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Global Product Safety: Trends & Updates

CANADA

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Outline

- What Hasn't Changed
  - CCPSA Prohibitions
  - Mandatory Incident Reporting
- What Is New?
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  - Children's Toys – New Guidance and Regs
  - New Food Safety Legislation
  - Bi-Lateral Cooperation
- Anticipated CCPSA Developments in 2013

Canada Consumer Product Safety Act Prohibitions

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.

Prohibited Products & Activities

- The CCPSA also prohibits the manufacture, importation, advertisement or sale of consumer products that are prohibited or do not comply with product-specific regulations.
- Prohibited products are listed in CCPSA s. 5, Schedule 2
- Regulated products include asbestos, candles, strollers, cribs, children's jewelery, ceramics, carpets, kettles, tents, phthalates, surface coatings, toys - 33 separate regulations

Mandatory Incident 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”?

- First you determine (i) whether an event is "related" to a consumer product that you manufacture, import or sell in Canada and (ii) that the event is an Incident;
- Then you become "aware" of an Incident and the 2 and 10 day reporting timelines start to run.

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 level of investigation is required
- Duty to report not avoided by insufficient or inadequate inquiry to permit a 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

Two-Day Reporting Requirement

- Within two days of awareness, an Incident must be reported to:
  - Health Canada; and
  - the person from whom you got the product.
- **All levels must report regardless of who 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

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

Consumer Product Incident Report: Form for Industry

7 Information about measures and other products

In your opinion, are corrective measures required?

Enter explanation of why corrective measures are not required OR enter details of corrective measures: Characters remaining: 4,000

Identify any other products that you manufacture or import that to your knowledge could be involved in a similar incident: Characters remaining: 1,500

8 Documents and Pictures

Add any additional information in your control regarding the incident

Browse | File Name: | Document Type:

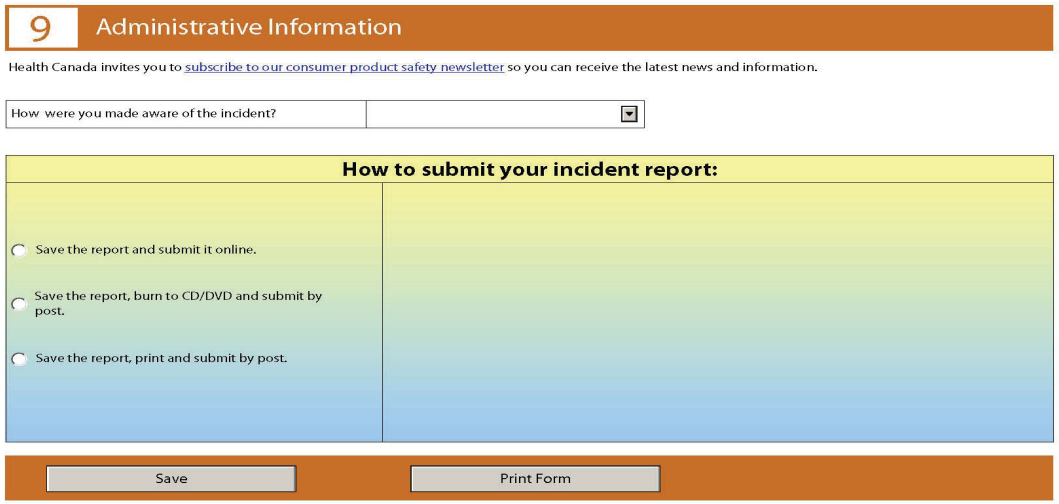
View Attachment | Title: | X

Attachment #: 1

Add another file

* - denotes mandatory

Consumer Product Incident Report: Form for Industry



* - denotes mandatory Page 4 of 4

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 product involved;
  - other products that could be involved in a similar incident; and
  - any proposed countermeasures
  - Focus will be on sections 4, 6 and 7 of the form

The Ten-Day Requirement Cont'd

- If your competitors are reporting on a similar product and you are not, Health Canada will suspect under-reporting
- If the your first report is a combined two and ten-day report, Health Canada will question whether your two day report was timely
- If 10 days is not sufficient 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 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 manufacturer or importer does not believe the event is a reportable Incident.
- 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 [yet] occurred)

Health Canada's Current Complaints

– Health Canada's main complaints
  - under-reporting – this and low population (relative to US) makes it difficult to identify trends – they want OVER reporting for now to address this
  - timing requirements not met; and
  - interpretation of "does the event indicate an unreasonable hazard" by industry has been too technical – perspective should be that of a consumer.

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

- Severity of injury
- "Near-miss" significance
- Victim age; target age for product
- Product factors (e.g. new/used)
- Product and 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 for their response which can create uncertainty.
- The triage system is focussed on “high risk” events.
- Reports may simply 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.

What Is New?

- New Guidance on Mandatory Reporting
  - Publication delayed to “early winter”
  - Lots of stakeholder consultation
  - Will likely be provided in draft with further consultation invited
  - Concept of “unreasonable hazard” to be retained but “guidance” provided

What is new?

- Children's Toys
  - New Guidance in October 2012
  - Per HC "policy", toy = for kids 13 and under
  - No express requirement for age labelling but strongly encouraged
  - "use and abuse" testing expected
  - Warnings on "adult" magnets not enough
  - New proposed regulation to prohibit children's foam products with TCEP

What is New?

- New *Safe Food For Canadians Act*
  - Consolidates 4 other Acts
  - Part of “Food and Consumer Safety Action Plan” announced in 2007 that gave us the CCPSA
  - Emphasis on traceability and improved import controls – importers now accountable
  - Broader enforcement and inspection powers
  - Still needs Royal Assent and extensive regs

What is New?

- OECD global on-line recall portal
  - Participants include Canada

- Cooperative Engagement Framework among Canada, the U.S. and Mexico on consumer product safety

Anticipated CCPSA Developments in 2013

- greater HC focus on addressing under-reporting and late 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

On-line 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