

VIA EMAIL

**February 9, 2010**

Ms. Athana Mentzelopoulos  
Director General - Consumer Product Safety Directorate  
Health Canada  
123 Slater Street, 4th Floor  
Ottawa, Ontario  
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Dear Athana,

**Re: Comments on January 28 Draft Guidance for Mandatory Incident Reporting for the CCPSA**

The Canadian Consumer Product Safety Coalition (the "Coalition") is grateful to Health Canada for sharing with us the updated draft Guidance document on January 28. As discussed during our meeting in Toronto, we have compiled our comments and recommendations to help facilitate Health Canada in redrafting its proposed Guidance document.

The Coalition hopes these comments will be helpful to Health Canada and we look forward to reviewing and offering further comment on the next draft. Please do not hesitate to contact me if we can offer any further support as Health Canada proceeds in its implementation of the CCPSA.

Sincerely,



Ralph Suppa  
Chair – Canadian Consumer Product Safety Coalition

CC.: Helen Ryan – Director – Health Canada – Risk Assessment Bureau  
Geoff Barrett – Manager – Health Canada – Surveillance Coordination Unit  
James Van Loon – Director – Health Canada – Risk Assessment Bureau  
Christopher Pollard – Information & Statistical Specialist – Health Canada – Info & Data Unit



**Comments and Recommendations on the Consumer Product Safety Directorate's**

**Draft Guidance on Mandatory Incident Reporting under the *Canada Consumer Product Safety Act* –  
Section 14 Duties in the Event of an Incident**

## **1. Introduction**

### **General Comments**

To improve clarity throughout the guidance document, critical terms should be used consistently and mirror the language used in the *Canadian Consumer Products Safety Act (CCPSA)*. For instance, the terms “*become aware*” or “*becoming aware*” should be modified to read “become/ing aware of the incident”. As well, references to a “commercial good” should be modified to read a “consumer product”.

## **2. Definitions**

### **2.1 Consumer Products**

#### **Comments**

There is confusion with respect to the definition of “consumer product” and specifically the phrase “may reasonably be expected to be obtained by an individual to be used for non-commercial purposes” and whether an incident is reportable if it occurs in a commercial environment.

The Guidance document should attempt to define “related to a product” as used in Sec. 14(2) of the CCPSA. This would help narrow the scope of reporting.

#### **Recommendations**

An example should be provided under “Consumer product” to clarify the meaning of “may reasonably be expected to be obtained by an individual to be used for non-commercial purposes” and whether an incident is reportable if it occurs in a commercial environment.

### **2.2 Days**

#### **Comments**

The reporting periods are extremely short, even if companies have done their investigation of a potential incident prior to reporting.

#### **Recommendations**

“Days” should be counted as business days, which excludes Saturdays, Sundays and both Federal and Provincial statutory holidays.

The example should include Thursday in the left hand column.

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### 2.4 Importer

#### Comments

The “importer of record”, ie. the person who has assumed responsibility for the customs clearance of products into Canada and is declared as the importer for customs purposes, may not be a resident of Canada.

#### Recommendations

“Importer” requires an explicit definition. There should be consultation with industry to define this term.

### 2.6 Seller

#### Comments

A company may have multiple business lines. For example, a raw materials supplier may also be a vendor of consumer products.

#### Recommendation

The text in the box should be modified to make it clear that the listed entities do not have reporting obligations if they are not offering consumer products for sale or lease.

### Other Definitions

In order to narrow the scope of reportable incidents to those products that present a danger to human health and safety, “related to a product” should be defined to require that (i) a causal link between the product and the incident be established; and (ii) that the product posed an unreasonable hazard – existing or potential – during or as a result of its normal or foreseeable use that resulted in or may reasonably be expected to result in an individual’s death or in serious adverse effects on their health, including a serious injury. See further discussion under Part 4.

## 3. Key Features

#### Comments

Third bullet point, second line, there is text missing after “that is”. We assume it should say “that is related to”.

The Guidance document provides that an incident includes a recall or a measure that is initiated for human health or safety reasons by, among others, a “foreign entity”. There is potential for confusion among users of the document as to the scope of the term “foreign entity”.

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A company may not be aware of a recall or measure initiated in a foreign jurisdiction, or if they are aware may have no means of determining whether it is the same product sold by the company in Canada. As well, recalls are initiated in other countries for products that fail to meet the standards established in other countries. The products, however, may meet the standard established by Canada.

### Recommendation

The Guidance document should define the term “foreign entity”.

It should also be clarified that mere knowledge of a recall or measure in a foreign jurisdiction does not obligate a company to report to Health Canada. The company’s obligation is to determine if an incident report is necessary. Such determination would be based in part on an evaluation of the product’s conformity to Canadian standards, not foreign standards. For example, reports made to the US Consumer Product Safety Commission should not automatically trigger an obligation to submit an incident report to Health Canada.

It should be clearly stated that companies will not be expected to establish international surveillance for product recalls. Governments are much better equipped to perform this function.

## 4. Determination of an ‘incident’

### Comments

The header “Determination of an ‘incident’” does not accurately reflect the substance of this section of the Guidance document and could cause confusion. The header should read “Becoming aware of an ‘incident’”. Furthermore, the substance of Section 5.1 of the Policy, which concerns how a person “becomes aware” of information concerning a potential “incident”, should be moved to Section 4. Receipt of such information would trigger an obligation to investigate whether an “incident” as defined in Section 14 of the CCPSA has occurred and thus the list belongs in Section 4 of the Guidance, rather than Section 5, which concerns making the report to Health Canada.

The Coalition is concerned that the Guidance document as drafted would trigger a vast amount of incident reporting that would be of no use to Health Canada or industry, could unnecessarily concern consumers if made public, and would be a significant burden to businesses. Such reports could lead to:

- False incident reports to Health Canada and the manufacturer
- Conflicting reports
- Duplicative reports
- Unnecessary resources being spent reporting on non-incidents
- Abuse by competitors or others

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Moreover, if the Guidance does not make it clear that there needs to be information that reasonably supports the conclusion that the product presents a “substantial product hazard” to determine there has been an “incident” the Canadian and US systems will be out of synch. There will be a major difference in what is reported in Canada and the US, and that will result in confusion for consumers, if the reporting is made public. Canada and the US are essentially a single market, and it would be very difficult for companies and Health Canada to explain why the same product was implicated in an “incident” in one country and not the other.

Further, many retailers will lack the resources or capacity to investigate to determine a reportable “incident” with respect to products that they have neither manufactured nor imported. Unless the obligations of retailers are circumscribed, they will be obligated to report anything that could potentially be an “incident,” thereby resulting in significant over-reporting that will impose unwarranted burdens both on manufacturers and Health Canada and detracting limited resources away from potentially significant safety concerns.

Experience from the US reporting model for both food and non-food products has confirmed the best practice for retailers is to notify the manufacturer and/or importer about an occurrence and to coordinate their intended corrective action together.

As well, Canada has a well established and highly effective recall system for food products. Under this system food manufacturers and importers make a determination of non-compliance and contact and work with retailers to determine whether a recall or other action is warranted. Where retailers have the knowledge of a potential issue they contact the manufacturer for the manufacturer to determine whether any action is required. This highly developed and efficient system results in over 90% recovery of recalled food products and an even higher recovery rate for large retailers.<sup>1</sup> Food retailers increasingly also sell non-food products and follow this same practice of working with manufacturers about potential incidents or recalls for consumer products.

### Recommendations

It should be clearly stated at the beginning of this section that Section 14(2) only requires a person to make a report to Health Canada after the person has “become aware” of an incident relating to a consumer product manufactured, imported or sold by the person and that this involves a two-part evaluation: (i) the person must first determine that the potential incident “related to” a consumer product manufactured, imported or sold by the person; and (ii) there was an incident as defined in Section 14 (1).

In order to better define the scope of reportable incidents, we recommend that the Guidance state that “related to the product” will be interpreted as meaning (i) that it was a product manufactured, imported or sold by the person; (ii) that there was a causal link between the product and the potential incident; and (iii) that the product posed an unreasonable hazard – existing or potential – during or as a result of its normal or foreseeable use that resulted in or may reasonably be expected to result in an individual’s death or in serious adverse effects on

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<sup>1</sup> Based information provided in 2005 by the Canadian Food Inspection Agency.

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their health, including a serious injury. In other words, an incident will not be considered to have been caused by a product unless the product poses a “danger to human health or safety” (CCPSA, Section 2). This would exclude, for example, incidents caused by misuse of a product. This approach would be consistent with the spirit and intent of the legislation as reflected in the definition of “danger to human health and safety” and Sections 3 and 5 – 9.

An alternative approach would be to interpret “related to” as set out in paragraphs (i) and (ii) above, and to define “occurrence” as used in Section 14(1)(a) with reference to the definition a “danger to human health and safety” (CCPSA). In other words, the Guidance would state that there would not be an “occurrence” unless the product posed an unreasonable hazard and the product had been used in a normal and foreseeable manner.

Regardless of the approach adopted, the Guidance should further clarify a company’s duties by providing an outline of the steps a company should follow in determining whether a reportable “incident” has occurred.

For example, a “decision tree” for Section 14(1)(a) would include a review of the following questions to determine that only truly serious incidents or near incidents be reported involving serious injuries or near injuries:

- Is it the company’s product?
- Did the report of the potential “incident” come from a person with actual, firsthand knowledge of the occurrence, defect, incorrect or insufficient information, or recall?
- Is there a causal link between the serious injury or potential serious injury and the product?
- Is there an “unreasonable product hazard”?
  - To determine if there was a “unreasonable product hazard”, the investigating individual would determine if the product was used as intended or in a foreseeable manner in light of factors such as whether warnings and instructions addressed the issue in question.

The obligation to determine if an incident has occurred should rest with the party with the ability to conduct the investigation addressing the above points. Therefore, it is recommended that retailers that do not have this ability should have to report consumer complaints that might qualify as an incident to the appropriate distributor, manufacturer or importer to make the determination if it is an actual incident. In such cases, retailers would not report potential incidents to Health Canada. The responsible company would report to Health Canada and to the retailer after it has done its investigation and determined that an incident has actually occurred. Depending on the nature of the incident, appropriate action would have to be taken by the retailer, such as removal from sale.

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### 4.1 Determine the consumer product involved

#### Comment

It should be explicitly stated that this step involves determining whether the potential incident “relates to” the product. This would involve first determining whether it is a product manufactured, imported or sold by the company and secondly whether there is a causal link. As part of determining whether there is a causal link, the company would determine whether the product posed an unreasonable hazard and whether the product was used in a normal or foreseeable manner.

#### Recommendations

Change the title of this section to “Determine whether the potential incident “related to” the product.”

See recommendation above regarding interpretation of “related to.”

### 4.2 Consumer product is involved in an incident

#### Comments

It is not clear from the current wording that a company does not “become aware” until it has been determined that there is an incident.

As discussed above, defining “occurrence” is an alternative approach to better defining the scope of incidents that must be reported.

The term “*may reasonably have been expected to result in*” is not clear to readers.

#### Recommendation

This section should clearly state that once a company has determined that the potential incident relates to a product of the company, the next step in order for the company to “become aware” is to determine whether there has been an incident.

This section should define “occurrence” if Health Canada chooses to adopt the alternative approach recommended above to better define the scope of reportable incidents.

Insert “occurrence” in the description of s. 14(1)(a).

The document should provide examples of what the term “may reasonably have been expected to result in” means.

## 5. Who Provides Information to Health Canada?

### Comments

First, we believe this section can be clarified by distinguishing between the “person” (the company) and the individual or individuals within the company who are responsible for providing information to Health Canada. This distinction may not be clear to the many companies who will use the document but have little or no background on the issue.

Second, we foresee a major problem for small companies and importers that do not have the resources or staff to meet the reporting requirement. For instance, there are many thousands of small independent retailers with very limited resources. Multiple reports of an incident would serve little purpose and would impose a burden on small and medium sized businesses.

### Recommendations

To increase clarity, there should be a separate term used to distinguish between “person” (the company) and the individual appointed by the “person” who has the responsibility of reporting to Health Canada. Section 5 should be redrafted to include the following edits:

The ***individual(s)*** with this responsibility is:

- Responsible for being knowledgeable on what an incident is; and,
- Authorized ***by the person*** to provide information to Health Canada within the specified timeframes.

The Guidance document should note that the reporting deadlines are triggered once the designated ***individual*** becomes aware.

Regarding the burden on small and medium sized businesses, Health Canada should explore methods of reducing reporting. For example, by allowing trade associations, such as the Retail Council of Canada and others, to file a single report on behalf of their members rather than have each member report individually. This might apply, for example, in the case of recalls in other jurisdictions.

### 5.1 How does a person who manufacturers, imports or sells ‘become aware’?

### Comments

As noted above, Section 5.1 should be moved to Section 4. It creates confusion about when an incident report is triggered. A company could interpret this section as meaning that a report is triggered as soon as the information is received.

There may be confusion about who must assume the responsibility to investigate and report incidents. The guidance document could be construed to obligate companies outside Canada to report.

**Recommendation**

To clarify that the responsibility to report lies in Canada and to be consistent with Sections 4 and 5 of the draft Guidance, Section 5.1 should be amended to add “consumer products in Canada” after “sells” .

**6. When and What to Provide to Health Canada?**

**6.2 Written report (evaluation and proposed measures)**

**Comment**

Given the lack of clarity in prior sections as discussed above, use of the term “evaluation” in the heading creates confusion about whether a company may conduct an evaluation to determine whether there has been an incident before they are considered to “become aware” for purposes of Section 14(2). We further note that the term “evaluation” is not used in the text of this section.

**Recommendation**

To help clarify the policy the terminology “evaluation and proposed measures” in the header should be removed.

**8. What Happens to the Information?**

**8.1 Overview of Health Canada process**

**Comment**

Companies that have filed an incident report need to be able to determine that the issue has been properly dealt with in order to confirm they have met their obligations and to close their files internally.

**Recommendation**

The guidance document should indicate a specific time frame within which Health Canada will report back to companies that further information is not required.

**8.2 Protection of Confidential Business Information**

**Comments**

Companies are understandably very sensitive about the potential for disclosure of their confidential business information (CBI). Confidence that CBI will be protected will encourage companies to share information early and often with Health Canada.

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We recognize that Health Canada may only disclose CBI in the limited circumstances provided for under Sections 16 and 17 of the CCPSA. However, there are a number of concerns relating to the disclosure of CBI.

The first relates to the definition of CBI in the CCPSA and the potential for disagreement between the company and Health Canada about whether or not the information provided constitutes CBI. The Guidance document, based on the definition of CBI in the CCPSA, requires a company to establish that the information it considers to be confidential meet all of the following criteria:

- a. Is not publicly available;*
- b. In respect to which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available; and*
- c. 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.*

Companies protect the reports that they receive from consumers about their products as the disclosure of the content in these reports could be seriously harmful to the company and benefit their competitors. Since the incident reports to Health Canada are based on the reports received from consumers which are kept confidential by the company, the Guidance should clearly state that Health Canada will presume that all incident reports are CBI. The mere disclosure that incident reports have been filed with respect to a company's products could be harmful to a company and therefore should not be disclosed by Health Canada without the consent to the company unless the criteria in Section 16 or 17 permitting disclosure have been met.

Companies are also concerned about the potential for disclosure of incident reports through the *Access to Information Act*. They can be seriously harmed by the release of incident reports and the damage can be compounded by large volumes of such reports. Moreover, the fact that reports are submitted to Health Canada does not necessarily establish that an incident has in fact occurred; some of the incident reports may be unsubstantiated. Further clarification should be provided by Health Canada with respect to how it handles access to information requests and the circumstances under which the government is obliged (with some exceptions) to refuse an access to information request. In particular, we note that under Section 20 (1) (c) of the *Access to Information Act*, the government must refuse to disclose the information if the disclosure "could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, a third party." There is no requirement that the three-part test for CBI in the CCPSA be met.

Finally, regarding Section 16 of the CCPSA for agreements with other jurisdictions to maintain confidentiality, there is a concern about what "agreeing to maintain confidentiality" means in the context of the access to information regimes in these foreign jurisdictions. The draft

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Guidance document should provide further clarification of what information will be disclosed to other jurisdictions and what the triggers will be for disclosure under Clause 16.

### Recommendations

For clarity, the guidance document should include the text from Sections 16 and 17 of the Act.

The Guidance should include an explanation of what “Protected” means on the incident reporting form.

The Guidance should state that companies should identify any information that they consider CBI.

The guidance document should make it clear that:

- Incident reports and related documents in the Government’s possession that address or reflect the substance of incident reports cannot be released if they contain CBI until it is established that there is a serious and imminent danger to human health or safety or the environment.
- The mere fact that incident reports have been filed does not establish that there is a serious and imminent danger.
- Incident reports, even if they have been substantiated in a 10-day report, do not necessarily establish that there is serious and imminent danger and should not be released.

The Guidance should clearly state that Health Canada will presume that all incident reports are CBI.

The guidance document should state that it is understood that the release of even partial information, such as product names or descriptions, company names or descriptions, category names or generic hazard descriptions could reasonably be expected to result in material financial loss to a company or could prejudice the competitive position of a third party.

The Guidance should also outline the process that Health Canada will follow in making a determination that the information provided is not confidential. There should also be a process whereby Health Canada notifies the company that it does not consider the information to be CBI and its plans to disclose it. This would allow the company the opportunity to respond. If Health Canada were to disagree with the CBI designation, there should be a review procedure, similar to the approach under the *Access to Information Act*, which provides an opportunity for relief before the information is disclosed publicly.

For greater clarity and assurance, the Guidance should reference Section 20(1)(a)(b) and (c) of the *Access to Information Act* (AIA) to ensure that CBI (as identified by the person submitting the

report) will be treated presumptively as falling within the AIA's exemption from disclosure provisions.

## **Appendix A: Types of 'Incident'**

### **14(1) (a) Death or Serious Adverse Effect**

#### **Comments**

Sections 14(1)(b) and (c) also include "death or serious adverse effect". The title to this section should be "Occurrence". The "occurrence" is not the "death or serious adverse effect". It is something which resulted in, or may reasonably have been expected to result in, death or serious adverse effect. See the discussion above under Section 4 with respect to the proposed alternative involving defining "occurrence".

The details and circumstances are vital to the determination of whether an incident occurred. For example:

- What happens if a child under 3 chokes on a product if such product was intended for over 4?
- What happens if the product in question did not spark but rather the cause was a child playing with matches?
- What happens if the child changed the product that lead to the sharp edge?

The examples may trigger reporting that is not justified.

The reference to "near miss" should be removed. Guidance should be provided with respect to "potential" for death or serious adverse health effects. Will one incident report be sufficient for purposes of determining whether there is potential, or will companies be expected to do a trend analysis? We do not expect Health Canada to be prescriptive in this regard as we recognize that determination of whether there is a trend will vary depending on the nature of the occurrence, the type of product involved, etc.

#### **Recommendation**

Examples of serious adverse effects on health should be clarified to address intended or reasonably foreseeable use.

Guidance should be provided with respect to how a company determines whether there is potential for death or serious adverse effects.

### **14(1) (b) Defect or Characteristic**

#### **Comment**

More guidance is required with respect to when a product would be considered defective. A defect should not be determined based on one customer report – as it is likely that there has

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been misuse of the product – but rather only after several reports have been made and the company has been able to duplicate the circumstances.

### **Recommendation**

Provide guidance with respect to what constitutes a “defect” or “characteristic”.

### **14(1) (c) Incorrect or Insufficient Information**

### **14(1) (d) Recall or Other Measure**

#### **Comment**

The first half of the fourth paragraph states the obvious and is unnecessary. The second half goes beyond what is required by the legislation.

#### **Recommendation**

Delete the fourth paragraph.

## **Appendix B – Form**

#### **Comment**

Determining which parts of the form must be completed for the Section 14(2) and Section 14(3) reports is confusing.

#### **Recommendation**

Identify on the form itself which parts are mandatory for the Section 14(2) report versus the Section 14(3) report.

## **Appendix C – Case Study**

#### **Comment**

The case study does little other than summarize the obligations outlined in the Guidance.

#2 is confusing, especially the "becoming aware of the incident" language.

#4 should also reference the manufacturer.

#### **Recommendation**

Develop a case study based on a specific example. We would be pleased to assist Health Canada with the development of the case study.