

DRAFT Guidance on Mandatory Incident Reporting under the Canada Consumer Product Safety Act - Section 14 Duties in the Event of an Incident

Health Canada, Consumer Product Safety Program

This is a draft document developed for the purpose of soliciting feedback and comments regarding guidance on Section 14 incident reporting under the CCPSA (“Duties in the Event of an Incident”). It is not intended to substitute for, supersede or limit the requirements under the CCPSA. In case of any discrepancy between this summary and the legislation, the legislation will prevail.

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1. Introduction

Globalization, increasing complexity of supply chains, more sophisticated products and evolving innovation have driven the need to modernize consumer product regulatory tools and legislation in Canada. The *Food and Consumer Safety Action Plan* was introduced in 2007 with the goal of raising the level of food and consumer protection in Canada to respond to these new technological and economic realities. Three pillars were identified under the action plan to address this new landscape: active prevention, targeted oversight and rapid response.

In pursuit of a modernized health and safety regime for consumer products in Canada, the *Canada Consumer Product Safety Act* (CCPSA), built on these three pillars, was enacted in June 2011. Under the authority of the CCPSA, Health Canada works with industry to help ensure safer consumer products are on the market. Health Canada also provides consumers with information that helps them make better decisions regarding the safety of the products they buy.

A critical element of ensuring safer consumer products is the legislative requirement for mandatory reporting by industry under section 14 of the CCPSA. This requirement states that it is the responsibility of a person who manufactures, imports or sells consumer products in Canada for commercial purposes to report to Health Canada when they become aware of an incident related to their product. This document provides high-level guidance on the practical implementation of industry obligations under section 14 of the CCPSA.

2. The Importance of Reporting Consumer Product Related Incidents

Incidents reported to Health Canada by all persons who manufacture, import or sell consumer products for commercial purposes are a key tool in the early warning and detection of potential health or safety issues related to consumer products on the Canadian market. These reports help Health Canada work with industry to proactively and efficiently respond, where appropriate, to consumer product concerns related to health or safety.

What is a Consumer Product?

Section 2 of the CCPSA defines a 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”.

As per section 4 of the CCPSA, excluded from this definition are products listed in Schedule 1 of the CCPSA (see Appendix A) as well as natural health products and tobacco products except with respect to their ignition propensity. Examples of Schedule 1 exclusions are cosmetics, drugs, medical devices, food, pest-control products and vehicles, all of which are covered under other legislation.

3. Industry Responsibilities under Section 14 of the Canada Consumer Product Safety Act

Section 14¹ of the *Canada Consumer Product Safety Act* (CCPSA) defines the duties in the event of an incident. Any person who manufactures, imports or sells consumer products in Canada for commercial purposes must report any incidents related to their consumer products to Health Canada and other organizations as appropriate and as directed in the CCPSA.

As per section 2 of the CCPSA:

“import” means to import into Canada

“manufacture” includes product, formulate, repackage and prepare, as well as recondition for sale

“sell” includes offer for sale, expose for sale or have in possession for sale – or distribute to one or more persons, whether or not the distribution is made for consideration – and includes lease, offer for lease, expose for lease or have in possession for lease.

When more than one of these roles is performed by a company, obligations for mandatory reporting under the CCPSA are those up to and including the highest applicable level of trade. For example, a person who both imports and sells a product in Canada must comply with the reporting requirements for both importing and selling; similarly, a person who manufactures and sells a product must comply with the reporting requirements for both manufacturing and selling of that product under the CCPSA.

¹ <http://laws-lois.justice.gc.ca/eng/acts/C-1.68/page-4.html#h-8>

Further information on reporting under section 14 of the CCPSA can be found in section 6 of this document.

4. What is an Incident?

An incident with respect to a consumer product is defined in section 14 of the *Canada Consumer Product Safety Act* (CCPSA) as follows:

14(1)(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 [further information below];

14(1)(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;

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; or

14(1)(d) A recall or measure that is initiated for human health or safety reasons by

- i. A foreign entity,
- ii. A provincial government,
- iii. A public body that is established under an Act of the legislature of a province,
- iv. An aboriginal government as defined in subsection 13(3) of the Access to Information Act, or
- v. An institution of an entity referred to in subparagraphs (ii) to (iv).

Factors for consideration that will help with the determination of whether an event is deemed an incident are presented in section 5 of this guidance document.

As noted in 14(1)(a)-(c), an event that may reasonably have been expected to result in a serious adverse effect on health is considered a “near miss”. A near miss is an event that could have resulted in harm, or in a greater degree of harm, under different circumstances. For example, property damage from a house fire that could reasonably have been expected to result in an individual's death or serious adverse effects on human health.

For the purposes of this guide, a serious adverse health effect includes a harmful effect resulting in, or that could have resulted in, a reversible or irreversible change to health requiring hospitalization or professional medical treatment. A serious injury includes the temporary or permanent impairment of a body function or temporary or permanent damage to a body structure, chronic health effects or any injury requiring hospitalization or professional medical treatment. This includes, but is not limited to:

- Threats to breathing such as choking, strangulation, suffocation, asphyxiation, aspiration, or other respiratory impairment;
- External physical injury (e.g., serious burn/laceration);
- Internal injury (e.g. internal bleeding, injury to an organ, fracture);
- Acute illness (e.g., poisoning);
- Allergic reaction (including anaphylaxis);
- Loss of consciousness;

- Convulsions; and/or
- Sensory impairment (e.g., sight/hearing).

Note that the determination of whether an injury is serious may also depend on other factors such as the age of the individual involved in the incident and part of the body affected (a laceration on the face may be deemed more serious than a similar laceration on the leg, for example).

5. Determining an Incident

This section explains whether an event involving a consumer product meets the definition of an incident under the *Canada Consumer Product Safety Act* (CCPSA); further information on how to report can be found in section 6 of this document.

5.1 Receipt of Information on an Event

A person who manufactures, imports or sells a consumer product in Canada may receive information on an event through a variety of sources, for example:

- Direct notification by a consumer, through returns, complaints or product liability lawsuits or claims;
- Direct notification by the person from whom they received the consumer product or to whom they sent the consumer product;
- Reports from experts, test reports, scientific or other studies or other relevant information;
- Other public communication such as news releases and media coverage; and/or
- Direct notification by government (including Health Canada) or standards-/certification-writing bodies. This may include transmission of voluntary event reports submitted to Health Canada by consumers.

Establishing policies and procedures and, where appropriate, contractual obligations can help to ensure that a company is positioned to meet its obligations under section 14 of the CCPSA.

5.2 Determination of an Incident

It is the responsibility of the person who manufactures, imports or sells a consumer product for commercial purposes to determine whether an event meets the definition of an “incident” under the CCPSA.

Determination of an incident is based on the following two criteria:

1. Is the event **connected** or **related** to a consumer product that a person manufactures, imports or sells in Canada for commercial purposes (see section 5.2.1)?
2. Does the event meet one of the situations outlined in subsections **14(1)(a) through (d) of the CCPSA** (see section 5.2.2)?

5.2.1 Criterion #1: Is the event connected or related to a consumer product (including its components, parts, accessories or packaging) that a person manufactures, imports or sells in Canada for commercial purposes?

The CCPSA requires a person to determine if the product involved in the event, including its components, parts, accessories or its packaging, is related to a consumer product that they manufacture, import or sell in Canada for commercial purposes. As such, the event does not need to directly involve the same consumer product as the one involved in the original report if they share the component which contributed to the health or safety hazard. The terms *connected* or *related* refers to the determination that the component or consumer product in question was not only involved in the event, but contributed to it.

For example:

A person replacing a light bulb gets dizzy and falls, hitting his/her head on a table. Although the light bulb was in the person's hand during the event, it did not contribute to the fall. Alternatively, a person is replacing a light bulb in a normal manner when the light bulb catches fire, burning the person's hand. In this case, the light bulb directly contributed to the injury.

5.2.2 Criterion #2: Does the event meet one of the criteria of an incident set out in paragraphs 14(1) (a) through (d) of the Canada Consumer Products Safety Act (CCPSA)?

5.2.2.1 14(1)(a) Death or Serious Adverse Effect

14(1)(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

Any actual death or serious injury connected with a company's consumer product should ALWAYS be reported to Health Canada. Other considerations may also inform whether an incident has occurred in situations where there may have been a less serious adverse health effect or near miss (see section 5.2.3).

For example:

A child choked on a small part that broke off of a toy, and without intervention from his/her caregiver may have asphyxiated. While no serious lasting injury resulted from this occurrence, the potential for injury or death means that this occurrence meets this criterion and should be considered an incident.

5.2.2.2 14(1)(b) Defect or Characteristic

14(1)(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.

A **defect** or **characteristic** may include a fault, flaw or irregularity – in any step from product conception, design, manufacturing and packaging to handling and delivery to the consumer – that causes weakness, failure or inadequacy in form or function that may reasonably be expected to result in an individual's death or in serious adverse effects on their health.

An injury need not have occurred to trigger this reporting requirement.

For example:

- non-compliance with regulations, certification requirements or standards related to health or safety;
- a manufacturing or production error; and/or
- a flaw in product design or materials used (contents, construction, finish, packaging).

5.2.2.3 14(1)(c) Incorrect or Insufficient Information

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

Incorrect information on a label or in instructions could include information that is inaccurate, deficient in force, quality or amount or otherwise inadequate, potentially leading to use of the product in ways other than intended. Lack of warnings and instructions for safe use in both official languages or concerns about the quality of the translation should always be reported.

An injury need not have occurred to trigger this requirement.

For example:

- inadequate precautionary or warning statements;
- pictures that show or encourage unsafe use contrary to instructions or written statements;
- contradictory statements related to the safe use of the product;
- important safety instructions available in only one official language; and/or
- inaccurate instructions (even in a language other than English or French)

5.2.2.4 14(1)(d) Recall or Other Measure

14(1)(d) a recall or measure that is initiated for human health or safety reasons by

- a foreign entity,
- a provincial government,
- a public body that is established under an Act of the legislature of a province,
- an aboriginal government as defined in subsection 13(3) of the [Access to Information Act](#), or
- an institution of an entity referred to in subparagraphs (ii) to (iv).

Upon learning of a recall or measure (e.g., safety announcement, product warning, etc.) initiated by another jurisdiction, the person who manufactures, imports or sells is

responsible for reporting to Health Canada and to the person from whom they received the consumer product.

A company should not wait to submit a report to Health Canada if it is considering a recall or measure for health or safety reasons. If it has identified a problem or issue concerning its product it needs to be reported as an incident under 14(1)(a), (b) or (c), and the company should not be waiting until their recall is ready to inform Health Canada.

For example:

A recall of a lawnmower is initiated in another country due to a faulty ignition switch. The same consumer product sold in Canada would be considered to be an incident under this criterion; further, a different product manufactured in Canada using the same faulty ignition switch would also be considered an incident under this criterion and should be reported to Health Canada.

5.2.1 Considerations that may assist in determining an incident

5.2.3.1 Unreasonable Product Hazard

The CCPSA is meant to protect against unreasonable hazards posed by products used in a normal or foreseeable manner. When determining whether a near miss or mild injury is reportable, companies should consider whether the event indicates an **unreasonable hazard** posed by the **normal or foreseeable use** of the product. Foreseeable use would not only include the use of a consumer product for its primary, ordinary or intended purpose, but also the misuse of a product that is reasonably foreseeable (and is not deliberate, grossly negligent or of a criminal nature). What constitutes normal or foreseeable use of a consumer product will depend on the particular product involved, the foreseeable users (including vulnerable sub-populations) and the circumstances surrounding the event. The person determining whether an event is an incident should consider whether a consumer would expect and understand that such a hazard exists when using the product in a normal or foreseeable manner and whether the hazard is unreasonable from a public perspective.

For example:

A consumer purchases a kitchen knife to cut food items. It is understood that there is an inherent hazard posed by such a product. A cut caused by using a knife in a normal or foreseeable way could therefore be considered as a reasonable hazard and would not be considered an incident. If, however, the knife handle breaks in normal use which may result in a cut, that would be considered an unreasonable hazard and would be considered an incident.

5.2.3.2 How long does it take to become AWARE of an incident?

In some cases, determination of an incident will be quite simple; for example, if a death or serious injury is involved, or if a recall has been issued in another jurisdiction, the company should report to Health Canada. No additional considerations would be required.

When evaluating unreasonable hazard or other considerations, it is important to note that this is not a formal risk assessment or hazard analysis and a determination should be arrived at relatively quickly.

Industry is encouraged to take all reasonable care to implement and use a system that will ensure that timely evaluation of events are consistently made to fulfill legal obligations under section 14 of the CCPSA. This includes ensuring that procedures are in place to allow that the evaluation generally occurs within a couple of business days.

Once it has been determined that the event is an incident, the time clock for the reporting obligations commence (within 2 days after the day of awareness of the incident for a 14(2) report, and within 10 days after the day on awareness of the incident for a 14(3) report).

“Awareness” of an incident does not necessitate or require full certainty of all aspects/details of an event. If at any point a company is not certain whether an incident occurred, they are encouraged to report to Health Canada on a precautionary basis.

6 When, What and How to Report Incidents

When a person has become **aware** of an incident with their product, they must provide, within two (2) days after the day on which they became aware of the incident, all available information regarding the incident to Health Canada and the person from whom they received the consumer product. Persons who manufacture and import must also provide a written report within ten (10) days after the day on which they become aware of an incident to Health Canada containing any additional information about the incident, the consumer product involved, any consumer products that they manufacture or import that may be involved in a similar incident and any measure they have taken or propose to take to address the health or safety concern

Failure to report as required by section 14 of the CCPSA constitutes an offence and is subject to enforcement action.

6.1 14(2) Requirement and Report: Information regarding the incident

Section 14(2) of the CCPSA:

A person who manufactures, imports or sells a consumer product for commercial purposes shall provide the Minister and, if applicable, the person from whom they received the consumer product with all the information in their control regarding any incident related to the product within two days after the day on which they become aware of the incident.

The intent of this mechanism is to notify all persons in the supply chain of the incident and increase the completeness of the information received by Health Canada from the person who manufactures, imports or sells. The following table outlines the timelines for 14(2) and 14(3) reports (14(3) reports to be explained in the next section of this document):

Table 1: Calculation of Due Dates for 14(2) Reports		
The person who manufactures, imports or sells a consumer product becomes aware of an incident on:	Information provided to Health Canada under subsection 14(2) due by 11:59 p.m. of the next*:	Information provided to Health Canada under subsection 14(3) due by 11:59 p.m. of the second*:
Friday	Monday	Monday
Saturday	Monday	Tuesday
Sunday	Tuesday	Wednesday
Monday	Wednesday	Thursday
Tuesday	Thursday	Friday
Wednesday	Friday	Saturday
Thursday	Saturday	Monday

Note 1: The report becomes overdue after 11:59 p.m. in the person's location (e.g., if the person is reporting from a city in British Columbia to Health Canada in Ottawa, Ontario, the report is overdue after 11:59 PT).

Note 2: This table assumes that there are no holidays (other than Sunday) that week.

It is always possible to provide updated 14(2) reports to Health Canada as further information becomes available and as the determination of the incident is refined and confirmed (including if it is ultimately determined that the event was not an incident under section 14 of the CCPSA).

6.2 14(3) Requirement and Report: Proposed Corrective Measures

Section 14(3) of the CCPSA:

The manufacturer of the consumer product, or if the manufacturer carries on business outside Canada, the importer, shall provide the Minister with a written report – containing 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 – within 10 days after the day on which they become aware of the incident or within the period that the Minister specifies by written notice.

Within ten (10) days after the day on which they became aware of the incident, a person who manufactures or imports is required to provide a written report to Health Canada including:

- Detailed information about the incident (e.g., the root cause analysis)
- Information about the product, such as:
 - Distribution numbers
 - Other incidents on the same or similar product, with numbers and a description
 - Standards the product is certified to
 - Steps the company took to ensure safety

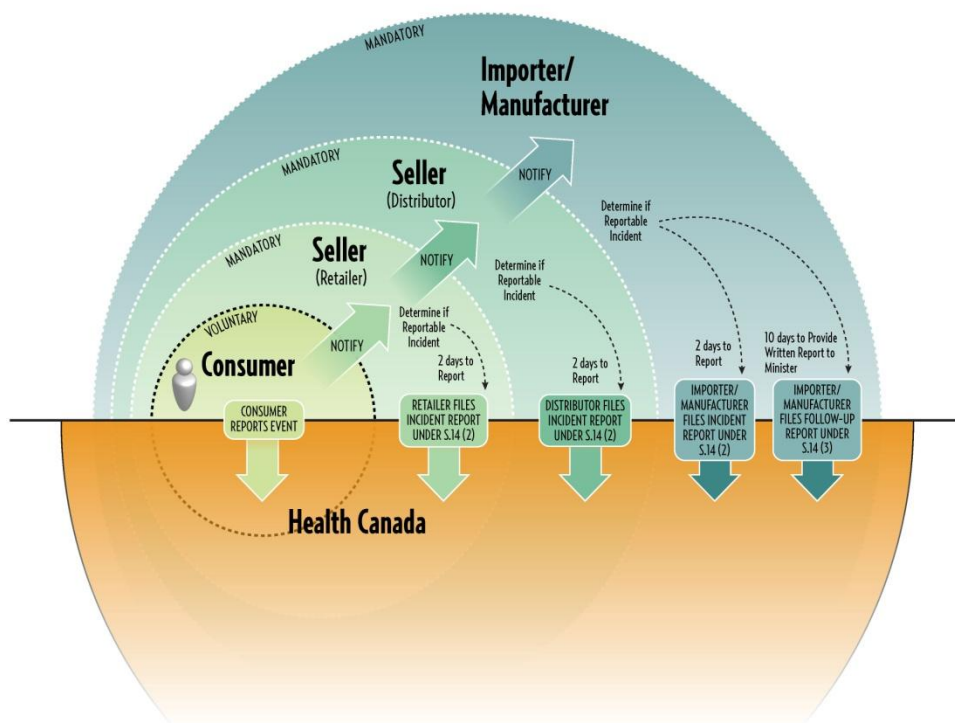
- If testing was undertaken, include test reports
- Warning labels and instructions on the product
- Pictures and diagrams of the product as necessary
- Other as appropriate
- Other products that may be affected (e.g., products that share same the same component that was involved in the incident)
 - Section 7 of the form completed with respect to whether or not a corrective measure is needed; either:
 - proposed corrective measure(s): explanation on how the corrective measure will address the issue, or
 - no proposed corrective measures: should include rationale for no corrective measure

Not every subsection 14(3) incident report will require that corrective measures be proposed with respect to the consumer product. A person may determine that no measures are required in response to the incident. Alternatively, based on the circumstances, they may recommend a range of measures to be taken to address the cause of the incident.

If the person who manufactures or imports anticipates that they will not be able to compile the required information within 10 days, they must request an extension from Health Canada, including a justification for their inability to meet these timelines and a proposed schedule of when they expect to be able to provide the required report(s).

The following figure demonstrates the general process flow of a consumer reporting an event through to completion of reporting obligations by industry under section 14 of the CCPSA (assuming the event is determined by industry to be an incident):

Figure 1: An Example of Reporting an Incident



6.3 Notifications: Reporting events that are not deemed incidents

Industry may want to report an event they have determined to **not** be an incident. The circumstances for submitting a notification to Health Canada are numerous and may include:

- A manufacturer or importer, upon receipt of the 14(2) report from a retailer or distributor, determines that the event is not an incident.
- An incident may be initially identified and reported to Health Canada through a 14(2) report but, as more information is acquired and considered, is ultimately deemed as not an incident.
- A company may want to inform Health Canada of an issue for health or safety reasons that falls outside the scope of the mandatory reporting.

Health Canada encourages such reports as it supports awareness of potential health or safety issues and the potential identification of emerging product safety trends. Reports should contain a clear rationale for the determination that the event is not an incident under the CCPSA. Submitting a notification in this situation is a pre-emptive action to assure Health Canada that the company is aware of the issue.

When filling out the online form for a notification, check the “Notification – evaluated as not an incident” box.

6.4 How Information is to be provided to Health Canada

Industry can use a variety of methods for providing information regarding an incident to Health Canada, but are strongly encouraged to make use of the online incident report form for industry available on Health Canada's website at www.healthcanada.gc.ca/reportaproduct. This electronic form will facilitate industry's responsibilities for reporting up the supply chain and for their own internal record keeping.

The form can be submitted online, saved and emailed to the above email address, or printed and mailed to Health Canada. Contact information for Health Canada can be found in section 8.

For 14(2) reports, Health Canada recommends that all sections, except section 7 of the form be completed to the best of one's abilities, while 14(3) reports should include ALL sections of the form. As per section 14(2) of the CCPSA, companies are required to provide all information within their control when reporting consumer-product-related incidents to Health Canada.

7 What Happens to the Information Provided to Health Canada?

Upon receipt of information regarding an incident, Health Canada determines if the report has sufficient information. If more information is required, Health Canada may follow up with the contact person identified on the form.

Incident information will inform analysis on emerging hazards and trends and allow Health Canada to work with industry proactively and to efficiently respond, where appropriate, to consumer product health or safety incidents.

7.1 Confidential Business Information

Sections 16 and 17 of the CCPSA allow Health Canada to disclose confidential business information (CBI) in specific circumstances for the protection of human health or safety or the environment. To be considered CBI under the *Canada Consumer Product Safety Act* (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.

Under section 16 of the CCPSA, the Minister may disclose CBI without the consent of, or notice to, the person whose business or affairs the information relates if certain conditions are met. The disclosure can only be in relation to a consumer product, and can only be made to a person or government that carries out functions relating to the

protection of human health or safety or the environment. In addition, the person or government to whom the information is to be provided must agree 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 of the CCPSA, the Minister may disclose CBI to the public, without the consent of the person to whose business or affairs the information relates and without notifying that person beforehand, about a consumer product that is a serious and imminent danger to human health or safety or the environment 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 no later than the next business day following the disclosure.

If a person filing an incident report under section 14 believes that information provided to Health Canada in relation to an incident meets the criteria for CBI under the CCPSA or third party information under the Access to Information Act, then they can indicate this to Health Canada at the time they provide the information.

Health Canada will work with manufacturers, importers and sellers to mitigate safety concerns without releasing CBI where possible.

7.2 Personal Information

The disclosure of personal information under the control of Health Canada must comply with the disclosure provisions set out in section 8 of the *Privacy Act*. Disclosure without the consent of the individual to whom the information relates must be made in compliance with subsection 8(2) of the *Privacy Act*.

Subsection 8(2) sets out 13 instances where such disclosure may be made. In particular, paragraph 8(2)(b) states that personal information under the control of a government institution may be disclosed “for any purpose in accordance with any Act of Parliament or any regulation made there under that authorizes its disclosure.”

Under section 15 of the CCPSA, the Minister’s authority to disclose personal information without the consent of the individual is subject to two conditions:

1. The information may be disclosed only to a person or government that carries out functions relating to the protection of human health or safety; and
2. The disclosure must be necessary to identify or address a serious danger to human health or safety.

The ability to share personal information in those rare and serious circumstances helps enable rapid response to serious dangers to human health or safety. The other disclosure provisions contained in section 8 of the *Privacy Act* continue to apply.

8 Contact Information for Health Canada

For further information, specific questions or clarification, contact a Health Canada Product Safety Office: 1-866-662-0666

Health Canada encourages the use of the online incident report form at www.healthcanada.gc.ca/reportaproduct. Alternatively, reports can be submitted by email or paper at the following addresses

Email:

Consumer Product Safety Reporting e-mail account:
CPS-SPC@hc-sc.gc.ca

Paper reports:

National Capital Region Consumer Product Safety Office
Consumer Product Safety Programme
Health Canada
269 Laurier XXX

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Appendix A: Schedule I of the *Canada Consumer Product Safety Act*

SCHEDULE 1

(Subsection 4(1) and paragraph 37(1)(c))

1. Explosives within the meaning of section 2 of the *Explosives Act*.
2. Cosmetics within the meaning of section 2 of the *Food and Drugs Act*.
3. Devices within the meaning of section 2 of the *Food and Drugs Act*.
4. Drugs within the meaning of section 2 of the *Food and Drugs Act*.
5. Food within the meaning of section 2 of the *Food and Drugs Act*.
6. Pest control products within the meaning of subsection 2(1) of the *Pest Control Products Act*.
7. Vehicles within the meaning of section 2 of the *Motor Vehicle Safety Act* and a part of a vehicle that is integral to it — as it is assembled or altered before its sale to the first retail purchaser — including a part of a vehicle that replaces or alters such a part.
8. Feeds within the meaning of section 2 of the *Feeds Act*.
9. Fertilizers within the meaning of section 2 of the *Fertilizers Act*.
10. Vessels within the meaning of section 2 of the *Canada Shipping Act, 2001*.
11. Firearms within the meaning of section 2 of the *Criminal Code*.
12. Ammunition within the meaning of subsection 84(1) of the *Criminal Code*.
13. Cartridge magazines within the meaning of subsection 84(1) of the *Criminal Code*.
14. Cross-bows within the meaning of subsection 84(1) of the *Criminal Code*.
15. Prohibited devices within the meaning of paragraphs (a) to (d) of the definition “prohibited device” in subsection 84(1) of the *Criminal Code*.
16. Plants within the meaning of section 3 of the *Plant Protection Act*, except for Jequirity beans (*abrus precatorius*).
17. Seeds within the meaning of section 2 of the *Seeds Act*, except for Jequirity beans (*abrus precatorius*).
18. Controlled substances within the meaning of subsection 2(1) of the *Controlled Drugs and Substances Act*.
19. Aeronautical products within the meaning of subsection 3(1) of the *Aeronautics Act*.
20. Animals within the meaning of subsection 2(1) of the *Health of Animals Act*.

Appendix B: Section 14 of the *Canada Consumer Product Safety Act*: “Duties in the Event of an Incident”

14. (1) In this section, “incident” means, with respect to a consumer product,
- (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) a recall or measure that is initiated for human health or safety reasons by
 - (i) a foreign entity,
 - (ii) a provincial government,
 - (iii) a public body that is established under an Act of the legislature of a province,
 - (iv) an aboriginal government as defined in subsection 13(3) of the *Access to Information Act*, or
 - (v) an institution of an entity referred to in subparagraphs (ii) to (iv).
- (2) A person who manufactures, imports or sells a consumer product for commercial purposes shall provide the Minister and, if applicable, the person from whom they received the consumer product with all the information in their control regarding any incident related to the product within two days after the day on which they become aware of the incident.
- (3) The manufacturer of the consumer product, or if the manufacturer carries on business outside Canada, the importer, shall provide the Minister with a written report — containing 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 — within 10 days after the day on which they become aware of the incident or within the period that the Minister specifies by written notice.

Appendix C: Definitions

Consumer product

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.

As per section 4 of the CCPSA, excluded from this definition are products listed in Schedule 1 of the CCPSA (see Appendix A) as well as natural health products and tobacco products except with respect to their ignition propensity. Examples of Schedule 1 exclusions are cosmetics, drugs, medical devices, food, pest control products, and vehicles, among others.

Import

To import into Canada.

*Section 2
of the
CCPSA*

Incident

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;

*Section
14(1)(a) of
the
CCPSA*

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;

*Section
14(1)(b) of
the
CCPSA*

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

*Section
14(1)(c) of
the
CCPSA*

A recall or measure that is initiated for human health or safety reasons by

- i. A foreign entity,
- ii. A provincial government,
- iii. A public body that is established under an Act of the legislature of a province,
- iv. An aboriginal government as defined in subsection 13(3) of the *Access to Information Act*, or
- v. An institution of an entity referred to in subparagraphs (ii) to (iv).

*Section
14(1)(d) of
the
CCPSA*

Manufacture

Includes produce, formulate, repackage and prepare as well as recondition for sale.

*Section 2
of the*

Near Miss

An event that could have resulted in **harm**, or in a greater degree of harm, under different circumstances.

Sell

Includes offer for sale, expose for sale or have in possession for sale – or distribute to one or more persons, whether or not the distribution is made for consideration – and includes lease, offer for lease, expose for lease or have in possession for lease.

*Section 2
of the
CCPSA*

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