and
  - any proposed countermeasures (s. 7 of the form).

The Ten-Day Requirement Cont'd

- If the manufacturer's first report is a combined two and ten-day report, Health Canada will question whether there was timely reporting following "initial awareness".
- If 10 days is insufficient to reach conclusions, extension can be requested.
- If company is awaiting CPSC approval of corrective action plan, that should be reported.

“Null Reports”

- Section 1 of the on-line reporting form also allows for submission of a report as a mere notification where an event has been evaluated as “not an Incident”.
- used where consumers or retailers file incident reports and the company does not believe the event is a reportable Incident.
- “Not an Incident” reports also used where a company does not believe there has been a reportable incident but wants to report out of an abundance of caution because of specific consumer reports or because they have reported to the CPSC.

Other Reporting Considerations

- Health Canada wants to hear from you early and often – they want a dialogue, not one-time reporting.
- Advise Health Canada if you are working with other agencies ESA, TSSA – dual reporting not always necessary
- Confidentiality - incident reports and attachments are not exempt from disclosure under the Access to Information Act (though actual grants of access have not occurred)

What Happens When You Submit a Report?

- Health Canada case number and submission number assigned (case number to be given to the supplier and used for any subsequent reports)
- Health Canada's "Triage" approach
  - Entry of report into HC system
  - Administrative screening of report
  - Prioritization of report
  - Report sent to group best placed to take action
  - Proposed mitigation/corrective/other measures considered (if necessary)

Examples of Prioritization Considerations

- Injury severity
- “Near-miss” significance
- Victim age; target age for product
- Product factors (e.g. new/used)
- Product industry history
- Usage of product
- Risk issue consideration (media attention, product attention, jurisdiction, etc.)

Not Every Report Will Generate a Response to the Reporter

- Health Canada will not respond to every report – “silence” is good news though there is no deadline by which they must respond which can create uncertainty.
- The triage system is focussed on “high risk” events.
- Reports may be used to collect information about emerging trends and how consumers are interacting with products.
- Health Canada less likely to intervene where company is known to have a robust field data evaluation program.

Health Canada CCPSA Powers

Recalls and Corrective Actions

- If the Minister believes on reasonable grounds that a consumer product is a danger to human health or safety, he or she may order a person who manufactures, imports or sells the product for commercial purposes to recall it.
- However, voluntary (as opposed to mandatory) recalls remain the norm in practice.

Health Canada Inspectors

- Inspectors visit all levels of the supply chain and inspect product at Canadian ports of entry.
- Inspectors have been given broad powers to:
  - enter establishments;
  - examine or test products;
  - seize and detain articles;
  - take documents and download computer information;
  - take photos; and
  - inspect conveyances.

Importers - Tests, Studies or Compilation of Information

– Consumer product importers may also be ordered to **conduct tests or studies or compile information** necessary to verify compliance with the *CCPSA* and regulations.

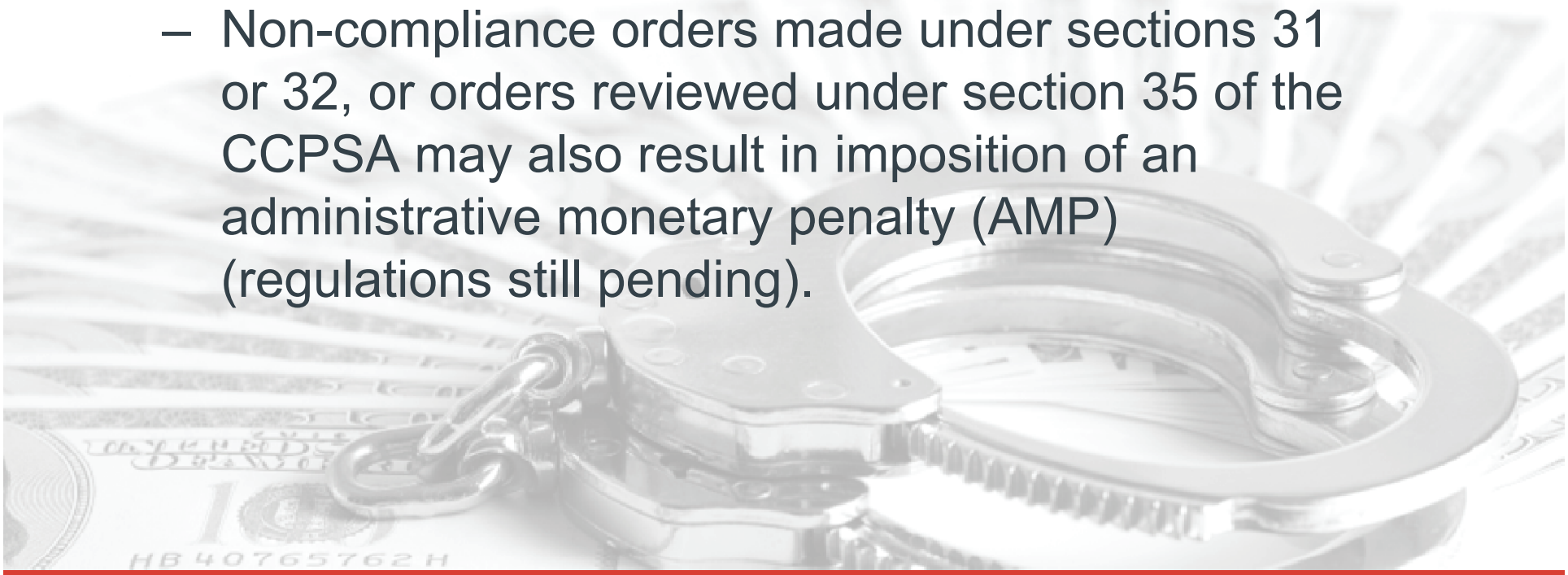
Enforcement

Enforcement and Compliance Powers

- Health Canada may issue orders to **stop the manufacturing, importation, packaging, storing, advertising, selling, labelling, testing or transportation** of a consumer product.
- Health Canada may **order any measure** considered necessary to remedy a non-compliance.

Health Canada Enforcement Measures

- Contravention of a CCPSA provision, regulation, or order, is **an offence that carries the risk of a fine and/or imprisonment**.
- Non-compliance orders made under sections 31 or 32, or orders reviewed under section 35 of the CCPSA may also result in imposition of an administrative monetary penalty (AMP) (regulations still pending).



Health Canada's Approach to Enforcement

- Voluntary corrective measures (preferred)
- Verification of corrective measures
- Seizure of product/documents/materials
- Recall and other corrective measure orders
- Issue notices of violation that give rise to AMPs
- Recalls/corrective measures carried out by by Health Canada
- Injunctions
- Prosecution

Examples of Enforcement Considerations

- Include:
  - risk to health and safety;
  - likelihood that the same problem will reoccur;
  - compliance history of the company;
  - whether the company acted with indifference or premeditation;
  - degree of cooperation offered by the company;
  - deterrence.

Anticipated CCPSA Developments in 2013

- greater focus on under-reporting and timing of initial report delivery
- new mandatory reporting guidelines
- more guidance on what "indicates an unreasonable hazard"
- possible Health Canada/ESA agreement to eliminate need for double reporting

Tips for Compliance and Preparedness

Compliance Tips

- BE PROACTIVE.
- Know, and stay current, on your obligations:
  - Track new guidance documents and regulations under CCPSA.
  - Make full use of Health Canada's multi-prong approach to industry education (sign up for electronic newsletter, use social media tools, take advantage of webinars and educational tools, become active recipients).
- Ensure accountability and clearly defined roles – you may wish to appoint a specific compliance and response person/team.
- Educate and train employees.

Compliance Tips (cont'd)

- Prepare and implement policies, processes and procedures to address CCPSA requirements, including for:
  - Record-keeping and retention;
  - Reviewing and assessing field data
  - Incident reporting;
  - Implementing recalls and corrective actions;
  - Inspections.

- ASK QUESTIONS! Seek advice BEFORE issues arise and when issues arise.

Additional Resources

- Act and Regulations, available through http://laws-lois.justice.gc.ca/.
- Guidance Documents and other industry guides, available through www.healthcanada.gc.ca/productsafety (not binding but can aid interpretation).
- To contact product safety officers in your region telephone 1-866-662-0666 or email CCPSA-LCSPC@hc-sc.gc.ca.
- Health Canada consumer product electronic newsletter, subscribe at http://www.hc-sc.gc.ca/cps-spc/advisories-avis/_subscribe-abonnement/index-eng.php

Questions?

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