CONSUMER PRODUCT SAFETY PROGRAM

RISK ASSESSMENT FRAMEWORK

December 2014

Prepared by the

Consumer Product Safety Directorate

&

Product Safety Program, Regions & Programs Bureau

Health Canada Santé Canada

Contents

1. TERMS AND DEFINITIONS

The following definitions apply to this Framework. Words within the definitions that appear in **bold** type are also defined in this section.

Danger to human health or safety: "means any unreasonable hazard — existing or potential — that is posed by a consumer product during or as a result of its normal or foreseeable use and that may reasonably be expected to cause the death of an individual exposed to it or have an adverse effect on that individual's health — including an injury — whether or not the death or adverse effect occurs immediately after the exposure to the hazard, and includes any exposure to a consumer product that may reasonably be expected to have a chronic adverse effect on human health" (*Canada Consumer Product Safety Act,* S. 2)

Foreseeable use: Any use or misuse of the **product** that could be reasonably foreseen, and will often exclude gross negligence, or criminal activity.

Harm: An injury, adverse health effect, loss of life, or any combination of these outcomes.

Hazard: A substance, product, human activity, condition, or situation that is a potential source of **harm** to human health or safety (adapted from ISO Guide 51).

Incident: For the purposes of subsection 14 (1) of the *Canada Consumer Product Safety Act,* with respect to a consumer product, an incident is:

(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 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).

Near Miss: An occurrence that could have resulted in **harm,** or in a greater degree of **harm**, under different circumstances.

Product: The term 'product' in this document includes both:

Consumer product: "Means 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" (*Canada Consumer Product Safety Act,* s. 2).

Cosmetic: "Includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes" (*Food and Drugs Act*, s. 2).

Program: Refers to the Consumer Product Safety Program, which delivers on Health Canada's Consumer Product Safety mandate. The Program includes the regional Product Safety Offices within the Regions and Programs Bureau and the Consumer Product Safety Directorate within the Healthy Environments and Consumer Safety Branch. The Consumer Product Safety Directorate is organized into three Bureaus (Risk Assessment Bureau, Risk Management Bureau and Program Development Bureau).

Report: the mandatory report regarding an **incident** with a consumer product submitted by **suppliers** regulated under s. 14 of the *Canada Consumer Product Safety Act*, evidence of safety submissions by **suppliers** regulated under the *Food and Drugs Act* for cosmetics, or a voluntary report submitted to the Program related to consumer products or cosmetics.

Risk: The effect of exposure to a hazard on human health or safety**,** which integrates the likelihood of occurrence of possible outcomes with an estimate of the magnitude of the associated severity of these outcomes.

Risk Assessment: A systematic process of evaluating the potential **risk** posed by a **product** in order to inform decision-making.

Risk Characterization: The final component of a **risk assessment** in which the level of risk is estimated according to the likelihood and the severity of the potential impact.

Risk Management: A term used to collectively describe the activities and considerations involved in addressing and communicating information about risks under conditions of **uncertainty.** Risk management generally includes a number of inter-related activities such as: risk identification, risk assessment, risk mitigation and risk communication (Adapted from Health Canada Decision Making Framework).

Suppliers: Any person subject to the requirements of the *Canada Consumer Product Safety Act* or, in relation to cosmetics, the *Food and Drugs Act* and *Cosmetic Regulations*. A supplier may include individuals, companies and other organizations that manufacture, sell, distribute, advertise or import **consumer products** or **cosmetics**.

User: Broadly defined to include persons affected by the **product,** including bystanders who may be exposed to the product.

Uncertainty: Imperfect or incomplete information that results in the inability to derive a precise estimate of the level of **risk**.

Variability: The range of characteristics among a population that may be exposed to a risk, and that should be taken into consideration when risks to that population are assessed and / or mitigated.

2. INTRODUCTION

The Consumer Product Safety Program (the Program) strives to protect the public by addressing or preventing risks to human health or safety posed by consumer products and cosmetics. While the safety of products is a shared responsibility among government, suppliers, consumers and other stakeholders, suppliers have the primary responsibility for the safety of the consumer products and cosmetics they manufacture, import, advertise or sell in Canada. They are responsible for supplying safe products that comply with the applicable legislative and regulatory requirements, preventing unsafe products from entering the marketplace and quickly taking appropriate action to correct the situation when non-compliance is determined. Consumers, for their part, are encouraged to use products safely and to inform suppliers and Health Canada of any health or safety related problems that they encounter when using consumer products or cosmetics.

The Program conducts risk assessment activities, which may include review of technical studies, data, assessments, etc. or the conduct of a risk assessment by the Program. Risk assessment activities are typically initiated by reports received as a result of mandatory reporting requirements, consumer complaints, monitoring and trend analysis, actions in other jurisdictions and in support of the development of risk management options for the Program or in the review of corrective actions proposed by manufacturers or importers. The quality and consistency of these functions are enhanced through the delivery of appropriate training for Program staff and monitoring of its effectiveness.

2.1 Purpose of the Risk Assessment Framework

The purpose of this Risk Assessment Framework is to provide clarity and transparency to internal and external stakeholders on the principles and processes associated with risk assessment in the Program. Because the Program operates primarily under a post-market regime and cannot address all issues, the Risk Assessment Framework also helps establish a risk based approach to determine on which issues the Program should focus its attention.

With the coming into force of the *Canada Consumer Product Safety Act* on June 20th 2011, the Program identified the need to establish a Risk Assessment Framework. This framework provides a foundation for consistent assessment of risks in a manner that is systematic, structured and based on the best available evidence to form a basis for decision-making on human health or safety risks posed by products. This framework supports the Government's Food and Consumer Safety Action Plan, a broad initiative to modernize and strengthen Canada's safety systems for food and consumer products. The Food and Consumer Safety Action Plan modernizes Canada's regulatory system to enable it to better protect Canadians from unsafe consumer products and cosmetics in the face of current realities and future pressures.

This document is not intended to be an implementation manual or guidance for industry on how to conduct risk assessment activities; rather, it is intended to act as a bridge between the larger policy direction provided through the Government's Food and Consumer Safety Action Plan and the Program's approach to decision-making to guide the development of specific risk assessment policies and procedures. This Framework helps the Program prioritize risk assessment work, and identify key factors

for analyzing risks and processes for undertaking risk assessment work. The Program is guided by the principles and process outlined in this document.

The principles and processes associated with risk management functions are articulated in a separate Risk Management Framework.

2.2 Guiding Legislation

The Consumer Product Safety Program is responsible for the administration and application of legislative requirements pertaining to consumer products and cosmetics. Legislative authority for the work of the Program originates mainly in the *Canada Consumer Product Safety Act*, regulations made under the *Canada Consumer Product Safety Act*, provisions relating to cosmetics in the *Food and Drugs Act* and the *Cosmetic Regulations* made under the *Food and Drugs Act*.

Canada Consumer Product Safety Act

The *Canada Consumer Product Safety Act* repealed and replaced certain sections of the *Hazardous Products Act*, and came into force on June 20, 2011. The purpose of the *Canada Consumer Product Safety Act*, a key deliverable of the Food and Consumer Safety Action Plan, is to address or prevent dangers to human health or safety that are posed by consumer products in Canada. In passing the *Canada Consumer Product Safety Act*, Parliament recognized that the Government of Canada, individual consumers and suppliers of consumer products all have important roles to play in addressing or preventing dangers to human health or safety that are posed by consumer products. The three Food and Consumer Safety Action Plan pillars of the Program are:

- ***Active prevention*** which involves avoiding product safety incidents through systematic risk assessment, increased scientific knowledge, improved standards, dissemination of best practices, provision of regulatory guidance, early identification of safety issues, and the provision of information to increase consumer awareness. *Canada Consumer Product Safety Act* provisions such as the General Prohibition and the ability to verify compliance by ordering tests, studies and compilation of information put the onus on industry to prevent unreasonable hazards from entering the marketplace.
- ***Targeted oversight*** works to improve product safety checks at various stages of the product lifecycle and to enhance the Program's ability to quickly detect potential dangers to human health or safety. This is achieved through mandatory reporting requirements for suppliers, establishment of systems for surveillance and risk assessment and systematic approaches to risk management.
- ***Rapid response*** through increased authority to government to take action to identify and respond to a risk related to consumer products. Related authorities include inspecting for compliance purposes, seizing products, ordering mandatory recalls and other measures, issuing administrative monetary penalties, and recordkeeping requirements to facilitate product tracing.

Under the *Canada Consumer Product Safety Act*, suppliers are expected to take all reasonable measures to promote and ensure the safety of the products they supply at every stage of the product lifecycle. They must also take appropriate action to correct the situation when non-compliance is determined. Consumers can also play a role by staying informed of risks, selecting and using consumer products safely, and informing suppliers and Health Canada of any health or safety related problems they encounter with consumer products.

The *Canada Consumer Product Safety Act* is a post-market regime, which places the primary responsibility on suppliers to ensure the products they supply do not pose a danger to human health or safety. Key provisions of the *Canada Consumer Product Safety Act* reinforce suppliers' obligations including, for example, the requirement for suppliers to prepare and maintain documents and report incidents to Health Canada. These provisions are further reinforced by new powers that the *Canada Consumer Product Safety Act* provides the Minister of Health to enable targeted oversight of consumer product safety and to respond rapidly to address hazards when necessary. This includes the ability to issue orders for recalls and to take measures such as stop sale, a system of administrative monetary penalties, the ability to seek injunctions, and to pursue criminal prosecutions.

Food and Drugs Act / Cosmetic Regulations

The Program is also responsible for the administration and application of provisions relating to cosmetics in the *Food and Drugs Act* (in particular ss. 3, 16, 17 and 18) and the *Cosmetic Regulations* made under the *Food and Drugs Act*. Cosmetics are excluded from the application of the *Canada Consumer Product Safety Act*. Cosmetics are also subject to the Food and Consumer Safety Action Plan. Risk assessments on cosmetics issues promote the FCSAP pillars of active prevention, targeted oversight and rapid response.

Health Canada works closely with manufacturers and industry associations to regulate and promote the safe use of cosmetics in Canada. The *Cosmetic Regulations* include requirements with respect to safety, notification of sale, ingredients and labeling of cosmetic ingredients. The *Food and Drugs Act* prohibits, among other things, any person from selling any cosmetic that has in it or on it any substance that may cause injury to the health of the user when the cosmetic is used according to the directions on the label or those accompanying the cosmetic, or for such purposes and by such methods of use as are customary or usual for that cosmetic. The Cosmetic Ingredient Hotlist is an administrative tool developed by the Program to communicate to manufacturers and others that certain substances, when present in a cosmetic, may contravene a) the general prohibition found in Section 16 of the *Food and Drugs Act* or b) a provision of the *Cosmetic Regulations*. Compliance is monitored, in part, through the mandatory notification provisions of Sections 30 and 31 of the *Cosmetic Regulations*

The *Food and Drugs Act* and *Cosmetic Regulations* provide authorities to seize non-compliant products and to prosecute contraventions of the *Food and Drugs Act* or of the regulations; however, unlike the *Canada Consumer Product Safety Act*, these do not provide authorities for mandatory recalls, orders to take measures, or administrative monetary penalties.

3. RISK ASSESSMENT PRINCIPLES

The Program's views about risk have helped to inform the selection of the underlying principles discussed in this section. The principles described constitute a structured policy framework that guides the conduct and review of scientific risk assessments in the Program. Understanding these principles is important in ensuring that the work and decisions of the Program are consistent and are in line with identified priorities, such as the broader policy principles of the Food and Consumer Safety Action Plan and regulatory reform initiatives such as the Red Tape Reduction Initiative. It is also important for decision-making related to the allocation of the Program's finite resources.

The risk assessment and risk management approaches taken by the Program are influenced by a number of factors. These factors include the overall departmental context, the Program's corporate history of addressing risks for products, and the purpose, principles, and intent of the governing legislation. The principles are further informed by the *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* (2000), the Treasury Board of Canada Secretariat (TBS) *Framework for the Management of Risk* (2010) and *Guide to Integrated Risk Management* (2010) as well as by best practices in other Canadian federal departments and other jurisdictions. The principles will also be incorporated into the Program's operational policies and procedures.

Risk management decisions that result from risk assessment processes will be tailored to the specifics of the situation and be informed by the risk assessment. The Program therefore seeks consistency in the application of risk assessment principles in its work. The implementation of these principles supports the consistent application of risk assessment and management approaches. Generally, the principles described here should be considered equally important as the others in the risk assessment process. Section 4 identifies the steps of the risk assessment process and identifies where the elements of the principles described here should be considered.

Table 1 outlines six principles that are intended to guide the implementation of risk assessment. Each principle is described in more detail in Sections 3.1 through 3.6.

Table 1: Risk assessment principles

Section	Principle	Description
3.1	The priority and level of effort given to conducting a risk assessment are determined by the potential risk to the health or safety of the Canadian public	Sets out the factors that are applied to prioritize issues and ensure that the risk assessment effort allocated is proportional to the potential risk.
3.2	Risk assessments are based on evidence and professional judgment	Explains the expectation that risk assessments are conducted according to methods and standards that are appropriate to the product hazard under consideration, the available evidence at the time and the use of professional judgment where information is lacking and for critical analysis of the issue.
3.3	Risk assessment processes are transparent	Sets out the aspects of the Program's risk assessment principles and process that are transparent to the public and other stakeholders.
3.4	Risk assessments will identify uncertainties	Describes the nature and magnitude of known uncertainties, and considerations for reducing and communicating uncertainty.
3.5	Risk assessments appropriately consider population variability and vulnerability	Describes the aspects of variability and vulnerability that are considered and prioritized in risk assessments.
3.6	Risk assessments consider foreseeable use and misuse	Describes the concept of foreseeable use and misuse and its relevance in the prioritization of issues for risk assessment effort.

3.1 The priority and level of effort given to conducting a risk assessment are determined by the potential risk to the health or safety of the Canadian public

The allocation of resources to conduct a risk assessment and other program components are generally based on, and are proportional to, the potential risk posed by the product or situation. Finite resources and limited timelines necessitate that the most urgent situations and most severe or potentially significant risks to members of the public should receive higher priority and more timely attention. The potential risk for a given issue is evaluated for all issues received by the Program and are based on a triage and prioritization process, to inform whether further risk assessment activity is required. Where further risk assessment activity is determined to not be required, the issue is monitored.

Reports and emerging trends are subject to an initial triage and prioritization process to determine the urgency of response and whether further risk assessment activity is necessary. The priority of an issue and the resources dedicated to its further assessment can be adjusted if they prove to be more or less serious than originally estimated.

A number of factors influence the initial triage and prioritization process which provides a preliminary indication of the level of potential risk to human health or safety to the Canadian public. These factors include:

- the severity of the actual or potential injury or near-miss or death;
- the age of the person affected (e.g. children or seniors);
- the extent of wear and age of the product in question;
- the number or pattern of reports related to the particular product or product type in question; and,
- a determination of whether the hazard is present when the product in question is used or misused in a reasonably foreseeable manner.

Reports or emerging trends involving specific vulnerable populations will receive higher priority. Generally, of these, young children will receive the greatest weight for this factor in the priority setting tool. Other vulnerable sub-populations, such as seniors, will also receive a higher weight than a healthy middle aged adult. Priority setting for a risk assessment may also be informed by human health or safety risks identified by another authority within or outside of Canada.

In those cases where further assessment activity is determined not to be necessary or a priority, surveillance experts may continue to monitor media, other international consumer product regulators, health and safety organizations and other sources for any further activities or information that may inform or identify the need to revisit or take further assessment activity on a given case.

3.2 Risk assessments are based on evidence and professional judgment

Assessments should be based on the best available evidence and professional judgment, and should follow the steps and considerations outlined in this Framework. Risk assessments will seek to maximize objectivity; the conduct of a risk assessment is independent from risk management, and it is not subject to external expectations of what a potential risk management outcome should be. The processes for scientific risk assessments should be based on established methods and information that are appropriate to the product hazard under consideration.

When undertaking a risk assessment, Program risk assessors will consider the weight of evidence by gathering available evidence, assessing the merits of the evidence and making a decision based on the evidence using professional judgment. The relevance of the evidence used is documented within the risk assessment. The risk assessor will seek appropriate sources for additional information when it is required. Information and considerations are based on informed and professional judgment and can come from a variety of sources. Collaboration with industry and subject-matter experts is often a source of information. Partners within Health Canada, and risk assessors in other jurisdictions (national and international) may also have relevant information.

In the event that there is insufficient scientific evidence available on the identified hazard, risk assessors will use professional judgment based on other information sources, information on similar products and similar incidents to assess risks to the health and safety of the public. The lack of information will not prevent an assessment of a risk that appears to be serious; the assessment will be based on the information that is available while identifying the uncertainties and assumptions made.

3.3 The risk assessment process is transparent

The Program is transparent with respect to the principles that guide risk assessments and the process by which they are conducted. To achieve this, the Program will make the Risk Assessment Framework available publicly. In addition, the Program endeavors to share product specific risk assessments with affected companies where further action is being considered. In some cases, the Program shares product category risk assessments more broadly, bearing in mind considerations respecting confidential business information and personal information. Risk assessments that support regulatory measures may also be published as part of the regulatory consultation process. This transparency provides companies and other stakeholders with a reasonable opportunity, where appropriate and given all of the circumstances, to present relevant information and have it considered. Transparency about the risk assessment process and principles will respect the constraints of the confidentiality of business and personal information as well as legislative requirements.

3.4 Risk assessments will identify uncertainties

The nature and magnitude of known uncertainties will be identified in a risk assessment. The communication of the uncertainty in a risk assessment is important, as identifying the sources and reasons for uncertainty will help to ensure that the basis of a risk management decision is well understood.

Uncertainty is intrinsic in risk decision-making and estimating risk. It can arise from the quantity and quality of information used in the assessment; information used as the basis for assumptions; the state of scientific knowledge relating to the risk being assessed; as well as the limitations of the methods used to generate a risk estimate.

Depending on its type and source, uncertainty may sometimes be reduced through the gathering of additional information, or the generation of more data/additional analyses. However, these activities require additional time and resources and may not be justified in many cases. It is important to consider the impact the uncertainty will have on assessing the risk, and how much time and other resources would be required to gather or to generate the additional information. In addition, consideration should be given to the degree to which additional information may improve the risk assessment, to provide the necessary information to support an informed risk management decision that is balanced with the need for a timely response. In these cases it may be important that the need for reducing the uncertainty and the timelines to do so be considered in consultation with risk managers.

The nature and degree of uncertainty should be described in a risk assessment, when appropriate, in terms of the information or knowledge lacking and the likely impact on the risk, if any.

3.5 Risk assessments appropriately consider population variability and vulnerability

Risk assessments will incorporate and reflect the variability and vulnerability in the populations and groups who use or may be affected by the use of a product. An estimate of the risks of a product may consider many potential sources of variability, such as whether the product poses risks to a vulnerable sub-population, whether there are any aggregate risks that could be present when a product is used in conjunction with another, or the likely circumstances surrounding the foreseeable product use or misuse.

Variability refers to the range of characteristics among a population that may be exposed to a risk, and that should be taken into consideration when risks to that population are assessed. A large and diverse group of users would have a high degree of variability in many factors, such as anthropometrics and age of the users in relation to the effects a risk may have; size, strength, skill, cognitive ability and sophistication in using a product; and personal, cultural, behavioral or professional factors that may lead some groups to a greater than average use of, or result in higher level of exposure to, a product.

Unlike uncertainty, variability is an inherent characteristic of a population and cannot be reduced, and it should be clearly described and distinguished from uncertainty. The extent of variability is often very difficult to establish, particularly as it relates to variations in user behavior.

Variability within any large society may result in some groups who are particularly vulnerable to the risks of a product. A vulnerable sub-population is any group of people who share a characteristic that causes each member to be more susceptible to the impacts of an unsafe exposure, or to be less resilient or able to cope with those impacts than the general public; these groups may include children, seniors, pregnant women, and persons with a disability. Susceptibility is a related characteristic that denotes a greater than average sensitivity to the effects of exposure to a hazard; a very common susceptibility may constitute a vulnerable group. Since a risk can have a greater negative impact on vulnerable people, risks that affect them disproportionately may be given a higher priority and decisions of risk management would incorporate a consideration of the relevant vulnerabilities. In cases where a range of different subpopulations or uses may be relevant to the assessment of the risk posed by a product, appropriate consideration of population variability will be included in the assessment.

In general, young children constitute a vulnerable group that is of great concern for the Program due to their unique physiology and behaviours, as well as their lack of awareness of and/or control over hazards to which they could be exposed. The Program places a high priority on setting and enforcing safety standards and Regulations for many children's products, and also provides safety information on, and assesses hazards associated with, products that are not necessarily intended for children, but to which they may be exposed. While young children constitute a vulnerable group of great concern to the Program, the other vulnerable groups identified are also of concern to the Program and will be considered in the risk assessment when warranted.

3.6 Risk assessments consider foreseeable use and misuse

Risk assessments of products include not only the uses intended by the manufacturer for the product, but also foreseeable uses and misuses of the product. The Program works to address and prevent risks to human health or safety posed by products when they are used in a normal or foreseeable manner. The Program considers that this includes hazards that result from a foreseeable use or foreseeable misuse of a product. Analysis of these use patterns is informed by the nature of the product, foreseeable users (including vulnerable sub-populations), obviousness of product hazards, trends in reports, etc.

4. RISK ASSESSMENT PROCESS

The Principles of Risk Assessment, described in Section 3, establish parameters for the conduct and review of risk assessments within the Program. Within each step of the risk assessment process, the elements identified within the principles in Section 3 are discussed to illustrate how they are applied.

The risk assessment process is a systematic science-based process of characterizing a risk that generally adheres to accepted methodology established in the sub-discipline of concern (such as mechanical/physical, electrical, toxicological, flammability, microbial, etc.) in which the assessment is conducted. This process is generally independent of the risk management function. Section 4 outlines the core set of steps, and criteria for conduct and quality, that are common to most risk assessment processes.

Figure 1 outlines the steps in the Risk Assessment Process. To meet the requirement for timely conduct and review of risk assessments, appropriate performance standards for the conduct of risk assessments are needed. Performance standards will be set in Standard Operating Procedure documents. The Program undertakes a prioritization process for reports received and emerging trends identified; however, further risk assessment activities are not carried out in all cases (e.g. for example for reports that are prioritized as low).

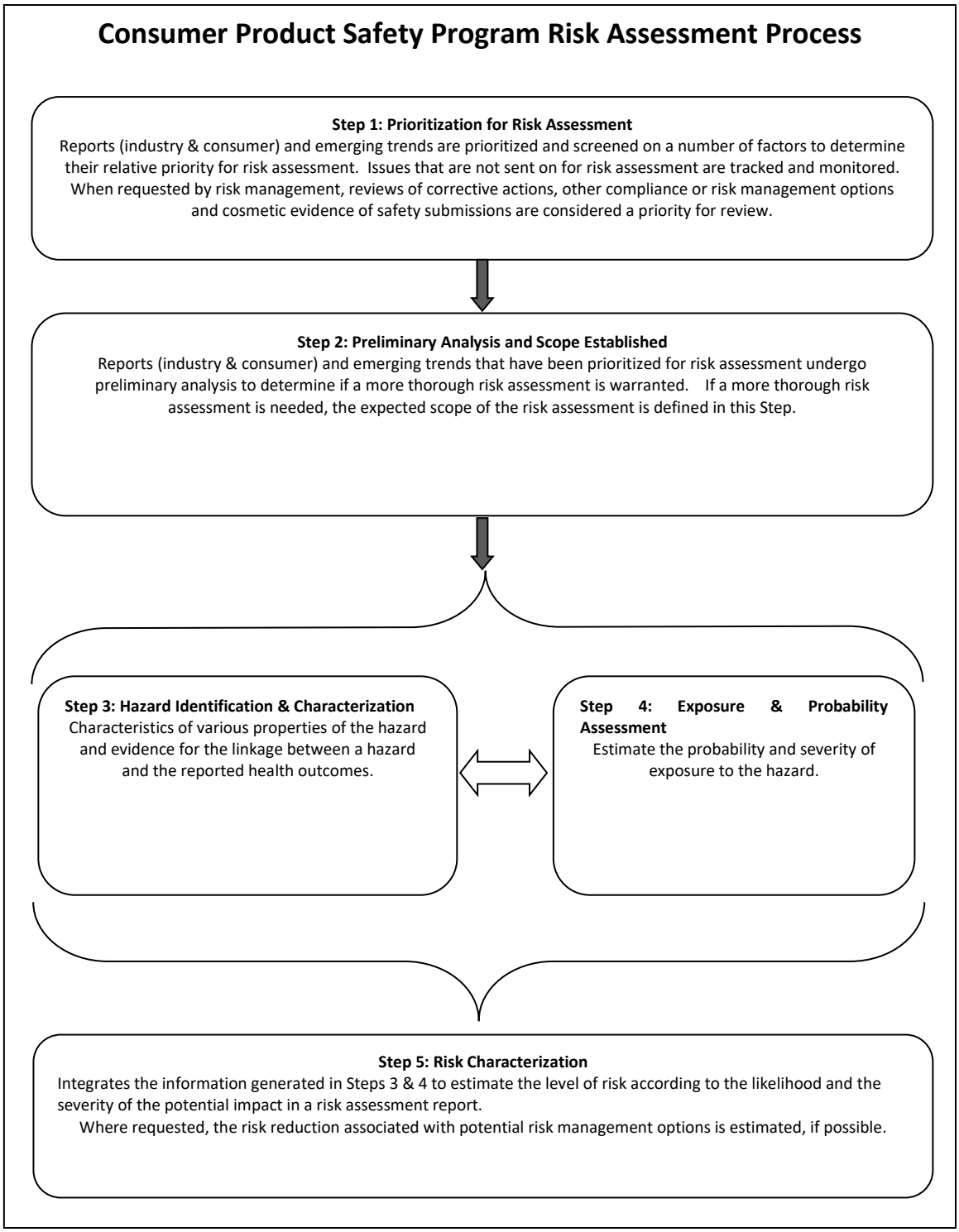

Figure 1. Schematic of the Product Safety Risk Assessment Process. This diagram provides an overview of key stages in the risk assessment process. The activities related to steps 3, 4, and 5 are interactive and iterative due to the nature of evaluating product safety issues. Note that in general the Program conducts risk assessment work in a variety of ways beyond reporting or emerging trends, which may encompass parts but not necessarily all of the stages outlined above.[1]

[1] An example of this would be the work that is conducted to support the Chemicals Management Plan.

4.1 Step 1: Prioritization for risk assessment

Reports and emerging trends[2] related to consumer products and cosmetics are subject to a prioritization process. Upon initial receipt of a report, from a source such as a consumer, supplier, medical professional or other organization, an administrative triage is undertaken that verifies the following:

- Does the report involve a "consumer product" or “cosmetic” as defined under the *Canada Consumer Product Safety Act* or *Food and Drugs Act*? If the product is regulated under different legislation (i.e., car tires, prescription glasses or other medical devices, etc.) these reports will be referred to the appropriate organization.
- Does the report involve a product or hazard that is subject to specific requirements set out in regulations, the submission of evidence of safety for a cosmetic, an issue regarding counterfeit products, recall effectiveness or a trade complaint? These reports are sent directly to risk management for consideration if further action may be needed and would not be prioritized for risk assessment. It is possible these cases may get referred by risk management to risk assessment for review.
- Does the report pertain to a health or safety related issue?

Those reports involving a health or safety issue with a product that are not addressed through an existing regulation are then prioritized to determine whether further risk assessment is necessary. As outlined in Principle 3.1, factors that inform the prioritization for risk assessments include:

- the severity of the reported or potential injury or near-miss or death;
- the age of the person affected;
- the extent of wear and age of the product in question;
- the number or pattern of reports related to the particular product or product type in question; and
- a determination of whether the hazard is present when the product in question is used or misused in a reasonably foreseeable manner.

The Program utilizes a prioritization tool to evaluate these factors. The tool assigns a weight to each of the risk assessment screening factors that either increases or decreases its priority for risk assessment. The consideration of all these factors combined will provide a preliminary indication of the priority for undertaking a risk assessment. For example, incidents involving a serious injury or children are given the highest weight for this factor, which will generally result in a higher priority for review. In cases where the weighting factor is very low, the case may not lead to an immediate risk assessment; instead it may be monitored for any possible emerging trends or new information that could signal a recurring problem

[2] In addition to consumer and industry reports, additional information on emerging trends may also inform risk assessment activities. The Consumer Product Safety Program looks for information / data from health or safety professionals, other federal regulators, media and other web-based news sources that may identify health or safety issues with respect to consumer products and cosmetics.

that may need to be addressed. Additional factors may also be considered, such as the risks to human health or safety identified by another authority within or outside of Canada.

At the request of risk management, risk assessments are also undertaken on a priority basis to support the review of effectiveness of corrective actions, other compliance or risk management options, and reviews of cosmetic evidence of safety submissions from manufacturers to determine if Cosmetic Ingredient Hotlist guidance is being followed.

4.2 Step 2: Preliminary analysis and scope is established

Following the prioritization of an issue (Step 1), cases that are determined to be a priority for risk assessment undergo a preliminary analysis by risk assessors to determine whether a product's normal or foreseeable use or foreseeable misuse have the potential to pose a serious adverse health effect or death to a user. The preliminary analysis will first verify the availability and quality of information. If any information is required to support the preliminary analysis, the Program may request this information from suppliers or other organizations. Should adequate information be available, the preliminary analysis will consider the following:

- whether it is reasonable to attribute the product use to an injury;
- whether a user would have an awareness of a potential hazard with the product; and,
- whether harm would only occur if a user used the product in an unreasonable manner, which may include gross negligence or criminal activity.

Based on this preliminary analysis and information available, the issue will then be evaluated and may in certain cases include preparation of a Level 1 report. A **Level 1** report will outline a summary of the product and incident information, product history, applicable regulations and standards, industry reporting, discussion on the potential hazard, product features that may influence the evaluation, may include some discussion on probability and foreseeable use/users of the product, and will identify any concerns the risk assessor has with the product. The Level 1 report would not include quantification of a risk level or the information to the level of detail outlined in Steps 3 to 5. The outcome of the preliminary analysis, which may include a Level 1 report, would then identify 1) if risk management action can be considered without further risk assessment, 2) if the issues should be monitored and included in trend analysis activities, or 3) if a more thorough risk assessment is warranted.

A Level 1 report will also be prepared to support the review of the effectiveness of proposed corrective actions and other compliance or risk management measures. In addition, a Level 1 report is also prepared to support the review of cosmetic evidence of safety submissions from manufacturers. A preliminary analysis is not conducted in these cases. The outcome of these Level 1 reports would indicate 1) if the corrective action was effective to address the risk identified, 2) provide recommendations related to the effectiveness of proposed compliance or risk management measure is addressing/reducing the risk, or 3) if cosmetic evidence of safety information followed the Cosmetic Ingredient Hotlist guidance.

Should the preliminary analysis or Level 1 report identify the need for a more thorough risk assessment, a **Level 2** report will be prepared. At this step the scope and objectives of the assessment are decided, including the products to be assessed (including relevance of similar products available), the range of users to be included, specifying any vulnerable or particularly susceptible groups that should be considered, and the types of exposures and exposure scenarios that should be assessed. The questions that surround the product hazard and the information needed to make an informed risk management decision (if warranted), should be determined and clarified, and the nature of the risk and the objectives of the risk assessment should be articulated, along with any uncertainties. While risk assessment is a

separate process, risk managers should be engaged in defining the scope and objectives of the risk assessment to ensure that the risk assessment reports provide risk managers with the information required, to make decisions to mitigate risks to the health and safety of the Canadian public. Initial estimates of likelihood and severity factors should be considered.

While the scope and objectives should be clearly defined at the outset to guide the risk assessment, they should not be unnecessarily narrow or rigid. Risk assessors will seek to ensure that assessments are flexible so that during the assessment process, new information can be considered. As the assessment proceeds, the scope and objective(s) may be revised as new information, findings or considerations become available.

4.3 Step 3: Hazard Identification and Characterization

Hazard identification is the process of determining if a product has the potential to cause an adverse health effect. Identification and characterization of the hazard needs to take place concurrently with exposure assessment (as indicated in Figure 1), as this is an interactive and iterative process. The likelihood of any particular scenario or health outcome is not established until the results are combined in the risk characterization step.

Consideration of part or all of the possible factors in the identification and characterization of the hazard will directly influence the methodologies to be used, the resources required, and the timelines for completing the risk assessment. This work requires collecting and examining relevant scientific data, considering sources of uncertainty and other limitations and, where appropriate, how these may impact the hazard identification. In addition, the overall weight of evidence and quality of data are taken into account during this process. Hazard identification and characterization may include consideration of some or all of the following elements (not necessarily an exhaustive list):

- Identifying the characteristics/properties (*e.g.* attributes, ingredients) specific to the product (considering the product design) potentially responsible for the adverse health effect(s) or which could be responsible for an adverse health effect(s);
- Identifying intended or foreseeable uses and misuses of the product and foreseeable users of the product (intended users and potential users including bystanders, or vulnerable sub-populations indirectly using, or being exposed to, the product);
- Identifying the potential health effects (e.g. asphyxiation), along with the mode/mechanism of action (*e.g.* pharmacokinetics, pharmacodynamics) associated with the intended or foreseeable use of, or exposure to, the product; and
- Identifying the nature of the potential harm and any range in its severity.

Some of the elements identified above are also considered and further described in the exposure assessment.

4.4 Step 4: Exposure and Probability Assessment

The hazard identification and characterization step identifies a list of pathways of potential harm that should be considered in the risk assessment (bearing in mind that an actual incident may have precipitated the risk assessment). The exposure assessment is the process of estimating the probability of specific events, chronic effects or of particular levels of exposure (repeated daily exposure, or one-time use) related to those pathways identified in the hazard identification and characterization. An exposure assessment is carried out by characterizing a series of use scenarios that could lead to potential harm, or pathways of potential exposure. An exposure scenario may include a combination of events for which the probability of joint occurrence is estimated.

An exposure scenario includes a number of different considerations, which will depend on the nature of the assessment (*e.g.* risks related to chemicals, mechanical/physical issues, electrical, microbial, flammability, etc.). This work requires collecting and examining relevant scientific data, considering sources of uncertainty and other limitations and, where appropriate, how these may impact exposure assessment, and considering the overall weight of evidence while taking into account the quality of the data. An exposure scenario and the estimation of its probability may include consideration of some or all of the following elements (not necessarily an exhaustive list):

- the user(s) for whom exposure is being estimated

  This would include consideration of the intended users, foreseeable users, potential bystanders, those potentially exposed when product is no longer in use, vulnerable populations (*e.g.* consideration by age group), or other important attribute of the user under consideration.

- the specific use of, or exposure to, the product and likely user behavior

  This would include intended use, foreseeable use and foreseeable misuse. The probability of different use patterns, user behaviors and conditions of use will depend on whether that use is intended, foreseeable use or foreseeable misuse.

  The risk assessor must decide whether a use is considered foreseeable. In addition, the relative likelihood of the scenario should be described since the fact that something is foreseeable does not necessarily imply that it will occur frequently.

- the phases of product use

  When undertaking an exposure assessment, it may be appropriate to give consideration to different phases of product use. There are at least four phases of product use, although they are not all applicable to all consumer products or cosmetics or relevant to the pathway of potential harm:

  - product preparation (*e.g.* assembly);
  - direct use;

- post-use; and
- disassembly or removal.

Each phase of activity will result in different exposure scenarios and may also result in different exposure levels. However, it may not always be relevant to examine each phase.

- the usual circumstances or environment(s) in which the use takes place (indoor/outdoor, consumer versus occupational, poorly ventilated versus well-ventilated areas, etc.)
- the hazardous property under consideration (flammability, sharpness, toxicity, etc.) and the chemical/physical characteristics of substances within the product that may influence their exposure (volatility, bio-accessibility, bioavailability, etc.). This includes aspects of the product, such as ingredients or concealed parts, which may/may not be accessible to users.
- how obvious or detectable the hazard is

  The probability of different use patterns, user behaviors and conditions of use will depend strongly on how detectable the hazardous properties of the product may be. In some cases, the hazard is self-evident and is an inherent and desirable property of the product (*e.g.,* the sharp edge of a knife, the flammability of fuels, the heat associated with an electric heater). In other cases, the nature of the potentially harmful exposure may be completely unknown to, or undetectable by, the user or bystanders.
- the route of exposure (oral, dermal, inhalation, etc.)

  A route of exposure is the manner in which the product hazard may present itself to the exposed user. Different routes of exposure may be more/less likely, and each may require specific considerations.
- the duration and frequency of use and exposure

  Exposure to a given product is directly dependent on the frequency and duration of a user's interaction with the product. It may be important to estimate the total amount of time that the average user is exposed to a product to estimate the probability or potential of the exposure.
- the product lifespan and wear

  It is not uncommon for products to destabilize (or, depending on the product, to fail, degrade or spoil) after a certain period of time, or after a certain amount of wear, which may or may not be obvious to the user; some hazards may be directly related to such wear and tear or other damage. It is also not uncommon for consumers to continue to rely on products beyond the manufacturer's recommended life of a product, particularly if the product is used infrequently.
- considering aggregate exposure

It may be relevant to consider simultaneous exposure to multiple sources. In some cases, exposures from individual sources may overlap. Risk assessors may consider the impacts of these sources in the assessment.

- the use of tiered exposure assessment strategies

  In a tiered assessment strategy, it is common to develop exposure scenarios that first include a worst-case scenario. This is generally achieved by assuming conservative conditions for multiple aspects of the scenario (*e.g.,* a person with a small body weight, a poorly ventilated area, frequent and intense use, susceptible health status, failure to detect a problem, lack of protective equipment, lack of access to emergency health care, etc.). Developing exposure scenarios that first include a worst-case scenario can be used to demonstrate early on whether or not there is a potential risk worth exploring further through refined estimates as the assessment proceeds. Should the worst case scenario demonstrate a potential risk, refinement of both hazard and exposure parameters should be considered to arrive at a more reasonable estimate based on the foreseeable use and users of the product. In addition, having a reliable range of foreseeable exposure conditions, including worst case scenarios, can be used to generate either individual or population-based estimates, depending on the situation.

  In some circumstances, a characteristic/property of a product may be hazardous enough that any exposure is unacceptable. Examples of such situations may include: contaminants (*e.g.*, glass, metal, incidental additives or microorganisms that are found in the final product), ingredients and/or characteristics of a product that are prohibited to be used in humans, or a defect in the product itself that could lead to potential serious health outcomes (*e.g.* a faulty cabinet lock intended to keep children from opening a hazardous container).

4.5 Step 5: Risk Characterization

Risk characterization is the final step in the risk estimation process. Risk characterization integrates the information generated through the process into a summary conclusion of the risk, in a manner that is relevant and useful for risk managers. The information provided by the risk assessment is one factor that will be considered in combination with other risk management considerations as required (*i.e.* technological, economic, social, and political) to inform the risk management decisions.

Risk characterization incorporates both quantitative or qualitative information, depending on the available data. It combines hazard characterization (described in Section 4.3) and estimates of exposure (described in Section 4.4) to yield estimates of the severity of the hazard and the likelihood that it will occur. The risk characterization provides an estimated risk level for the exposure scenarios identified through the risk assessment process.

The following are some key components of the risk characterization, which may be presented depending on the context of the risk assessment:

- Injury severity – An accurate determination of the level of risk requires an accurate estimation of the severity of potential or incurred injuries.
- Likelihood of injury – An estimation of the likelihood of injury based on a defined scale that is consistent across the different types of hazards (*i.e.* chemical hazards, mechanical/physical hazards, and electrical hazards.
- User risk and population risk - Injury Severity and Likelihood of Injury are combined in a matrix to determine both a user risk and a population risk. A risk matrix is being developed by the Program which reflects the principles and processes within this Framework.
- Uncertainty rating – An uncertainty rating that reflects the level of confidence that the risk assessor has in the outcome of the risk. The known uncertainties that underlie the risk assessment are described. Where appropriate and possible, the effect of different assumptions can be demonstrated quantitatively to show the sensitivity of the estimate of risk to key sources of uncertainty.

Suppliers may provide, or in some cases may be required to provide, information to inform the steps in the risk assessment process of their product, and may be given an opportunity to review the risk assessment report, where appropriate in the circumstances of specific cases. Where appropriate, the Program may also collaborate and engage with Health Canada partners, subject-matter experts and other jurisdictions (national and international), while respecting the constraints of confidentiality of business and personal information and legislative requirements.

Prior to finalization, communication and discussion with risk managers on the outcomes of the risk assessment will be undertaken. Other outputs of a risk assessment process (intermediate calculations, the results of validation exercises) may be provided for context, and to provide assurance of the content and quality of the process producing those results. These outputs provide further background evidence in the decision-making process and foster the appropriate levels of confidence in the decision-making process among stakeholders.

5. COMMUNICATION OF RISK ASSESSMENT INFORMATION TO RISK MANAGERS

In general, risk communication is the exchange of information and opinion concerning the existence, nature, form, severity, and acceptability of risks to human health and safety. The term is usually used to describe communication on risk estimates, perceptions, acceptability and management between technical experts and non-experts.

Risk assessors prepare written reports (Level 1 report and/or Level 2 report) of all risk assessments undertaken in order to communicate the results of the risk assessment. Risk assessments within the Program are used by risk managers to inform risk management decisions.

Risk assessment reports are written in an objective manner that clearly and succinctly explain the nature and level of the risk, and should cite the sources of information used in the assessment, including information from suppliers, other jurisdictions or organizations, and scientific literature. The report identifies and describes the elements considered during the risk assessment process as outlined in this Framework and describes how these were evaluated and the associated uncertainty with these elements. They are written in plain language with a minimum of jargon, and in a consistent format.

The Level 1 risk assessment reports typically conclude with an identification of areas of concerns with the product, but will not necessarily conclude with an estimation of the level of risk. The Level 2 reports conclude with an estimate of the level of risk associated with use scenarios, the level of confidence in the estimate, and a discussion of any important factors that significantly affected the risk assessment.

The results of the risk assessment will be provided to risk managers to form a basis for further risk management actions as necessary. In addition, where appropriate in the circumstances of individual cases, the Program shares product specific risk assessment reports with affected companies where further action is being considered. Although informed by risk assessments, risk management decisions are based on a variety of factors and are the responsibility of Program risk managers.

The risk assessment process should consider and evaluate all relevant evidence and reach decisions on the most relevant and reliable evidence. Application of the risk assessment process in a consistent manner in accordance with the principles outlined in this Framework provides transparency to stakeholders on how risks are assessed by the Program.