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PRODUCT RISK ASSESSMENT PRACTICES OF REGULATORY AGENCIES

Summary of discussions at Workshops and Meetings of the OECD Working Party on Consumer Product Safety

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FOREWORD

This report provides a summary of discussions held at workshops and meetings of the Working Party on Consumer Product Safety between 2012 and 2014 on regulatory agencies' product risk assessment practices. This project was led by delegates of the Working Party from Australia.

The report was approved by the Working Party on Consumer Product Safety at its 10th Session in May 2015. It was declassified by the Committee on Consumer Policy on 21 October 2015 at its 90th Session.

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**PRODUCT RISK ASSESSMENT PRACTICES OF REGULATORY AGENCIES
SUMMARY OF DISCUSSIONS AT WORKSHOPS AND MEETINGS OF THE OECD WORKING
PARTY ON CONSUMER PRODUCT SAFETY**

Background

This document summarises the material presented at workshops and meetings of the Working Party on Consumer Product Safety (WP) between 2012 and 2014 on product risk assessment as practised by regulatory agencies. More specifically, the report reflects WP discussions about regulatory agency risk prioritisation and triage, and product risk assessment more broadly. The document summarises parts of those discussions from a regulator's perspective and does not represent the views of individual regulatory agencies. This is not a comprehensive review of the risk assessment practices of the participating agencies but some similarities and differences are described.

The report references the risk assessment terminology used in the international standard ISO 10377:2013 *Consumer product safety – Guidelines for suppliers*. It reflects comments received from the WP, as well as from several independent experts, on product risk assessment from an industry perspective.

While the report does not provide guidelines for assessing product risk, it may be useful for regulators and industry experts and contribute to the body of knowledge in this area. Some of the feedback from industry experts suggests that a guideline or checklist for risk assessment could be a useful tool that might be developed in the future. It is the hope of the WP that this document might assist in any such endeavour.

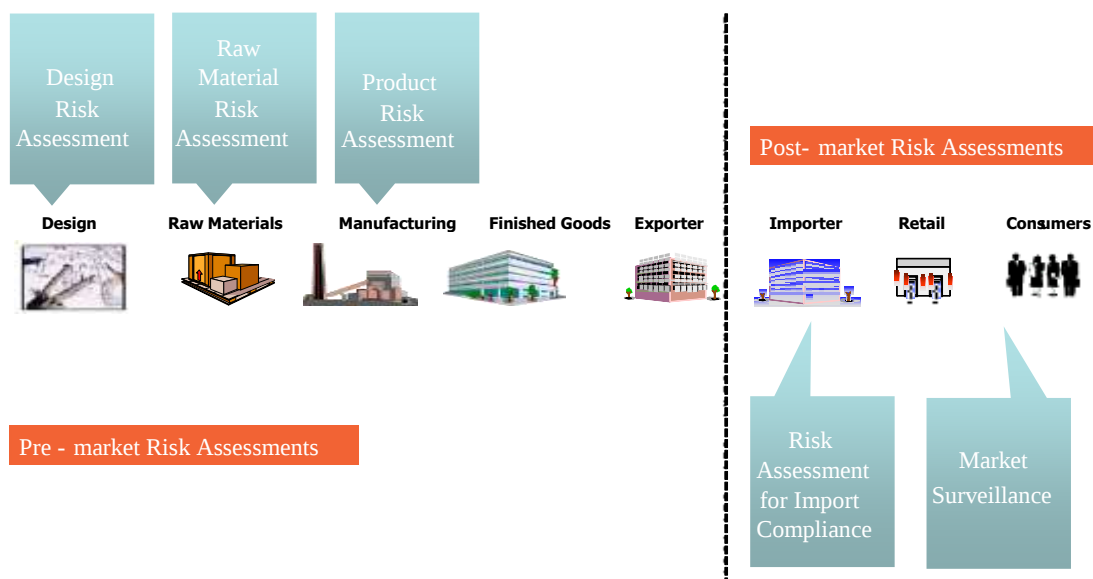
I. Product risk assessment through the supply chain

Regulatory agencies and businesses use product risk assessment to determine whether action is required to reduce the risk that users might be injured using a product.

Product risk assessments performed by suppliers

The ultimate responsibility for product safety sits with suppliers. Product safety regulators have an oversight or governance role with responsibility for ensuring that suppliers comply with the law and supply products that present an acceptable safety risk to consumers. If available to regulators, product risk assessments performed by suppliers provide one source of information about risk issues.

Risk assessments are performed by various suppliers at different stages of the supply chain. As illustrated in Figure 1, risk assessment often starts during the design of the product, in order to achieve safety by design. Suppliers of component parts and ingredients often conduct risk assessments and manufacturers may also conduct risk assessments of the raw materials that they receive. Manufacturers often conduct risk assessments in relation to their production, and brand owners, importers and retailers often conduct a risk assessment of the final product.

Figure 1. Pre-market and post-market risk assessment

Source: Adapted from GS1 graphic.

Product risk assessment may be addressed or required under a range of voluntary safety standards relevant to particular products or types of products. In some jurisdictions, depending on the type of products and their role in the supply chain, suppliers may be required by law to conduct or hold product risk assessments.

Third parties may be engaged to assist in performing product risk assessments. This can vary, from a simple outsourcing arrangement to acquire appropriate expertise and specialist knowledge in risk assessment, through to engaging an accredited test laboratory, conformity assessment body or certification body to assess the product.

An individual supplier's risk assessment of their own product may not be relevant to similar products from other suppliers, because of differences in product design, production, intended users, and risk tolerance.

Product risk assessments performed by regulators

In contrast, product risk assessments performed by regulators often assess the risks presented by a product category or type, supplied by a range of suppliers in a broad range of contexts.

Product risk assessments performed by regulators also tend to occur in a post-market context. Regulators are usually not involved in assessing the risk of products during design and development or for the purpose of demonstrating compliance with pre-market regulatory requirements such as prohibitions or mandatory standards.

Some regulators prioritise safety issues as part of risk assessment. This process is sometimes referred to as “triage”, “initial assessment” or “risk prioritisation”. Regulators use the process to efficiently and objectively assess numerous reports of safety concerns from consumers, industry, and other sources.

The risk prioritisation process identifies the most serious potential product safety hazards for more thorough risk assessment involving a larger allocation of time and resources to obtaining and analysing reliable information about the risks. Many regulators use a similar process to plan and prioritise market surveillance activities for particular products.

Regulators may use the same product risk assessment elements during risk prioritisation and for more thorough risk assessments.

Product risk assessments performed by regulators can be used in the process of establishing new pre-market regulatory requirements, to evaluate the effectiveness of existing pre-market regulatory requirements, or to determine whether some kind of government action is necessary to reduce the risk to consumers.

The international standard ISO 10377

The international standard ISO 10377:2013 *Consumer product safety – Guidelines for suppliers*, includes guidance for suppliers about product risk assessment and considers safety in design, production and in the marketplace. The guidance addresses areas such as hazard identification, foreseeable use and misuse, exposure analysis, developing injury scenarios, and evaluation of severity and probability of injury. The guidance also describes an iterative process of risk assessment that is repeated as risk reduction measures are established. Post-market product risk assessment is further addressed in the parallel international standard ISO 10393:2013 *Consumer product recall – Guidelines for suppliers*.

ISO 10377:2013 includes practical guidance about product risk assessment. The standard draws on *ISO/IEC Guide 51* for its risk vocabulary, as detailed in Table 1. *ISO/IEC Guide 51* was republished in 2014, after *ISO 10377:2013*, and some definitions were modified in the revised version. Table 1 incorporates the changes.

When applied to product safety, the ISO definition of “harm” in Table 1 is consistent with the description of “consumer detriment” in the *OECD’s 2014 Recommendation on Consumer Policy Decision Making*, which includes “the harm or loss that consumers experience, when, for example ... goods or services ... are defective or dangerous” (OECD, 2014a).

The standard addresses consumer product safety from a supplier’s perspective and is not designed for use by regulators. However, the terms and definitions from the standard provide a valuable starting point for developing a vocabulary for use by international product safety regulators.

Table 1. ISO 10377 (ISO/IEC Guide 51) – Selected terms and definitions

Term	Definition
Risk assessment	Overall process comprising a risk analysis and a risk evaluation
Risk analysis	Systematic use of available information to identify hazards and to estimate the risk
Risk evaluation	Procedure based on the risk analysis to determine whether the tolerable risk has been exceeded
Tolerable risk (acceptable risk)	Level of risk which is accepted in a given context based on the current values of society
Hazard	Potential source of harm
Harm	Injury or damage to the health of people, damage to property or the environment
Risk	Combination of the probability of occurrence of harm and the severity of that harm

Noteworthy features of the vocabulary from the standard include:

- Risk combines probability of occurrence and severity of harm.
- Risk assessment incorporates both risk analysis and risk evaluation.
- Risk analysis involves the systematic use of available information.
- Risk evaluation is based on the risk analysis.
- Risk assessments of the same product may yield different findings for different user groups, societies and over time.
- Unacceptable risks require action to reduce risks to users.

II. WP goals in relation to product risk assessment

The WP has identified goals for its work on product risk assessment that include:

- Developing an international vision for sound consumer product safety risk assessment.
- Improving understanding of risk assessment by consumer product safety regulators.
- Identifying the attributes of risk assessment in the consumer product safety context.
- Sharing tools, processes and practices for undertaking consumer product safety risk assessments.
- Working towards greater alignment of risk assessment practices by regulators.
- Possible extension to risk management considerations in the longer term.

In April 2012, the WP hosted a *Workshop on product risk assessment* in Israel to critically evaluate the different risk assessment practices being used in jurisdictions. A summary report of the workshop was published in January 2013 (OECD, 2013). The WP also discussed product risk assessment at subsequent meetings, including at a workshop held in October 2013 in Australia. A summary report of the second workshop is provided in document (OECD, 2014b).

The workshops suggested that different jurisdictional approaches to product risk assessment and risk management result from a number of factors, such as differences in regime, culture and risk tolerance. Product safety priorities are often driven by political issues and expectations from the general public within and across jurisdictions. Decisions on whether a product presents an acceptable risk may be taken due to political pressures or cultural considerations in a jurisdiction. As a result, products which are recalled in one jurisdiction may still be sold in another. Different risk assessment approaches may thus indirectly become a non-tariff barrier for globally traded goods and a lack of coherence between product safety standards and/or regulations may disadvantage imported and/or exported goods in a market. Different philosophies have led to the development of different product risk assessment approaches across jurisdictions.

In addition, jurisdictions maintain different levels of risk tolerance, which affects the measures taken for products considered unsafe. Some jurisdictions may for instance tolerate low levels of risks while others may seek to achieve no risk. The goal is to reduce a risk to an acceptable or tolerable level. Risk tolerance may also be influenced by how widely a product is used and by what group of consumers. Children and the elderly, for example, are often characterised as vulnerable groups which are more susceptible to injuries from some products.

Product risk assessments are sometimes based on assumptions that can lead to different conclusions. Many jurisdictions are therefore seeking to develop more coherent and robust risk assessment methods. These methods focus on the use of scientific evidence as a means to improved reliability and credibility. There is also a desire to achieve greater alignment with the pre- and post-market product risk assessments performed by suppliers.

Where possible, regulators may engage stakeholders in the early stages of product risk assessment. This is a potential means to reduce subjectivity and identify uncertainty but also acknowledges that product safety is a collaborative effort involving governments, businesses and consumers.

The WP hopes that an improved understanding of product risk assessment, as performed by regulators in different jurisdictions, may facilitate greater alignment of product safety regulatory outcomes across jurisdictions over time. However, a single approach to product risk assessment is unlikely to be adopted by regulators in all jurisdictions in the first instance. The WP aims to articulate areas of commonality and has developed agreed principles and elements of product risk assessment in the regulatory context.

III. Product risk assessment principles

At its April 2012 workshop, the WP discussed and identified the following common vision, or principles, for product risk assessment in a regulatory context (Table 2).

Table 2. OECD WP product risk assessment principles (April 2012)

Principle	Details
Consistency	Experts using the same methodology would draw the same conclusion. Regulatory risk assessments aim for objectivity.
Transparency	Transparent methodology facilitates identification, sharing and constructive discussion. Subject to confidentiality, privacy and legal constraints, regulators aim to share risk assessment outputs with affected stakeholders.
Completeness	Methodology should identify all relevant considerations (e.g. injury scenario, affected sub-populations, injury severity, likelihood of exposure, hazard recognition, and reasonably foreseeable uses of the product). Risk evaluation factors are clearly explained in risk assessment outputs.
Communicates uncertainties	Risk assessment outputs should identify uncertainties, assumptions and the parameters considered in the analysis. Sources of uncertainty can include the quantity and quality of information, un-validated assumptions, the state of current scientific knowledge, and limitations of the risk assessment methodology itself. Regulatory risk assessments may need to be completed with incomplete information since further information gathering or research may not always be justified.
Evidence based	Risk assessment should draw on scientific evidence and sound judgment, including contribution from relevant experts in the products, technologies and behavioural and health sciences as necessary.
Addresses vulnerable sub-populations	Risk assessment should take into account special considerations where a variety of populations may be exposed to a product (including children, the elderly and people with a disability). Variability within populations should also be considered, particularly in order to identify vulnerable sub-populations. Vulnerable populations may be more susceptible and/or less resilient to exposure to a particular product safety hazard.

IV. Product risk assessment elements

Product risk assessment performed by regulatory agencies addressing product safety issues is summarised in Box 1. The elements of product risk assessment include:

- Identifying the product.
- Understanding the use of the product.
- Scenario development.
- Severity of injury and potential health effects.
- Probability of harm occurring.
- Risk estimation.
- Risk evaluation.
- Risk evaluation factors.
- Combining risk evaluation factors with the estimated risk.

Box 1. Product risk assessment

Product risk assessment is the systematic use of available information to:

1. Identify products, or features of products, which may cause or contribute to physical injury or death,
2. Describe the mechanisms that cause injury or death for specific user groups (injury scenarios),
3. Estimate the severity of injury and the likelihood of occurrence or exposure, and
4. Evaluate whether these are acceptable based on current laws and the values of society.

Regulatory agencies use product risk assessment to determine which products require government action to reduce or manage the risk to users

Identifying the product

Product risk assessments must explain and define the types of products being assessed. The range of products covered may vary during the course of the assessment as more information about the hazards become available, with subsets of the products either falling out of the scope of the assessment or becoming captured by the risk assessment. For example, a risk assessment prompted by an injury involving a product from a single manufacturer may quickly expand to consider similar products from competing manufacturers.

It can be useful to employ a product categorisation scheme, such as the GS1 GPC taxonomy used in the OECD *GlobalRecalls* portal, to facilitate clear communication between jurisdictions with language differences and in which common household products often have different names.

Any technologies used in the products being assessed that are relevant to the hazard should also be considered. The scope of the risk assessment will sometimes be defined by such technologies (e.g. products utilising nanomaterial or button-batteries) rather than by the intended purpose (e.g. skin moisturisers or kitchen-scales). In some instances, the source of ingredients or components will determine the scope of the assessment: products from a particular factory for example.

Some hazards are only associated with a product's accessory or component part and this should also be considered at an early stage of the analysis.

Understanding the use of the product

The population groups that use or come into contact with the product need to be determined. This includes whether vulnerable groups such as children or the elderly are exposed to risk of harm. For some cases, the hazard may be different for, or limited to, unintended-users of the product who are nonetheless exposed to the risk (e.g. desk-toys with hazardous small magnets used by adults but ingested by children).

The frequency and duration of use of the product should be determined. This influences the extent to which people are normally exposed to a hazard associated with that product. Holiday decorations used during religious festivals for example, can be subjected to intensive but infrequent use at known times of the year.

The risk assessment should consider all observed or reasonably foreseeable use scenarios relevant to the hazard, including misuse of the product. The inclusion of reasonably foreseeable misuse scenarios in the assessment can yield critical insights into the safety of the product.

Scenario development

The key to a robust risk assessment is a robust modelling of the injury scenarios. This means systematically identifying and documenting the sequence of events that potentially lead to injuries, including alternative events that may lead to alternative injury outcomes. This relies on a good understanding of the environments in which the product is used and the interaction between the product, the environment, the users, and bystanders.

Multiple scenarios may need to be considered for different jurisdictions, product variants, use environments, users (e.g. intended user, bystander, vulnerable user, etc.) and circumstances (e.g. intended use and reasonably foreseeable use).

Many products are supplied with warnings and safety features such as alarms, safety shut-offs, and barriers that limit access to dangerous parts. Any safety features of the product should be explicitly considered in the injury scenario. For example, critical steps in an injury scenario analysis could include whether the user noted and observed a safety warning, whether they had disabled safety alarms or shut-offs, and whether the safety features operated as intended.

The use, or otherwise, of personal protective equipment may also be critical in the injury scenario (e.g. wearing a helmet when riding a bicycle). Other behavioural issues may also be relevant (e.g. what happens if the user leaves the product running and unattended?) and cultural issues may also be important (e.g. do some population groups avoid wearing bicycle helmets for religious or cultural reasons?).

Scenario development lends itself to group work that utilises a broad range of experiences and that generates and challenges ideas about the way the injury occurs. The quality of the injury scenario is generally improved by the contribution of relevant experts in the products, technologies and behavioural and health sciences.

Severity of injury and potential health effects

A key task of risk assessment is to understand the nature of the potential harm presented by the hazard. The injury scenario (described above) explores the nature of the product, the environment in which it is used, the people who use or are exposed to the product, and how these factors interact to create potentially hazardous situations. However, the end-result of the injury scenario analysis is a set of identified potential injuries that may result from the use of the product.

For each scenario being assessed, each potential injury needs to be characterised and graded for severity. A common lexicon of terms used to characterise different types of injury and common methods used to grade the severity of different injuries are important tools for regulators to achieve consistency and avoid ambiguity in risk assessment.

The injury lexicon should address the full range of injuries that can result from the use of products. For example, it can be challenging to compare injuries resulting from chemical exposure from a product with electric shock hazards or mechanical trauma from a product. An injury severity grading scale that covers the full spectrum of injury allows regulators to respond consistently regardless of the type of hazard presented by the product.

Ideally, the lexicon should also align with the terms and practices employed in contemporary health systems such as the injury coding schemes used in emergency medicine and hospital admission processes. Those health system processes reflect contemporary medical practice and thereby influence consumer expectations. This alignment assists in achieving an objective risk assessment that is valid for stakeholders.

Health system factors can influence the severity of the injury. Appropriate early treatment can reduce the severity of product related injuries such as burns and magnet/battery ingestions. Health practitioners may not be aware of product related risks or know the diagnostic or treatment protocols for some product-related injuries. Health system structures and practices vary between jurisdictions and this can result in different injury severity outcomes for the same kinds of products. The health system response may be an important element of the injury scenario and the risk assessment.

Risk assessment tools incorporate injury coding manuals or reference tables as an important feature. These tools were explored in detail during the WP's workshops on product risk assessment in 2012 and 2013.

Probability of harm occurring

One of the difficult elements of a product risk assessment is the estimate of the probability, or likelihood, of harm occurring. In practice, this element may be prone to subjective judgement, a paucity of reliable data, and difficulties in communicating the associated uncertainty in the estimate that is used.

Estimating the probability of harm occurring is therefore an area in which reliable data, systematic technique and an explicit enunciation of uncertainty can greatly improve clarity and assist users to interpret and evaluate the result.

The WP workshops on product risk assessment showed that different jurisdictions approach the problem of estimating likelihood in different ways. Some take a "bottom-up" approach and tie the estimate of the likelihood of injury closely to the injury scenario – separately estimating a probability for each step in the scenario and multiplying the probability for each step together to yield an overall probability. Other jurisdictions take a "top-down" approach using overall injury statistics and an estimate of the population's exposure to the product.

For both the top-down and bottom-up approaches, the outcome is highly dependent on the quality of the available statistical information.

In recognition of the uncertainty often associated with probability estimates, some jurisdictions use peer review or group work (e.g. using the Delphi technique) to attempt to achieve more reliable estimates.

It is common to conduct some kind of sensitivity analysis in which key parameters that are used to develop the estimate are varied (up and down) and the effect on the result is used to provide an indicator of the uncertainty and robustness of the estimate.

Regulators often estimate the probability of injury occurring using risk assessment tools. These tools were explored in detail during the WP's workshops on product risk assessment in 2012 and 2013.

Risk estimation

Risk is the combination of the probability of occurrence of harm and the severity of that harm (see Table 1). The technique used to combine these parameters and to derive an estimate of the risk is an important part of the risk assessment process.

This step can be automated with calculation tools. The tools effectively apply a weighting to the probability and severity estimates and arrive at a combined qualitative result that then places the risk somewhere in a spectrum between minimum and maximum risk.

At its simplest, the process maps low probability and low severity harms to the minimum risk level. Conversely, high severity and high probability harms are mapped to the maximum risk level. Other situations are mapped to risk levels between these extremes, based on the weighting parameters.

The risk estimation process culminates in a derived risk level. The meaning of this risk level should be interpreted by reference to a policy or guideline that defines each of the possible levels of derived risk. The guideline will define whether the derived risk is higher or lower than other known risk levels and whether the derived risk is potentially tolerable. Tolerable risk is discussed further in the next section.

The derived risk level is rarely considered in isolation from all of the factors that contribute to its derivation. Risk assessment tools do not make decisions but support decision makers to do so.

Risk evaluation

The risk assessment framework described in ISO 10377 (and ISO/IEC Guide 51) includes risk analysis (steps 1 to 3 in Box 1) followed by risk evaluation (step 4 in Box 1). The risk evaluation determines whether the risk estimated in the risk analysis is acceptable or tolerable.

Risk evaluation determines whether action is necessary to reduce the risk to consumers but the nature of such action (if deemed necessary) is not considered. All actions to reduce the risk are distinct from risk assessment.

A product safety regulator analysing different product safety hazards, with identical estimates of injury severity and likelihood of occurrence, may rationally come to different conclusions about the acceptability of the different risks. There are several factors that may account for these different evaluations of the risks.

Risk evaluation factors

Risk evaluation factors were discussed in detail as part of the WP's workshop on product risk assessment in 2013.

Discussion at the 2013 workshop identified that the strongest risk evaluation factor was whether the risk affected vulnerable groups such as young children or the elderly. Risk tools and practices used by regulators routinely consider whether vulnerable groups are affected. Whilst the effect of this safety margin has not been quantified, regulators from all jurisdictions appear to be far less tolerant or accepting of product safety hazards that affect young children in particular.

Many jurisdictions explicitly include reasonably foreseeable use (and misuse) as part of their product safety mandate. The fact that an injury may be attributed to reasonably foreseeable misuse of a product does not influence estimates of injury severity or likelihood of occurrence. However, this may influence subsequent risk evaluation decisions in some jurisdictions in some situations. For example, the foreseeable scenario of a teenager accidentally swallowing small powerful magnet balls when misusing them as a tongue piercing may be considered an unacceptable risk.

Compliance with mandatory safety standards is important for some products and jurisdictions. A regulator's assessment for a product that breaches a product safety prohibition or mandatory safety standard is likely to include legal aspects of non-compliance rather than rely on risk analysis considerations alone.

Some jurisdictions emphasise compliance with relevant voluntary safety standards as an important consideration that influences their risk evaluation. Voluntary standards often specify safety requirements for the product.

Safety concerns associated with defective and/or counterfeit products may be evaluated as less tolerable than similar risks associated with genuine products or products with no identifiable defect. Products that do not incorporate state-of-the-art risk reduction measures in the design, production and presentation of the product may be evaluated as posing higher risk than products that do incorporate recognised safety features such as an inherently safer design, safer packaging or prominent warnings.

The age of a product is also often a relevant consideration in the risk assessment. Second-hand goods or goods supplied some time ago may develop defects because they are outside of the expected normal useful life. A higher risk may be tolerable in relation to such goods in some jurisdictions, as reflected in legal frameworks and consumer expectations.

The potential for hazard recognition: the ability of a user to recognise and avoid the hazard; is a risk evaluation factor used in some jurisdictions. Adults easily recognise the hazard inherent in some products, such as knives, but often are unable to recognise other hazards such as the presence of a toxic chemical. Warnings on the product may increase the hazard recognition in some situations. The risk may be more tolerable for products that incorporate effective warnings but less tolerable if there are no warnings or the warnings are ineffective. For vulnerable groups such as children, the extent to which responsible caregivers such as parents can realistically act to recognise and avoid the hazard on behalf of the vulnerable group should also be considered.

The utility of the product is a risk evaluation factor considered by some product safety regulators. A safety concern associated with a product with apparently low utility could be considered less tolerable than if the product provided great practical and economic benefit to a large part of the population. Such considerations are likely to exert a stronger influence after the risk assessment is completed, when considering the nature of a regulatory intervention, rather than during the risk assessment to consider whether any intervention is required at all.

Some risk assessment tools incorporate “availability” as a factor. A product that is available in only a small number of specialist retail outlets in only small quantities would have a lower availability than a product used in almost every household. Availability is generally not used by regulators as a true risk assessment parameter that assists them in deciding whether action is required to reduce the risk to consumers. The availability parameter is used after the risk assessment phase, as an indicator of the most effective risk reduction strategy.

Combining risk evaluation factors with the estimated risk

Some jurisdictions include risk evaluation factors at the same time as combining probability and severity during risk estimation. Other regulators derive the risk based on probability and severity alone, and consider risk evaluation factors later.

Risk assessment tools can capture information about risk evaluation factors and integrate this information with the risk estimate in a sometimes seamless way. Each risk evaluation factor is given a weighting and these are combined to derive a qualitative result.

In practice, the risk evaluation factors effectively shift the tolerable risk to higher or lower levels, dependent on the weightings applied.

V. Tools and approaches

Risk assessment tools can influence the consistency of outcomes and the objectivity and transparency of decision making. The WP product risk assessment workshops in 2012 and 2013 explored several risk assessment tools, used in several jurisdictions, in detail. The tools and approaches used for risk assessment in the EU, Australia and Canada are summarised below.

Risk assessment in the EU

In the European Union, the Community Rapid Information System (i.e. RAPEX) establishes a mechanism for the rapid exchange of information between the Member States and the Commission on measures and action taken in relation to products posing a serious risk to the health and safety of consumers. The Commission drew up guidelines to ensure that RAPEX and the notification procedures are properly applied and to set out a risk assessment method, in particular, with specific criteria for identifying serious risks.

The risk assessment guidelines provide a transparent and practicable method for appropriate use by EU Member States' competent authorities. They are based on a risk assessment method developed for other purposes adapted to the specific requirements of non-food consumer products. These guidelines do not replace other guidelines that may address very specific products or may be specifically provided for in legislation, such as in the area of chemicals and cosmetics.

For chemicals, risk assessment follows the same principles as for other consumer products:

- Hazard identification.
- Exposure assessment: exposure is expressed as the likely dose of the chemical that the consumer may take up via oral, inhalation or dermal routes, separately or jointly, when using the product as anticipated in the injury scenario.
- Risk characterisation: comparing the dose of the chemical that the consumer is likely to take up (= exposure) with the derived no-effect level (DNEL) of that chemical.

The REACH Regulation is the legal framework for the registration, evaluation, authorisation and restriction of chemicals in the EU and there are specific instructions on how to prepare a risk assessment. For cosmetics, there is also specific guidance for the safety evaluation.

The RAPEX risk assessment guidelines describe a three step process of *i)* injury scenario development that establishes a link between the product and an estimated severity of injury; *ii)* estimating the probability of occurrence of that injury using a “bottom-up” approach; and *iii)* estimating the risk by combining the estimated severity and probability. Risk evaluation factors are not described in detail and are acknowledged as considerations for the relevant national market surveillance authorities.

Risk assessment in Australia

The Australian Competition and Consumer Commission (ACCC) utilises the ACCC Product Safety Nomograph to inform many of its product safety risk assessment decisions. The ACCC Nomograph is based on the model originally developed for the New Zealand Ministry of Consumer Affairs by H.G. Benis in 1990. The original tool was graphical and paper-based but a mathematical version has been derived and established in electronic form.

More recently, the ACCC has updated the model by adopting the EU RAPEX injury severity levels. The ACCC Nomograph is used in risk prioritisation as follows. For injury reports involving less severe injuries (severity level 1 or 2), no other parameters are estimated and the report is normally filed, unless other risk evaluation factors indicate otherwise. For more severe injuries (severity level 3 or 4), a complete Nomograph is completed.

A complete Nomograph includes a “top-down” estimate of probability based on available injury statistics, an estimate of the potential for hazard recognition, and an estimate of the product availability. The Nomograph combines these estimates to derive an estimate of the risk that informs the risk prioritisation decision. The report is normally filed if the derived risk level is “moderate” or below, unless other risk evaluation factors indicate otherwise. For higher risks, a detailed risk assessment is normally initiated.

The Nomograph is also used during the detailed risk assessment to inform subsequent decisions about the need for risk reduction. However, the Nomograph is not the primary decision tool in detailed assessments and is only one consideration in a more comprehensive consideration of all of the risk assessment elements.

Risk assessment in Canada

Health Canada’s Consumer Product Safety Program has drafted and recently released a Risk Assessment Framework to articulate how it characterises and assesses risk.

The goal of the Consumer Product Safety Program is to carry out its risk assessment activities in a manner that is consistent, systematic, structured and based on the best available evidence. In doing so, the Program is guided by the following principles:

1. The priority and level of effort given to conducting a risk assessment will be determined by the potential risk to health or safety.
2. A risk assessment will be based on evidence and professional judgement.
3. The risk assessment process will be as transparent as possible.
4. A risk assessment will identify uncertainties.
5. A risk assessment will consider population variability and vulnerability.
6. A risk assessment will consider foreseeable use and foreseeable misuse of a product.

The Consumer Product Safety Program, in carrying out its risk-assessment functions, gathers information from a variety of sources. Sources of information may include incident reports from industry or consumers, reports of activities (e.g. recalls) in other jurisdictions, and actions proposed by manufacturers or importers aimed at reducing the risk to the public. Health Canada also conducts monitoring of science, information from health and safety professionals, media and other web-based news sources that may identify health or safety issues regarding consumer products and cosmetics.

When the Consumer Product Safety Program identifies an emerging trend or becomes aware of an incident involving a consumer product or cosmetic, it will review the information related to the case and determine whether or not the seriousness of the incident warrants doing a risk assessment.

The first step in a risk assessment involves prioritisation, a process which assigns a weight to several screening factors that increase or decrease the assessment's priority. During the second step a preliminary analysis and scope are established; if a more thorough risk assessment is warranted, scope & objectives need to be defined. The third step involves hazard identification and characterisation, a process of determining if a product has an intrinsic ability to cause an adverse health effect. The fourth step, exposure & probability assessment, characterizes the probability that a series of scenarios could lead to potential harm or pathways of potential exposure. The final fifth step involves risk characterisation, a process which integrates the risk assessment information into a summary conclusion of the risk in a manner that is useful for decision-makers

If the Program determines that a risk assessment is not warranted, the issue is still tracked and monitored.

In gathering this information, the Program may consult subject-matter experts within or outside of government. Manufacturers and importers may provide, or in some cases may be required to provide, information to inform the steps in the risk assessment process of their product. They may also be given an opportunity to review the risk assessment report, where appropriate in the circumstances of specific cases. All of this information is fed into the next level: risk management. Risk management officials will consider the risk assessment, among other considerations, to determine how to respond to the issue.

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