CONSUMER PRODUCT SAFETY PROGRAM

RISK ASSESSMENT FRAMEWORK

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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 resulting from a **hazard**.

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

Incident: For the purposes of subsection 14 (1) of the *Canada Consumer Product Safety Act,* 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 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).

Report: the mandatory report regarding an **incident** submitted by **suppliers** under s. 14 of the *CCPSA* or voluntary report submitted to the Program.

Near Miss: An event 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).

Risk: The impact of exposure to a **hazard,** which integrates the frequency or probability of occurrence of possible outcomes with an estimate of the magnitude of the associated consequences of these outcomes.

Risk Assessment: A systematic process of estimating the level of **risk,** considering both the probability and consequences of exposure to a **hazard**, for the purpose of informing decision-making.

Risk Management: A systematic approach to setting the best course of action under conditions of **uncertainty** by identifying, assessing, understanding, acting on, and communicating **risk**.

Suppliers: Includes individuals, companies and other organizations that manufacture, sell, advertise or import **consumer products** or **cosmetics**.

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

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.

2. INTRODUCTION

2.1 Purpose of the Risk Assessment Framework

The purpose of this Risk Assessment Framework is to provide clarity and guidance to internal and external stakeholders on the principles and processes associated with risk assessment in the Consumer Product Safety Program (Program). Because the Program is a post-market program and cannot address all issues, the Framework helps establish a risk based approach to determine where 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 (FCSAP), a broad initiative to modernize and strengthen Canada's safety systems for food and consumer products. The FCSAP bolsters Canada's regulatory system by committing to amending or replacing outdated health and safety legislation with new legislative regimes that respond to modern realities, and by enhancing safety programs in areas where modern legislative tools already exist.

The risk assessment and risk management approaches taken by the Program are influenced by a number of factors. These 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 of risk assessment at the Consumer Product Safety Program outlined in Section 4 of this Framework 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) *Guide to Integrated Risk Management (2010)* as well as by best practices in other Canadian federal departments and other jurisdictions.

The principles described in this framework provide a foundation for the way the Program considers risks to human health and safety posed by products, including the importance placed on key factors in assessing these risks. While each principle provides information and guidance in a specific area, they are all interrelated. As such, they should be viewed and considered as a cohesive package. This framework helps with prioritizing risk assessment work, setting clear objectives for risk assessments, considering key variables that could affect a risk assessment, and identifying and articulating uncertainties. It is important to note that the Program may not conduct risk assessments in all cases. Manufacturers and importers are responsible for ensuring that their products do not pose a danger to human health or safety. When they report an incident related to a consumer product to Health Canada they must provide all the information in their control regarding the incident which may include technical data, studies, or assessments. In these cases, the Program will be guided in the review of this information by the principles and the process outlined in this Framework.

The framework will help to guide future work on the elaboration of risk assessment methodologies and standard operating procedures. It further provides clarity and transparency to stakeholders on the Program's approach and expectations related to risk assessment.

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

2.2 Consumer Product Safety Program

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* (CCPSA), regulations made under the CCPSA, provisions relating to cosmetics in the *Food and Drugs Act* (FDA) and the *Cosmetic Regulations* made under the *FDA*.

The Program identifies, assesses, manages, and communicates risks to human health or safety posed by products in Canada. Under the CCPSA, suppliers are responsible for ensuring that the products they supply do not pose unreasonable dangers to the health or safety of the public, and comply with the requirements of the Act and regulations. Similarly, the FDA prohibits the sale of cosmetics that have in it or on it any substance that may cause injury to the health of the user. To support compliance and to improve product safety, the Program undertakes outreach activities and collaborates with other jurisdictions. Information is shared with suppliers concerning product safety and their legislative obligations.

The Program also 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.

Recognizing that consumers also have an important role to play when it comes to consumer product safety, the Program encourages consumers to report issues and concerns to industry. The Program promotes safety and the responsible use of products by providing information to help Canadians make informed decisions. Recall notices, advisories, information bulletins and other methods are used to notify the public of product hazards.

Where appropriate, the Program works with Health Canada partners, other federal, provincial and international organizations.

The Program includes the Consumer Product Safety Directorate (CPSD) which is organized into three Bureaus and is within the Healthy Environments and Consumer Safety Branch, as well as the regional Product Safety Offices in the Regions and Programs Bureau.

Risk Assessment Bureau

The Risk Assessment Bureau of CPSD provides centralized scientific risk assessment (conduct of risk assessments and review of technical studies, data, assessments, etc.), and monitoring and trend analysis. The Product Safety Laboratory provides technical expertise and analytical services that support this work as well as risk management activities. Risk assessments are based on information from a

number of sources, such as incoming reports, cyclical enforcement activities, monitoring of developing product-related trends, and emerging hazards [1]. Information is also obtained from other jurisdictions and organizations. Risk assessment outcomes are communicated to the Risk Management Bureau to help inform decision-making.

Risk Management Bureau

The Risk Management Bureau is responsible for developing and implementing risk management strategies, promoting and verifying compliance, preventing non-compliance, and undertaking enforcement. Risk management decisions are informed by the risk assessments undertaken in the Risk Assessment Bureau. The Risk Management Bureau maintains expertise in the development and application of a suite of risk management tools, including communication, voluntary agreements, standards, and guidelines, as well as tools rooted in the legislation such as orders to recall or correct products, and supporting prosecutions.

Program Development Bureau

The Program Development Bureau is responsible for managing legislative and regulatory priorities within the broader portfolio of the Consumer Product Safety Program, providing policy guidance, analysis and development; and for integrated and coordinated international and intergovernmental relations. It is also responsible for effective external relations and integrated planning and performance measurement.

Regional Offices of the Regions and Programs Bureau

The Regions and Programs Bureau (RAPB) is responsible for the delivery of the compliance and enforcement activities for the Consumer Product Safety Program in partnership with the Consumer Product Safety Directorate. RAPB's product safety program teams are located in regional offices across Canada. They administer and enforce legislation pertaining to consumer products and cosmetics and engage in activities aimed at compliance promotion and public awareness.

[1] In addition to consumer and industry reports, additional information on emerging trends may also inform risk assessment activities. Under the Consumer Product Safety's Risk Assessment Bureau, the Surveillance Coordination Unit look for other information / data from other health and / 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.

2.3 Guiding Legislation

The guiding pieces of legislation for this work are the *Canada Consumer Product Safety Act* (CCPSA) and regulations made under it, as well as the *Food and Drugs Act* and the *Cosmetic Regulations* made under it. Key provisions of the legislations are outlined below.

Canada Consumer Product Safety Act

The CCPSA repealed and replaced certain sections of the *Hazardous Products Act*, and came into force on June 20, 2011. The purpose of the CCPSA is to address or prevent dangers to human health or safety that are posed by consumer products in Canada. The CCPSA is premised on the three Food and Consumer Safety Action Plan (FCSAP) principles:

- ***Active prevention*** involves avoiding product safety incidents through systematic risk assessment, increased scientific knowledge, improved standards, early identification of safety issues, and increased consumer awareness.
- ***Targeted oversight*** works to improve product safety checks at various stages of the production process. This is achieved through new mandatory reporting legislation for suppliers, establishment of systems for surveillance and risk assessment, and modernization of regulatory oversight.
- ***Rapid response*** gives increased authority to government to take action when it identifies a risk related to consumer products. Actions include mandatory recalls, increased fines and recordkeeping requirements to facilitate product tracing.

In passing the CCPSA, Parliament recognized that the Government of Canada, individuals and suppliers of consumer products have an important role to play in addressing dangers to human health or safety that are posed by consumer products. The CCPSA requires manufacturers and importers of consumer products to ensure that the consumer products they supply do not pose unreasonable dangers to the health or safety of Canadians. Specifically, the CCPSA prohibits (among other things) the sale, manufacture, advertising or import of consumer products that are a danger to human health or safety (this "general prohibition" is set out in paragraph 7(a) and 8(a) of the CCPSA). The CCPSA places additional obligations on certain suppliers of consumer products. For instance, the CCPSA indicates that persons who supply consumer products may have to conduct tests and provide information about their products (s.12) to verify compliance or prevent non-compliance with the CCPSA or the regulations, prepare and maintain documents (s.13) and report incidents to Health Canada and to their suppliers within two days after they become aware of an incident related to one of their products (ss.14 (2)). Manufacturers and importers have additional obligations to report further details on the product and incident within ten days after they become aware of an incident, including any measure they have taken or propose to take to address a non-compliance issue (ss.14(3)). Record-keeping provisions facilitate tracing of consumer products through the supply chain.

The CCPSA enables targeted oversight of consumer product safety and the ability to take action to address hazards when necessary including the ability to issue orders for recalls and to take measures, 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 of provisions relating to cosmetics in the *Food and Drugs Act* (FDA) and the *Cosmetics Regulations* made under the FDA. Cosmetics are excluded from the application of the CCPSA. The FDA 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. Where a cosmetic poses an avoidable hazard, its label must include directions that tell the user how to use the cosmetic safely. Where a manufacturer does not provide information establishing the safety of a cosmetic under the recommended or normal conditions of use when requested to do so by the Minister, the manufacturer must cease the sale of that cosmetic.

The *Cosmetic Regulations* include requirements respecting safety, notification of sale, ingredients and labeling of cosmetic ingredients. The Cosmetic Ingredient Hotlist is an administrative tool developed by CPSD to communicate to manufacturers and others that certain substances, when present in a cosmetic, may contravene the General Prohibition found in Section 16 of the FDA or a provision of the *Cosmetic Regulations*. Compliance is monitored, in part, through the mandatory notification provisions of Section 30 of the *Cosmetic Regulations*.

The FDA and *Cosmetic Regulations* provide authorities to help address risks, including an authority to seize non-compliant products and to prosecute contraventions of the FDA or of the regulations; however, unlike the CCPSA, these do not provide authorities for mandatory recalls, orders to take measures, or administrative monetary penalties.

3. RISK MANAGEMENT AND RISK ASSESSMENT

Risk management and risk assessment are related but separate processes. Risk assessment is a systematic process of estimating the level of risk, considering both the probability and consequences of exposure to a hazard, for the purpose of informing decision-making. Risk management decisions are informed and supported by risk assessments; however risk management has a wider scope of functions that range from policy development to operational functions like enforcement measures. The principles and processes that guide risk management functions within the Program are articulated in the Risk Management Framework.

Figure 1 illustrates the position of risk assessment within the broader risk management context.

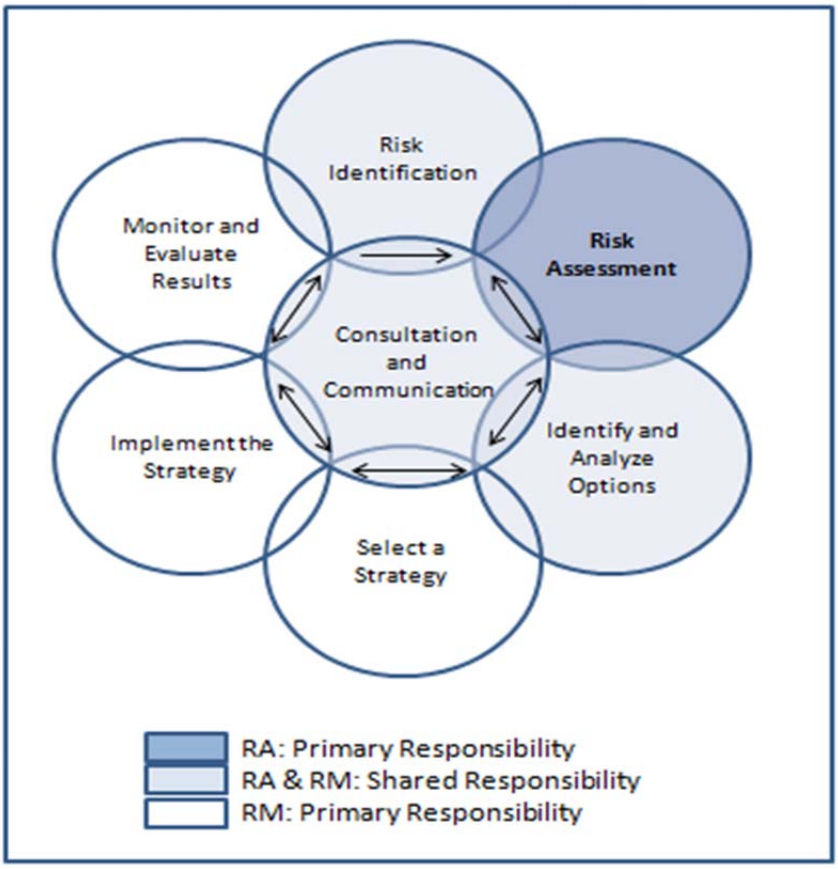

Figure 1. The Decision Making Process and the Roles of Risk Assessment and Risk Management. The figure identifies primary and shared responsibilities of the risk assessment and risk management functions. (Adapted from Health Canada's Decision-Making Framework, 2000.)

Risk assessment in the Program is guided by principles that include criteria for prioritizing risks for assessment, the identification of uncertainty, consideration of vulnerable groups, and transparency. It is this sub-set of the Program's functions that is described in this Framework.

The risk assessment process is a systematic science-based process of characterizing a risk that generally adheres to accepted methodology established in the subdiscipline 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 5 outlines the core set of steps, and criteria for conduct and quality, that are common to most risk assessment processes.

Although risk assessments serve as an important source to inform risk management decisions, risk management takes a broader range of factors into account in order to make these decisions; some risk management decisions may be influenced by factors that are outside of the scope of risk assessment. In some cases, for example, measures may be taken to address high levels of public concern with a product where there is low risk to human health or safety; in others, management of a risk may involve communications with the public rather than an intervention related to the product itself.

4. RISK ASSESSMENT PRINCIPLES

The Program's views about risk have helped to inform the selection of the underlying principles discussed below and to better define risk thresholds. Understanding these risk thresholds 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 (FCSAP). It is also important for decision-making related to the allocation of the Program's finite resources.

The CCPSA and FDA apply to a wide range of products that vary in availability and usage in different parts of Canada, the risk management decisions that result from risk assessment processes will be tailored to the specifics of the situation and be informed by the technical studies, data, assessments, etc... undertaken by manufacturers and importers. The Program therefore seeks consistency in the application of risk assessment principles in its work. The principles described in this section constitute a structured policy framework that guides the conduct and review of scientific risk assessment in the Program. Their implementation supports the consistent application of risk assessment and management approaches. Generally, the principles described here should be considered equally in the risk assessment process. Section 5 identifies the operational 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 4.1 through 4.6.

Table 1: Risk assessment principles

Section	Principle	Description
4.1	The priority and level of effort given to a risk assessment are determined by the potential danger 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.
4.2	Risk assessments are based on evidence and professional judgment	Explains the expectation that risk assessments are conducted according to the methods and standards of the discipline involved, the available evidence at the time and the use of professional judgment where information is lacking and for critical analysis of the issue.
4.3	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.
4.4	Risk assessments will identify uncertainties	Describes the nature and magnitude of known uncertainties, and considerations for reducing and communicating uncertainty.
4.5	Risk assessments appropriately consider population variability and vulnerability	Describes the aspects of variability and vulnerability that are considered and prioritized in risk assessments.
4.6	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.

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

The allocation of resources to conduct risk assessment and other program components are generally based on, and are proportional to, the potential risk posed by the product or situation and its urgency. It is not possible for a risk assessment to be undertaken for all issues brought to the attention of the Consumer Product Safety Program. 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 based on a triage and prioritization process to inform whether further risk assessment activity is required.

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 it proves to be more or less serious than originally estimated.

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

- the severity of the actual or potential injury (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.

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. 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 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.

4.2 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 to the extent that this is possible; the conduct of 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, risk assessors will consider where and when additional information is required and seek the appropriate sources for it. Information and considerations are based on informed and professional judgment can come from a variety of sources. Collaboration with industry and subject-matter experts is often a source of information. Partners within Health Canada, risk assessors in other jurisdictions (national and international) may also have information.

Where there is a lack of information, or that involves a hazard that does not lend itself to established scientific assessment methods, risk assessors will use professional judgment and available evidence related to the product and any reports 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 based on the information that is available.

4.3 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 shares 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 where confidential business information or personal information is not compromised. Risk assessments that support regulatory measures are also published as part of the regulatory consultation process. This transparency assures companies and other stakeholders that they are being treated consistently and that they are provided with a reasonable opportunity, given all of the circumstances, to present relevant information and have it considered. Transparency about risk assessment process and principles will respect the constraints of the confidentiality of business and personal information as well as legislative requirements.

4.4 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.

The determination of 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 will not be justified in many cases. It is important to consider the magnitude of uncertainty underlying the characterizing of risk, how much time and other resources would be required to gather or to generate the additional information, and the degree to which additional information may improve the ability of the risk assessment to provide the information needed for a risk management decision that is balanced with the need for a timely response. It is important that timelines be established in consultation with risk managers.

If additional information is not available, or cannot be efficiently acquired, when appropriate the nature and degree of uncertainty should be described, in terms of the information or knowledge lacking and the likely impact on the risk characterization.

4.5 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. 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.

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 include children, the elderly, 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 general, young children constitute a vulnerable group that is of greatest 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.

4.6 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 dangers 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 both the nature of the product and the foreseeable users (including vulnerable sub-populations), as well as by the obviousness of product hazards.

5. RISK ASSESSMENT PROCESS

The risk assessment process must both consider risk management needs and meet scientific standards of method, data and information used, and analysis (including testing as needed) appropriate for the type of hazard. For the Program, this means that the Principles of Risk Assessment, set out in Section 4, 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 4 are discussed to illustrate how they are applied.

Figure 2 outlines the steps in the Risk Assessment Process. In order 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. It is important to note that the Program may not conduct risk assessments in all cases, for example reports that are prioritized as a lower priority.

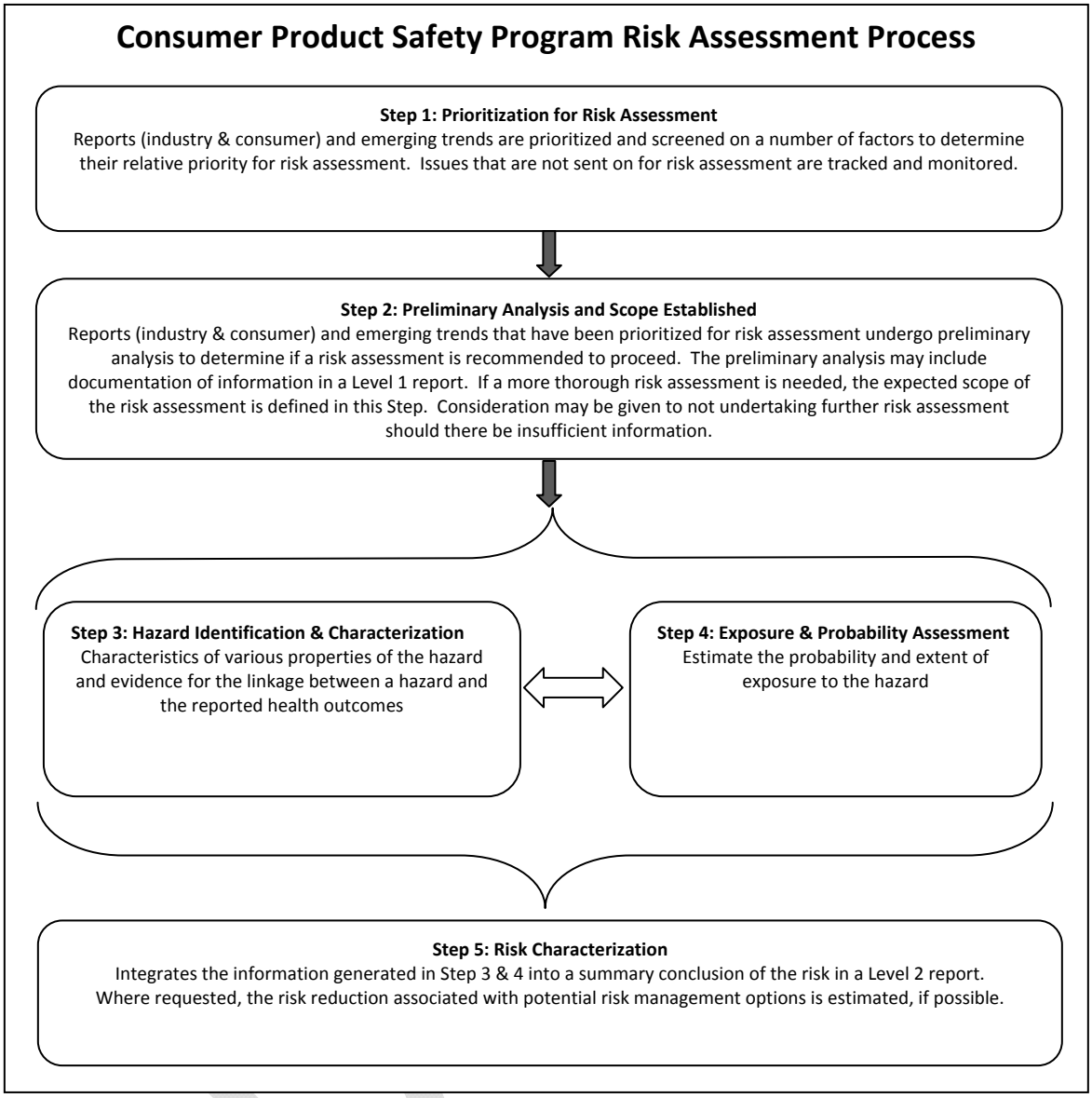

Figure 2. Schematic of the Product Safety Risk Assessment Process. This diagram provides an overview of key stages in the risk assessment process. The activities related to steps 3, 4, and 5 are interactive and iterative due to the nature of evaluating product safety issues. Note that in general the 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.[2]

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

5.1 Step 1: Prioritization for risk assessment

Reports and emerging trends are subject to a prioritization process. Upon initial receipt of a report an administrative triage is undertaken that first verifies:

- Does the report involve a "consumer product" or “cosmetic” as defined under the CCPSA and FDA? 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 regulated product or regulated hazard, an issue regarding counterfeit products, recall effectiveness or a trade complaint? These reports will be sent directly to risk management for consideration and would not be prioritized for risk assessment.
- 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 4.1, considerations 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. 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 the risk may be monitored for any possible emerging trends or new information that could signal a recurring problem 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.

Risk assessments are also undertaken on a priority basis to support the review of effectiveness of corrective actions and other compliance or risk management options.

5.2 Step 2: Preliminary analysis and scope is established

It is important to define the problem so that risk assessment outcomes accurately and consistently classify risks with respect to the need for further action and, where risk management is required, provide risk managers with the information required to make decisions that address risks to the health and safety of the Canadian public.

Following the prioritization of an issue (Step 1), a preliminary analysis is undertaken 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.

Should the evaluation 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, should be determined and clarified, 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. Initial estimates of likelihood and severity factors should be considered.

While the scope and objectives should be clearly defined at the outset in order 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.

5.3 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 2), 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, and deciding the overall weight of evidence taking into account the quality of the data. Hazard identification and characterization may include consideration of some of or all of the following elements:

- Identifying the characteristics/properties (*e.g.* attributes, ingredients) specific to the product potentially responsible for the 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.

5.4 Step 4: Exposure and Probability Assessment

The hazard identification and characterization 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 deciding the overall weight of evidence taking into account the quality of the data. An exposure scenario and the estimation of its probability may include consideration of some of or all of the following elements:

- 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 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 level. However, it may not always be relevant to look at 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 in order 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).

5.5 Step 5: Risk Characterization

Risk characterization is the critical final step in the 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 parallel assessments as required (*i.e.* technological, economic, social, and political) to inform the risk management option selection process.

Risk characterization has both quantitative and qualitative aspects. It combines hazard characterization (described in Section 5.3) and estimates of exposure (described in Section 5.4) to yield estimates of the magnitude of consequences and the probability that they will occur. The risk characterization should provide a risk estimate for the exposure scenarios identified through the risk assessment process.

The following are some key components of risk characterization, which may be presented depending on the exposure scenarios considered as part of the risk assessment:

- Individual versus population risk estimates. While available data may only allow an assessment of individual risk, population-level estimates of risk may be important to put the risk issue in a broader context.

- Sub-population risk estimates. Where appropriate, the estimation of risks for specific sub-populations or unique exposure conditions may be presented. The nature and significance of uncertainty and variability in the risks to individuals should be explained.

- Uncertainty characterization. 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 manufacturers and importers may be required to provide, information to inform the steps in the risk assessment process of their product, including an opportunity to review the risk assessment report. Where appropriate, the Program may also engage with Health Canada partners. The Program will also collaborate and engage where appropriate with 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.

6. 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.

Within the Program, risk assessors prepare written reports (Level 1 report or Level 2 report) of all risk assessments to communicate the results of the risk assessment to risk managers.

Reports will be 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 should identify and describe the elements considered during the risk assessment process as outlined in this Framework and describe how these were evaluated and the associated uncertainty with these elements. They will be written in plain language with a minimum of jargon, and in a consistent format. Unfamiliar technical terms should be defined. Any tables and graphics used will be clear and will be explained so that they are understandable.

The Level 2 report will 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. 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.