Office for Product Safety & Standards

Product Safety Risk Assessment Methodology (PRISM)

A Guide for GB Market Surveillance Authorities and Enforcing Authorities Responsible for Regulating Consumer Product Safety

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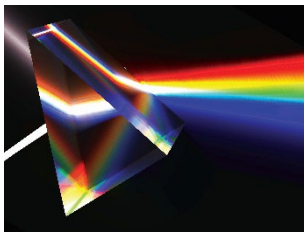
Contents

Part One – The Fundamentals of Product Safety Risk Assessment



Section 1: Introduction

1.1 Background

Many staff working within British market surveillance authorities (MSAs) will be familiar with the EU Safety Gate risk assessment guidance and methodology, often referred to as the RAPEX methodology. The EU's risk assessment guidelines were introduced "to provide a transparent and practicable method for appropriate use by Member States' competent authorities when they assess the risks of non-food consumer products"[1].

The UK's exit from the EU has provided opportunities for aspects of the system for ensuring the safety of consumer products to be reviewed. Accordingly, a review has been undertaken of the RAPEX risk assessment guidelines, involving representatives from a range of MSAs.

The findings of the review indicated that while there is much within the RAPEX approach that remains valid and useful, there are nevertheless a number of areas where changes are required to deliver an improved approach to product risk assessment within the GB context. This document sets out the revised approach.

Part 1 of this document introduces product safety risk assessment within the context of the wider risk identification, evaluation and management process. The key parts of the risk assessment methodology are explained. Part 2 of the document provides additional information relevant to certain aspects of the methodology. MSA staff undertaking product risk assessment should be familiar with and able to apply the approach set out in Part 1 in its entirety; the information within Part 2 will not be relevant to every risk assessment but the assessor should be aware of its existence and refer to it where necessary.

1.2 Application

This guidance applies to product safety risk assessment undertaken by GB[2] market surveillance authorities[3] in the following contexts:

a. Products covered by Regulation 3 of the General Product Safety Regulations 2005: this includes products intended for use by consumers and products which, while intended for use by professionals, it is reasonably foreseeable are likely to be used by consumers. The latter are often referred to as migrating products.

b. Products covered by Article 15 of Regulation (EC) No. 765/2008 on the accreditation and market surveillance of non-food products, which has effect as retained EU law (GB RAMS).

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1 Commission Implementing Decision (EU) 2019/417 - Guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC (the General Product Safety Directive) and its notification system.

2 Relevant MSAs in Northern Ireland should continue to use the risk assessment methodology as set out in the EU Safety Gate system. Notifications concerning non-compliant products should be made via the OPSS Product Safety Database.

3 References to "market surveillance authorities" within this document includes relevant enforcing authorities.

The guidance does **not** apply to the following:

a. Food and feed, and other products covered by Regulation (EC) No. 178/2002 (which has effect as retained EU law);
b. Medicinal products covered by the Human Medicines Regulations 2012 and the Veterinary Medicines Regulations 2013);
c. Medical devices covered by the Medical Devices Regulations 2002;
d. Antiques, or products to be repaired or reconditioned prior to use; and
e. Equipment used by professional service providers to supply a service.

Even with regard to those contexts where this guidance does apply, there may be circumstances where alternative risk assessment methodologies may be more suitable, particularly where they have been developed to address specific products (for example there is guidance relating to chemicals[4] and cosmetics[5]), or specific users. Nor is this guidance intended to replace any risk assessment approaches provided for in legislation.

In practice, however, this guidance applies to the vast majority of non-food consumer products. The types of harm potentially within scope of the risk assessment are those covered by GB RAMS, and this includes not only injuries and adverse health effects impacting consumers but also harm to animals, to the environment, and damage to property.

As noted above, this guidance is intended for use by market surveillance officers. It is not intended to be used by businesses when undertaking pre-market risk assessment as part of the process of assessing the conformity of their products to relevant essential requirements or when considering the general safety requirement contained within the General Product Safety Regulations 2005 (GPSR).

1.3 Terminology

Unless the context specifies otherwise, the risk-related terms[6] used within this guidance are defined as below:

Hazard: A potential source of harm.

Harm: Adverse impact on individuals, the environment, infrastructure, property, animals, [or businesses], and which can include human injury and ill health, damage (including disruptions) to property, damage to the environment, or economic loss.

Severity of harm: The harm (physical[7], psychological[8], environmental, etc[9]) that a hazard can potentially cause can have different degrees of severity. The severity of the harm thus reflects the effect the hazard has on the subject under the conditions described in the particular scenario.

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4 For example, see: https://joint-research-centre.ec.europa.eu/jrc-news/new-guidance-using-computational-models-chemical-risk-assessment-2021-04-13_en, and https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_056.pdf

5 For example, see: https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_224.pdf

6 For further information on risk-related terms and definitions, see the OPSS Risk Lexicon: https://www.gov.uk/guidance/opss-risk-lexicon

7 Solomon, M. (2009). Consumer behavior: Buying, having, and being. Upper Saddle River, NJ: Pearson Education International.

8 Jacoby, J., & Kaplan, L. B. (1972). The components of perceived risk. *ACR special volumes*.

9 Kozup, J. (2017). Risks of consumer products. In *Consumer perception of product risks and benefits* (pp. 23-38). Springer, Cham.

Probability of harm: The likelihood (probability estimate) of the identified hazard causing harm; this refers to a harm scenario that may indeed materialise during the expected duration of a hazard.

Risk: A function of the level of a hazard and the likelihood (or probability) that the hazard will cause harm.

Risk assessment: The process by which the level of risk associated with a particular hazard/s is/are identified and categorised.

Risk evaluation: The process by which the outcome of a risk assessment is combined with policy considerations to characterise the risk and inform decisions on risk management.

Risk management: The elimination, control or mitigation of risk.

Risk tolerability: The acceptability of a perceived risk based upon the current values of society[10].

Risk differential: The difference between the level of risk presented by a non-compliant product and the level of risk the product would present if it was fully compliant.

Precautionary principle: The principle under which protective action is taken for the purpose of avoiding harm from an identified hazard, in circumstances where there is limited or no reliable evidence on the extent of the risk posed by that hazard. This is on the basis that taking no action could allow significant harm to occur[11] [12].

Migrating products: Products designed and intended for professional use but which are reasonably foreseeably likely to be used by consumers.

1.4 Purpose of risk assessment by MSAs

When market surveillance officers identify a product that is not or may not be compliant with applicable legal requirements, decisions need to be made as to what action might be necessary to:

a. protect the public;
b. address the non-compliance; and
c. help prevent future non-compliance.

Fundamental to making such decisions is the level of risk presented by the product. An understanding of the level of risk presented is vital in determining a proportionate enforcement response and effective risk management action that will remedy the non-compliance within a suitable timescale, deal with any risks to which the public may be exposed within a suitable timescale, and deter future non-compliance.

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10 Hanna, H., Wozniak, R., & Hanna, M. (2013). Consumer behaviour. Dubuque, IA: Kendall Hunt.

11 The three main conditions for invoking the precautionary principle are identification of potentially adverse effects, evaluation of the scientific data available and the extent of scientific uncertainty, which need to be specified in advance to avoid ambiguity. Kovess-Masfety, V. (2017). Individual and Population Risks. In *Consumer Perception of Product Risks and Benefits* (pp. 105-124). Springer, Cham.

12 Regulation 10(5) of the General Product Safety Regulations states “An enforcement authority shall in enforcing these Regulations act in a manner proportionate to the seriousness of the risk and shall take due account of the precautionary principle.”

This guidance sets out a general methodology for assessing product risk that is recommended for use by relevant GB MSAs in circumstances where there is no specific risk assessment methodology required or recommended by relevant product / sector legislation or guidance (see section 1.2). While other general risk assessment methodologies can be used, any GB MSA doing so should satisfy themselves that the alternative methodology is at least as effective in providing a suitable and sufficient assessment of product risk. It is also worth noting that the adoption of an agreed method for assessing product risks across MSAs provides a number of benefits including a common risk 'language' and transparency in approach and outcomes.

There is no specified level of risk above which a product is deemed in law to be non-compliant, and below which it is compliant, and therefore without any additional context the extent to which risk assessment can be used by MSAs to determine *whether* a product is compliant is limited. Nevertheless, in some circumstances an assessment of risk can prove indicative of whether the GPSR requirement for products to be safe[13] is being complied with, and may be required in the context of certain product-specific legislation which includes obligations relating to the overall risk presented.

1.5 Risk process overview

The key stages of the risk process are shown in Figure 1 below.

[13] "A 'safe product' means a product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use…" Regulation 2, General Product Safety Regulations 2005

Figure 1: PRISM Risk Process Flowchart

1) Identification of a non-compliant product

Can the product be deemed to present a serious risk?
Yes – Go to stage 4 / **No** – Go to next question

Is a full risk assessment required?
Yes – Go to stage 3 / **Unclear** – Go to stage 2
No – End process and take action to address non-compliance if required

▼

2) Risk Triage

Undertake risk triage

Is a full risk assessment required?
Yes – Go to stage 3 / **No** – End process and take action to address non-compliance if required

▼

3) Risk Assessment

A) Prepare for the risk assessment, considering:

i) Availability of information / data
ii) Product life cycle
iii) Expertise required
iv) Priority and urgency

B) Undertake the risk assessment:

i) Define the product
ii) Identify the hazard/s
iii) Determine who or what could be harmed
iv) Describe one or more harm scenarios
v) Determine the severity of the harm
vi) Determine the probability of the harm occurring
vii) Determine the level of risk
viii) Consider the level of uncertainty

What is the determined level of risk?
Low / **Medium** / **High** / **Serious**

▼

4) Risk Evaluation

Is the risk tolerable to the public?
Yes, and no action required to address non-compliance – End process
Yes, although action is required to address non-compliance – End process at stage 5 and take action to address non-compliance as required
No – Go to stages 5 and 6

▼

5) Quality Assurance and Reporting / Recording

- Record risk assessment and upload findings to OPSS Product Safety Database
- Review assessment findings in the light of any subsequent new information

▼

6) Risk Management

- Confirm that action is required
- Identify the nature of the action needed
- Implement the action

Although the focus of this guidance is stage 3 in Figure 1– risk assessment – an explanation of the other stages is also included to provide MSAs with a fuller context. The six stages are summarised below, and stages 3-6 are subsequently described in detail at sections 2-5 of this document.

Stage 1 – Identification of a non-compliant product: The starting point is usually where a MSA identifies a product that is or might be non-compliant with relevant product safety legislation. Such a product may come to light through a number of routes, for example a report of a person being injured or made ill by the product, complaints, media reports, gathering of relevant intelligence, a notification received from the producer of the product, a referral from the OPSS Border Profiling Unit, etc.

Note: there are some (limited) circumstances where it is appropriate to treat a non-compliant product as likely to present a serious risk, without the need to undertake a full risk assessment. This could be because of the nature of the non-compliance (such as products containing prohibited chemicals and non-compliant category III personal protective equipment) or because the particular type of risk has already been assessed by OPSS as serious. Note that this presumption of serious risk should be seen as rebuttable, and therefore the purpose of the risk assessment is primarily to confirm that the product or the hazard involved is of a type where a serious risk can generally be assumed and that there is nothing unusual about the particular circumstances that might indicate the risk to be less than serious. Once confirmed, the assessor can then move to stage 4 (risk evaluation) of the risk process.

Read further information and a list of circumstances where non-compliance can be deemed to present a serious risk.

Stage 2 – Risk triage: the level of risk presented by a non-compliant product can obviously vary considerably, and in some cases a full risk assessment (as per stage 3 below) may not be required, for example it may be clear from the outset that the level of risk presented will be very low or negligible, such as in relation to an incomplete marking, and in such cases there is unlikely to be anything gained by undertaking a risk assessment (even though action may still be required to address the non-compliance). Conversely, in many cases it will be clear that the non-compliance will present risk and a full risk assessment will be required to properly understand the nature and level of the risk presented. Some non-compliance will fall between these two scenarios, and it is in these cases where a triage approach can be useful to identify whether a particular issue warrants a full risk assessment, thereby avoiding time being spent undertaking full risk assessments where they are not warranted. Further guidance on risk triage is provided within Part 2(1) of this guidance ‘Risk triage’.

Access the PRISM triage tool in the PRISM toolkit.

Stage 3 – Risk assessment: at the heart of any risk assessment lies consideration of two factors: the *severity* of any harm that could occur and the *probability* that it will occur[14]. Risk assessment methodologies consider these two factors and then apply a rating to the level of risk presented[15]. See section 2 below.

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[14] O'Bryen, G. (2002). Product safety–are we managing the risks?. *Injury control and safety promotion*, *9*(3), 157-159.

[15] Hunte, J. L., Neil, M., & Fenton, N. E. (2021). A causal Bayesian network approach for consumer product safety and risk assessment. *Journal of Safety Research*. https://doi.org/10.1016/j.jsr.2021.12.003

Access the PRISM risk assessment tool in the PRISM toolkit.

Stage 4 – Risk evaluation: after being assessed, the risk then needs to be *evaluated* so that any other relevant factors, such as whether the risk is generating a high level of public or political concern, can be taken into account [16]. Ultimately a decision is required on whether the risk is tolerable[17]. See section 3 below.

Stage 5 – Quality assurance and recording / reporting: once the risk assessment and evaluation are complete, it will often be helpful for a colleague or other third party to check the assessor's findings. The risk assessment and evaluation should be recorded and reported, and in many cases ongoing monitoring will be required to ensure the findings remain valid and are updated as necessary[18]. See section 4 below.

Stage 6 – Risk management: this final stage involves determining the nature of the action needed to manage the risk and implementing that action. It will often involve risk communication[19]. See section 5 below.

[16] Otway, H. J., & Pahner, P. D. (1976). Risk assessment. *Futures*, *8*(2), 122-134.
[17] Bouder, F., Slavin, D., & Löfstedt, R. (2007). The tolerability of Risk. *A New Framework for Risk Management. London: Earthscan*.
[18] Löfstedt, R., & Asselt, M. V. (2008). A framework for risk governance revisited. In *Global risk governance* (pp. 77-86). Springer, Dordrecht.
[19] Löfstedt, R. E. (2004). Risk communication and management in the 21st century. *Available at SSRN 545724*.

Section 2: Risk Assessment

2.1 Preparation

To enable a comprehensive and accurate risk assessment to be carried out, the following should be considered in advance of the assessment being made:

a. **The availability of relevant information and data about the product**: that could assist in facilitating an accurate assessment of risk. This could relate to any aspect of the assessment such as the nature of the product, the intended users, the severity of the injuries that the product may cause, the probability of injury occurring, and the number of people currently exposed to the risk presented by the product. Potential sources of such information include:

- the manufacturer / supplier of the product;
- warnings, instructions and other information accompanying the product;
- relevant accident / injury databases; (see Part 2(3), 'Use of data')
- records of complaints from consumers and other sources;
- test reports; (see Part 2(3), 'Use of data')
- relevant product recalls;
- relevant legislative requirements and standards[20];
- scientific evidence that has examined the presence of the relevant hazards and resulting exposure to harm; and
- risk assessments that have been undertaken previously for the product or closely related products.

It is recognised there will be circumstances where risk assessments may need to be performed quickly, at least initially, for example in certain situations where consignments of goods are examined at points of entry into the UK. In such circumstances it may not be possible to obtain all of the information listed above and the risk assessment will need to proceed on the basis of the information available at the time. However, it should be recognised that such risk assessments could be subject to challenge, and additional information should subsequently be sought to update the risk assessment where necessary. A triage approach may be helpful in identifying where a fuller risk assessment is required (see section 1.5, stage 2 above and under Part 2(1) 'Risk Triage').

b. **Product life cycle**: the risk assessment will need to cover the entire lifetime of the product[21], and therefore the assessor will need to have an understanding of:

- risks that could be created as a result of errors made during any assembly, installation or maintenance required;

[20] For an example of the differences between legislative requirements and standards see Marucheck, A., Greis, N., Mena, C., & Cai, L. (2011). Product safety and security in the global supply chain: Issues, challenges and research opportunities. *Journal of operations management*, *29*(7-8), 707-720.

[21] There are several examples where the lifetime of the product interacts with consumer behaviours and consumer perceptions. Koide, R., Murakami, S., & Nansai, K. (2021). Prioritising low-risk and high-potential circular economy strategies for decarbonisation: A meta-analysis on consumer-oriented product-service systems. *Renewable and Sustainable Energy Reviews*, 111858. Cox, J., Griffith, S., Giorgi, S., & King, G. (2013). Consumer understanding of product lifetimes. *Resources, Conservation and Recycling*, *79*, 21-29.

- any points in the life cycle where risks can be expected to increase, which will often (but not exclusively) be associated with increasing product age[22];
- types of use that could create or increase risk, including reasonably foreseeable misuse, failure to properly maintain, and excessive wear and tear;
- whether the product has a safe operating life[23];
- expected end of life failure mode[24], and whether this could present any increased risk.

The extent to which the above factors are relevant will vary between products[25]. For many commonly used products they are often well understood, however in the case of new or innovative products the availability of relevant information is likely to be limited.

c. **The expertise required**: to produce a reliable risk assessment[26]. The knowledge and experience required to competently undertake the assessment will vary; some assessments are more complex than others[27]. An experienced risk assessor, with good access to the types of information listed under (i) above, may not need any assistance to undertake the assessment. A less experienced assessor, in a situation where the availability of relevant data and information is minimal, may need to seek assistance from more experienced colleagues or from outside their organisation.

d. **Priority and urgency:** Having begun the process of gathering the information referred to under (i) above, the assessor may quite quickly form a view that the level of risk involved is potentially both serious and intolerable and, accordingly, swift risk management action may be required. Any risk assessment provided to the MSA by the business involved may be indicative in this regard, although such risk assessments should always be scrutinised for accuracy and subject to challenge by the MSA. The key point is that where there are strong early indications that a risk might well be serious/intolerable, it is important that the risk assessment is progressed without delay. This might mean that the first draft of the risk assessment is completed quickly and without the assessor necessarily having access to the full range of information potentially available.

   If that first draft indicates the level of risk **is not** serious, then the assessment (and the broader risk process) can proceed in the normal way and be updated if and when further information becomes available (bearing in mind that the wider context of the risk assessment should indicate what is a proportionate amount of time to spend on it and the priority it should be given).

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22 Hunte, J. L., Neil, M., & Fenton, N. E. (2021). A causal Bayesian network approach for consumer product safety and risk assessment. *Journal of Safety Research*.

23 Haug, A. (2018). Defining 'resilient design'in the context of consumer products. *The Design Journal*, *21*(1), 15-36.

24 Kara, S., Manmek, S., Kaebernick, H., & Ibbotson, S. (2008). Assessment of products for optimal lifetime. *CIRP annals*, *57*(1), 1-4.

25 Hunte, J. L., Neil, M., & Fenton, N. E. (2021). A causal Bayesian network approach for consumer product safety and risk assessment. *Journal of Safety Research*.

26 Barnett, J., & Breakwell, G. M. (2001). Risk perception and experience: Hazard personality profiles and individual differences. *Risk Analysis*, *21*(1), 171-178.

27 Slovic, P. (2001). The risk game. *Journal of hazardous materials*, *86*(1-3), 17-24.

If the first draft indicates that the level of risk **is** serious, then there should be a presumption that suitable risk management action is required and the risk process should move swiftly towards taking such action. In parallel, any additional information that might be relevant should be sought and the assessment and any planned risk management action updated in the light of such information once available. Note that the precautionary principle may be applicable in these circumstances (see Part 2(8) 'Applying the precautionary principle').

2.2 The risk assessment

Undertaking the risk assessment comprises 8 key stages, as shown in Figure 1 and described below.

Stage (i): Define the product

The product being assessed should be clearly identified and defined, which should include, where relevant, the:

- name;
- brand;
- model name / number;
- batch reference / production lot no.;
- name of the person / business who placed the product on the market;
- country of origin;
- any certification reference.

A picture of the product, its packaging and any marking plate can be useful, particularly if the product becomes the subject of a product safety notification.

In some circumstances the hazard may be linked to a distinct part of a product, which may be sold separately to it, for example rechargeable batteries used in certain computers. In these cases it will normally be sufficient to assess the distinct part only.

Finally, the product safety legislation and any standards applicable to the product in question should be identified.

Stage (ii): Identify the hazard/s

The more common types of physical hazard presented by products are listed in Table 1.

The relevant hazard/s forming the subject of the risk assessment need to be clearly identified. In the majority of cases it will not be necessary to identify all of the hazards associated with the product, as the focus of the assessment will be the hazard/s relevant to the non-compliance under consideration[28].

Where two or more separate hazards are identified that are or may be a source of harm, the risk created by each such hazard should normally be assessed, although this may not be necessary in the case of a hazard where it is clear from the outset that any risk created by that hazard will be negligible. However, if there is any doubt then a risk assessment should be undertaken (or a triage process deployed (see Part 2(1) 'Risk triage).

[28] Rider, G., Van Aken, D., Van de Sman, C., Mason, J., & Chen, X. (2009). Framework model of product risk assessment. *International journal of injury control and safety promotion*, *16*(2), 73-80.

Table 1: Common product safety hazards	
Hazard category	**Hazard examples**
Mechanical	Sharp edges, trapping hazards, crushing hazards, impact hazards
Size and shape	Small parts with the potential to be inhaled or ingested Suffocation or strangulation hazards such as blind cords and clothing with sashes or drawstrings
Electrical	Live 240v conductors; arcing; overload; short circuit
Fire and explosion	Ignition sources and fuel sources, e.g. naked flames, hot surfaces, poorly designed machinery, flammable furniture and furnishings
Thermal	Hot or cold surfaces of equipment
Ergonomic	Poorly designed chairs and I.T equipment
Noise and vibration	Noisy and vibrating machinery
Microbiological	Bacteria, viruses, e.g. bacterial contamination of cosmetics
Chemical	Substances that are carcinogenic, toxic, corrosive etc. e.g. cadmium in jewellery, cadmium and other heavy metals (lead, nickel, mercury & arsenic) in care products[29], phthalates in toys, asbestos in building materials or as a contaminant in consumer products
Lack of protection	Smoke alarms that fail to activate; infant car seats and PPE that do not provide the specified level of protection

However where a more general consideration of the hazards is required, the essential requirements contained within product-specific legislation (where applicable) can assist in identifying and defining those hazards because they describe the requirements that must be fulfilled to ensure adequate protection from the risks created by relevant hazards. Applicable standards, the Declaration of Conformity, relevant technical documentation, the results of testing, and any instructions or warnings accompanying the product can also assist with hazard identification.

[29] Attard, T., & Attard, E. (2022). Heavy Metals in Cosmetics. Intec_openbook series. DOI: 10.5772/intechopen.102406

Stage (iii): Determine who or what could be harmed

Most product safety risk assessments will be concerned with physical injury or ill health to people, which will form the focus of the assessments. However, some hazards have the potential to cause harm to other subjects, such as to the environment[30], animals, or damage to property[31]. They may also cause economic losses[32]. Ill health to people includes psychological harm, which can arise as a consequence of physical harm caused, as well as through economic losses and/or as a consequence of harm to other subjects such as to pets or to a person's property. Where harm to other subjects (animals, property, the environment etc) or psychological harm is foreseeable, this should be noted and discussed as part of the risk evaluation (see section 3). Such harms would not normally, however, form the focus of harm scenarios (stage iv).

In terms of injury / ill health to people, two key considerations will be:

1. Who is the product aimed at?

A key consideration is whether the product is intended for use by a particular group of people or by the general population.

(a) Particular groups: where a product is aimed at a particular group, for example children (and children of a particular age range), men or women, the elderly, certain ethnic or cultural groups, people with differing abilities[33], people in certain living environments such as tower blocks, particular socio-economic groups, etc., the risk to that group will form the focus of the assessment[34]. There may be factors associated with the group that increase (or decrease) the risk to which people will be exposed. Factors that increase risk can be connected to individual vulnerability arising from, for example, age, gender, biological factors, capacity, disability, ethnicity, or to external factors such as living conditions. The increased risk can arise as a result of a group's reduced ability to recognise hazards and to take the appropriate action needed to avoid or mitigate injury, physical issues associated with (for example) old age, pregnancy, predisposition to certain health problems, etc. The risk factors might increase the expected severity of injury (stage (v) below) and/or the probability of injury (stage (vi) below).

(b) General population: where a product is aimed not at a particular group but broadly at the general population[35], the risk assessment will be undertaken in that context. However, the possibility that some people within the population will be at increased risk, for example as a result of the factors referred to under (a) above, will need to be considered and harm scenarios (see stage (iv) below) developed where relevant.

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30 Hansen, S. F., Jensen, K. A., & Baun, A. (2014). NanoRiskCat: a conceptual tool for categorization and communication of exposure potentials and hazards of nanomaterials in consumer products. *Journal of nanoparticle research*, *16*(1), 1-25.

31 Property damage is treated separately from income loss (for example see Productivity Commission. (2006). Review of the Australian consumer product safety system).

32 Broussalian, V. L. (1976). Risk Measurement and Safety Standards in Consumer Products. In *Household Production and Consumption* (pp. 489-528). NBER.

33 Sanford, J. A., Story, M. F., & Ringholz, D. (1998). Consumer participation to inform universal design. *Technology and Disability*, *9*(3), 149-162.

34 Mahmoudi, H., Renn, O., Vanclay, F., Hoffmann, V., & Karami, E. (2013). A framework for combining social impact assessment and risk assessment. *Environmental Impact Assessment Review*, *43*, 1-8.

35 Often referred to as "universal design" Steinfeld, E., & Mullick, A. (1990). Universal design: The case of the hand. *Innovation, Fall*, 27-31.

There is also the possibility that people who are not usually at increased risk could become so in some circumstances, for example where instructions or warnings are in a language that the user cannot read or the user is unable to interpret any warning symbols used.

2. Who else might be at risk?

Products can present risks to people other than the intended users[36]; these include:

(a) Unintended users: the assessment should consider the circumstances where the product might foreseeably be used by people other than those it is aimed at, and whether such people would be at an increased risk[37]. Examples include young children using products intended for their parents or older children, and professional products being used by non-professional users (migrating products).

(b) Non-users: some products can present risks to people other than (or as well as) the user. For example products that present fire hazards with the potential to cause a multi-occupied building to catch fire, and products that either in normal use or as a result of failure can produce projectiles placing people in the general vicinity at risk.

Further guidance on the issue of people at increased risk can be found in Part 2(4) 'People at increased risk'.

Stage (iv): Describe one or more harm scenarios

Creating a harm scenario requires consideration of how a product hazard identified at stage (ii) could cause harm to people. The scenario will normally be described in 3[38] or more steps, the three fundamental steps covering:

1. The existence of a hazard which can foreseeably cause harm during the lifetime of the product;
2. How the user (and/or other subjects) becomes exposed to risk;
3. How exposure to the risk results in harm.

One or more of the steps may need to be broken down further to explain the scenario clearly, but the number of steps should be kept to the minimum needed to achieve that objective. The nature of probability is such that the more steps there are, in general the lower the probability will be. It is rare that more than five steps are necessary.

Consideration of the behaviour of the *product* and the behaviour of the *user* will be key[39]. Predicting the behaviour of the product will be assisted by, for example, test results and consideration of the extent to which the product is homogeneous (see Part 2(5) 'Testing and Product Homogeneity'). Predicting the behaviour of the user can be more challenging, though achievable through careful consideration of normal and reasonably foreseeable human behaviour, taking into account the people at whom the product is aimed. In both cases, injury data and details of any specific reported injuries or ill health will assist in describing harm scenarios.

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[36] Stoltman, J. J., & Morgan, F. W. (1995). Product safety, information, and behavior. *American behavioral scientist*, *38*(4), 633-645.

[37] Beran, M., Nielsen, E., Altkorn, R., Milkovich, S., & Rider, G. (2007). Lifespan perspectives on the foreseeable use of consumer products. *Ergonomics in Design*, *15*(3), 12-16.

[38] There can be exceptions to this, for example harm scenarios involving exposure to certain airborne chemicals that are intrinsic to the product.

[39] Zackowitz, I. B., Vredenburgh, M. J., Bench, M., & Vredenburgh, A. G. (2017). Types of Consumer Products. In *Consumer Perception of Product Risks and Benefits* (pp. 3-22). Springer, Cham.

Potential influences on behaviour should also be considered, for example susceptibility to certain behavioural influences such as 'life hack' videos.

The first scenario identified will usually assume the product is being used as intended by the intended user. That first harm scenario may be the only scenario required, for example where there is only one hazard to be assessed and at stage (vii) – where the level of risk is determined – the risk is shown to be serious, then further scenarios will not usually be required. However, multiple scenarios will typically be required where:

1. there are separate hazards that need to be assessed; or
2. at stage (vii), the level of risk associated with the first scenario is found to be less than serious (unless the assessor can be confident there are no other scenarios that will produce a higher level of risk).

As regards (2) above, the alternative scenarios may need to take account of, for example:

- different harm severity levels (see stage (v) below): a lower severity level can generate a higher level of risk if the harm is much more likely to occur;
- vulnerable users and other people who may be at increased risk (see stage (iii) above); and
- any foreseeable unintended use or misuse of the product.

Any assessments of risk undertaken specifically in the context of people at increased risk or unintended use / misuse will often produce higher levels of risk. This should not usually result in a change to the overall level of risk associated with the product but should be highlighted within the risk evaluation narrative – see section 3.

Stage (v): Determine the severity of the harm

In the light of the findings at stages (i)-(iv) the anticipated severity of the harm[40] can now be determined, which will depend upon the effect the identified hazard/s will have upon the subject in the circumstances described in the injury scenario/s[41]. Factors of relevance are:

- **The type of hazard (see Table 1 at stage (ii))**: different types of hazards cause different types of harm[42]. In some cases the symptoms of harm are immediately apparent, which is typically the case with safety hazards, whereas symptoms following exposure to health hazards are often delayed. Some hazards can cause harm to the environment, property, or to animals, and can result in psychological harm to people. Where any of these types of harm are applicable, they should be noted as part of the risk evaluation (see section 3).

[40] Zunjic, A. (2011). Consumer product risk assessment. In *Human Factors and Ergonomics in Consumer Product Design* (pp. 23-32). CRC Press.

[41] Hunte, J. L., Neil, M., & Fenton, N. E. (2021). A causal Bayesian network approach for consumer product safety and risk assessment. *Journal of Safety Research*.

[42] van Aken, D. (1997). Consumer products: Hazard analysis, standardization and (re) design. *Safety Science*, *26*(1-2), 87-94.

- **The parts of the body affected**: for example, an impact hazard is likely to produce a more severe injury if it will affect the head as compared to a limb. Some hazards can affect the whole body, for example those that can result in fires or explosions, and some exert their effects internally, for example when inhaled or ingested. Note also that certain types of injury are particularly likely to result in psychological harm when they affect certain parts of the body, for example burns to the face (the potential for psychological harm would be considered during risk evaluation, see section 3).
- **How the hazard affects those body parts**: this will depend upon such factors as the ***power*** of the hazard (for example with what force will an impact hazard strike the body? Just how hot is a hot surface? what is the voltage of an electrical hazard? etc.); the ***duration*** of the hazard (for what time period can the hazard be expected to exert its effects upon the body); and the ***nature*** of the hazard (what is the exact nature of the harm that the hazard causes).
- **The subject:** in some circumstances certain people can be expected to suffer more severe harm than others. For example, children are more susceptible than adults to the effects of many toxic chemicals, and other vulnerable users (e.g. people with disabilities) may not be able to respond quickly to limit the severity of the harm being experienced.
- **The number of subjects affected:** some hazards have the potential to harm more than one subject in a single incident, for example those hazards that can result in fires or explosions, and hazardous chemicals in some types of cosmetics.

Once the above factors have been considered, the assessor should be able to place the expected severity of harm into one of the four levels shown in Table 2. Typically, the assessor would start with the most severe type of harm that is plausible in the context of the particular harm scenario. However if the level of risk that is subsequently generated at stage (vii) of the risk assessment is anything less than serious, then the assessor should consider whether there is a less severe but more probable type of harm could potentially generate a higher level of risk and, if so, produce another assessment on that basis. The assessor is also asked to consider whether more than one person could be affected in a single incident.

Where there is more than one harm scenario under consideration, the severity level for each should be assessed separately in the context of each particular scenario.

Table 2: Harm severity levels		
Level	**Nature of harm**	**Potential for multiple casualties?**
1	Injury or ill health that after basic treatment (first aid, normally not by a doctor) does not substantially hamper functioning or cause excessive pain; usually the consequences are completely reversible. *Examples: **minor** cuts, bruising, pinching, sprains and strains, piercing, 1 degree burns or 2 degree burns <6% of body surface; poisoning causing diarrhoea or vomiting; local slight irritation; mild or local allergic reactions.*	Yes / No
2	Injury or ill health for which a visit to A&E may be necessary, but in general, hospitalisation is not required. Functioning may be affected for a limited period, not more than about 6 months, and recovery is more or less complete. *Examples: cuts >10 cm on body and >5 cm on face, requiring stitches; major bruising (> 50 cm^2 on body and >25 cm^2 on face); concussion involving a short period of unconsciousness; dislocations or fractures of finger, toe, hand, foot, jaw; fractures of wrist, arm, rib, nose, jaw; piercing deeper than the skin; 2 degree burns 6-15% of body surface; electric shock causing temporary cramp or muscle paralysis; temporary loss of sight or hearing; poisoning causing reversible damage to internal organs; allergic reactions and widespread allergic contact dermatitis; reversible damage from microbiological infection.*	Yes / No
3	Injury or ill health that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function. *Examples: cuts / laceration or bruising to trachea or internal organs; concussion causing prolonged unconsciousness; sprains and strains causing muscle, ligament or tendon rupture/tear; dislocation of ankle, wrist, shoulder, hip, knee or spine; fracture of ankle, leg, hip, skull, spine (minor compression fracture), jaw (severe), more than 1 rib; crushing of extremities, arm, leg, trachea, pelvis; amputation of finger/s, toe/s, hand, foot, arm, leg, eye; piercing of eye, internal organs, chest wall; ingestion causing internal organ injury; internal airway obstruction or suffocation / strangulation without permanent consequences; 2 degree burns 16-35% of body surface and 3 degree burns up to 35% of body surface; epileptic seizure; permanent loss of sight (one eye) or hearing (one ear); poisoning causing irreversible damage to internal organs; strong sensitisation provoking allergies to multiple substances; irreversible effects from microbiological infection.*	Yes / No
4	Injury or ill health that is, or could be, fatal, including brain death; consequences that affect reproduction or unborn children; severe loss of limbs and/or function, leading to more than approximately 10% of disability. *Examples: cuts / laceration of spinal cord, brain, oesophagus, deep laceration of internal organs; bruising of brain stem or spinal cord causing paralysis; concussion resulting in coma; dislocation or fracture of spinal column; fracture of neck; crushing of spinal cord, chest (severe), brain stem; amputation of both arms or both legs; piercing of aorta, heart, bronchial tube or causing deep injuries in organs; ingestion causing permanent damage to internal organ; internal airway obstruction with permanent consequences; 2 or 3 degree burns >35% of body surface; electrocution; permanent loss of sight (both eyes) or hearing (both ears); poisoning causing irreversible damage to nerve system; anaphylactic reactions; prolonged hospitalisation from microbiological infection.*	Yes / No

Stage (vi): Determine the probability of the harm occurring

At this stage the assessor determines how likely it is that the harm described within the harm scenario/s will occur during the lifetime of the product. As at stage (v) above, this will need to be done separately for each harm scenario identified.

The recommended approach is to attach a probability to each of the steps within the harm scenario, then to multiply them to provide an overall probability. This should help provide accuracy and transparency. Identifying a reliable probability can be challenging, and the starting point should be to obtain and consider any relevant empirical evidence that can inform probability decisions.

However, even where such evidence exists, it is unlikely to provide the complete answer. For example, data relating to injuries caused by a particular product can only cover those injuries that (a) have already happened (and not those yet to happen) and (b) have been reported and made available within a dataset. Further information on the use of data is provided in Part 2(3), 'Use of data'.

Some degree of probability estimation by the assessor will therefore nearly always be required, and will often be the sole or main means of determining probabilities. Such estimations will inevitably involve a degree of uncertainty, which can be addressed in part by consulting with relevant colleagues and over time through experience. Guidance on how to deal with uncertainty is contained within stage (viii), below.

Other factors of relevance include:

- **Who the product is aimed at and who might foreseeably be exposed to the risk**: and in particular whether the product is aimed at a vulnerable group of people who as a result of their vulnerability are more likely to suffer harm.
- **Whether the particular risk will be identifiable:** (and potentially flagged through the use of suitable warnings) thus allowing precautions to be taken to reduce the probability of harm occurring, or whether the risk is 'hidden' which can be the case with, for example, chemical hazards and many electrical hazards.
- **How the product will be used**: for example some products are intended to be used day and night – and thus while the occupants of the premises are asleep – such as fridges and freezers, while others might foreseeably be used while occupants are asleep. A product with the potential to catch fire is more likely to result in injury if the fire occurs when people are sleeping rather than awake.
- **Frequency of use**[43]: for many products a key factor in determining the probability of harm occurring will be the number of times the product is used and thus the frequency of exposure to the hazard(s), over the foreseeable lifetime of the product. For example, the number of exposures to an electric shock risk associated with a kettle can be expected to far exceed the number of exposures to a similar risk associated with a blender. However, there will be some products and scenarios where this factor is not particularly relevant (e.g. products to which exposure is largely constant, such as fridges and freezers, or where it can reasonably be anticipated that the risk will eventually be realised at some point during the lifetime of the product, even if used infrequently).

[43] Hunte, J. L., Neil, M., & Fenton, N. E. (2021). A causal Bayesian network approach for consumer product safety and risk assessment. *Journal of Safety Research*.

- **The conditions required for harm to occur**: it will generally be the case that where only a small number of conditions need to coincide for harm to occur, and those conditions can occur readily, the probability of harm will be high (and vice versa).
- **Test reports**: test results should not be seen as a simple pass or fail in the context of risk. Products that fail tests by large margins will often involve a greater probability of harm than those that fail by small margins. Further information on the significance of test results can be found in Part 2(5), 'Testing and product homogeneity'.

Stage (vii): Determine the level of risk

This stage involves combining the outcomes of stages (v) severity of harm and (vi) probability of harm to determine the level of risk associated with a product. It will need to be done more than once where there is more than one hazard under consideration and where more than one harm scenario has been identified in relation to a particular hazard. The assessor will need to consider the risk presented by a single item of the product, and in most cases will also need to consider the level of risk presented by the totality of the product items in use (population risk) assuming the assessor is able to access this information.

Level of risk (single item)

Table 3 below can be used to identify the level of risk presented by a single item of the product being assessed.

Table 3: Level of risk (single item)

Probability of harm over lifetime of product	**Severity of harm**			
	Level 1	Level 2	Level 3	Level 4
>50%	**High**	**Serious**	**Serious**	**Serious**
>1 in 10	**Medium**	**Serious**	**Serious**	**Serious**
>1 in 100	**Medium**	**Serious**	**Serious**	**Serious**
>1 in 1000	**Low**	**High**	**Serious**	**Serious**
>1 in 10,000	**Low**	**Medium**	**High**	**Serious**
>1 in 100,000	**Low**	**Low**	**Medium**	**High**
>1 in 1,000,000	**Low**	**Low**	**Low**	**Medium**
<1 in 1,000,000	**Low**	**Low**	**Low**	**Low**

Single hazard risk assessments

Where only one harm scenario has been identified for the single hazard under consideration[44], then (subject to the application of Table 4) the level of risk indicated within Table 3 will form the risk level for the product. Where there is more than one harm scenario, the scenario involving the greatest risk will form the risk level for the product.

Multiple hazard risk assessments

Where the risks created by two or more separate hazards have been assessed, the assessor has two options:

Option 1: the hazard creating the greatest risk forms the risk level for the product;

Option 2: the risks created by the separate hazards are considered together to inform the risk level for the product[45] (see Part 2(2), Risk assessing multiple hazards).

In most cases option 1 will be the most suitable option, particularly where one hazard is creating significantly greater risk than the others, because this will normally be sufficient to point the way towards an effective and proportionate risk management response (though the need for risk management in relation to other, less significant risks should also be considered).

The option 2 route may be preferable in circumstances where the separate hazards are creating similar levels of risk and when considered individually do not indicate a significant level of risk, but considered in combination indicate a higher level of risk (which can sometimes be the case with generally poor quality products).

Level of risk (all items)

Table 3 identifies the risk presented by a single item of the product being assessed. However the assessor should also consider the risk presented by the total number of items in use across the UK, where such information is available or can be estimated. This risk can be viewed as the risk to the UK population as a whole from the product, because the risk reflects a prediction of the actual number of incidences of harm that can be expected to occur across the UK while the particular product remains in use.

The population risk can be identified via Table 4, in which the single item risk level identified in Table 3 is cross referenced with the total number of those items estimated to be in use. In practice what this means is that where high numbers of the product are estimated to be in use, the overall level of risk associated with the product may increase as shown within the Table.

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[44] For an example see Trantallidi et al (2015) iteratively examining a single hazard for a variety of cleaning product types. Trantallidi, M., Dimitroulopoulou, C., Wolkoff, P., Kephalopoulos, S., & Carrer, E. P. (2015). EPHECT III: Health risk assessment of exposure to household consumer products. *Science of the Total Environment*, *536*, 903-913.

[45] For an example of a cumulative risk assessment combining multiple hazards see Chang, W. H., Chou, W. C., Waits, A., Liao, K. W., Kuo, P. L., & Huang, P. C. (2021). Cumulative risk assessment of phthalates exposure for recurrent pregnancy loss in reproductive-aged women population using multiple hazard indices approaches. *Environment international*, *154*, 106657.

Table 4: Level of risk (all items)				
Estimated number of items in use	**Risk associated with single item (derived from Table 3)**			
	Low	Medium	High	Serious
>1m	**High**	**Serious**	**Serious**	**Serious**
500k – 1m	**Medium**	**High**	**Serious**	**Serious**
100k – 500k	**Medium**	**High**	**High**	**Serious**
50k – 100k	**Low**	**Medium**	**High**	**Serious**
10k – 50k	**Low**	**Medium**	**High**	**Serious**
1k – 10k	**Low**	**Medium**	**High**	**Serious**
<1k	**Low**	**Medium**	**High**	**Serious**

Table 4 is applied at the current point in time. However the assessor should also consider whether going forward the total number of items in use is expected to significantly increase or decrease over time, as part of the risk evaluation (see section 3).

Stage (viii): Consider the level of uncertainty

Every risk assessment that involves some degree of estimation will come with an associated degree of uncertainty[46]; this is normal and does not in itself mean that the risk assessment is flawed. The level of uncertainty does, however, have implications for the confidence that can be placed in the risk assessment findings.

Uncertainty arises most commonly in relation to the identification and accuracy of the harm scenarios (stage iv), accurately estimating the severity of harm (stage v) and, most commonly of all, identifying accurate probabilities of harm occurring (stage vi). The level of uncertainty can be reduced where relevant and reliable data can be obtained, see Part 2(6), though some uncertainty will usually remain[47].

The level of uncertainty should be categorised as low, medium or high:

- A **low** level of uncertainty would typically exist where the risk being assessed is well understood, has been the subject of previous similar risk assessments by MSAs, and / or relevant evidence is available.
- A **medium** level of uncertainty would typically exist where some relevant data exists but there are gaps and/or some of the evidence used is unvalidated, old, or otherwise limited.

[46] Neil, M., Fenton, N., Osman, M., & Lagnado, D. (2021). Causality, the critical but often ignored component guiding us through a world of uncertainties in risk assessment. *Journal of Risk Research*, *24*(5), 617-621.

[47] Osman, M., Heath, A. J., & Löfstedt, R. (2018). The problems of increasing transparency on uncertainty. *Public Understanding of Science*, *27*(2), 131-138.

- A **high** level of uncertainty would typically exist where there is little relevant evidence and the risk is not well understood, which will often be the case with novel products and those new onto the market (though products new onto the GB market may have previously been available in other countries)[48].

The basis upon which the level of uncertainty has been categorised as low, medium or high should be explained, particularly where a 'low' categorisation has been applied. Sources of information, data and other evidence that have been used should be cited, along with an explanation of how the source has informed the assessment.

Sensitivity analysis

The implications of the uncertainty can be considered by undertaking a sensitivity analysis[49]. This involves varying one or more of the component parts of the risk assessment (i.e. the severity level and / or the probability as per Table 3, and / or the estimated number of products in use as per Table 4) to reflect the boundaries of the uncertainty, and then identifying whether the risk level changes as a result[50]. For example, where there is uncertainty surrounding one or more of the probabilities within the injury scenario, then stage (vi) of the assessment can be repeated using different probabilities (which can be higher, lower, or both) that fairly reflect the extent of the uncertainty.

The outcomes of assessments where the risk is close to the boundary between one level of risk and the next will be more sensitive to changes in the component parts of the assessment than those where the risk lies within the middle of a particular risk level. An alternative approach to sensitivity analysis is to start from this point, i.e. to consider the extent to which the component parts of the risk assessment would need to change to produce a change in the risk level. In some cases this method can quickly identify that a change in risk level is unrealistic.

Where the outcome of sensitivity analysis indicates that the risk level could change when the uncertainty is taken into account, this should be noted.

Over time some components of uncertainty can often be reduced as investigations proceed and more information and knowledge become available. However, other components are inherent within the scenario/s under consideration and cannot be reduced.

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48 Osman M (2016) Making a meal out of uncertainty. Journal of Risk Research.

49 There are broadly three different types of sensitivity analyses (mathematical, statistical, graphical) for a review see Christopher Frey, H., & Patil, S. R. (2002). Identification and review of sensitivity analysis methods. *Risk analysis*, *22*(3), 553-578.

50 For a Bayesian example of this see Fenton, N., & Neil, M. (2018). *Risk assessment and decision analysis with Bayesian networks*. Crc Press.

Section 3: Risk Evaluation

Staged approaches to dealing with risk have often moved directly from risk assessment to risk management. However there is an important stage that sits between assessment and management – that of risk evaluation[51].

Risk evaluation is required because decisions on whether action is required to deal with a particular risk, and the nature of that action, should not usually be made purely on the basis of the level of risk involved (albeit the level of risk is a fundamental consideration). Other factors potentially need to be taken into account, and these as well as the outcome of the risk assessment are considered at the risk evaluation stage.

The risk evaluation would normally be expressed as a narrative, with the aim of identifying any factors that would or might influence the degree of priority that should be afforded to the issue and the need for risk management action to be taken (or not). The contextual factors informing a risk evaluation can be considered under two broad headings: those related to the nature of the risk, and those related to the way the risk is perceived by the public.

3.1 Factors related to the nature of the risk

Relevant factors include:

- **The subjects at risk:** risk assessments will usually focus on physical harm to people. However some hazards can pose risks to other subjects such as the environment, animals and property. The assessor should note where subjects other than people are at risk, as this could add weight to the need for risk management action.
- **The potential for psychological harm:** where the assessment identifies the potential for significant psychological as well as physical harm, this should be noted because this too could influence the need for risk management action. Further information is provided in Part 2(9), ‘Psychological harm’.
- **Prevalence forecast:** the number of products estimated to be in use will usually have been considered at stage (vii) of the risk assessment (Level of risk – all items) however this figure might be expected to rise, fall, or stay roughly constant in the short or medium term. Any expected significant changes in the number of products in use could have relevance to the need for risk management action.
- **The level of uncertainty:** this will have been considered at stage (viii) of the risk assessment, and identified as low, medium or high. The higher the level of uncertainty in the risk assessment findings, the more relevant the issue will be at the risk evaluation stage. The assessor will need to consider the implications of the level of uncertainty, and the areas in which uncertainty exists, for subsequent risk management decisions.

[51] “Risk evaluation” is defined in section 1.3.

Also, the precautionary principle is potentially relevant (see Part 2(8)), particularly where sensitivity analysis has indicated that the risk level could move to 'serious' when uncertainty is factored in.

- **How the level of risk compares with that presented by comparable products**: comparing the level of assessed risk with the level of risk presented by similar and comparable products (sometimes referred to as risk benchmarking) can in some circumstances assist the assessor when considering whether and what corrective action is justified. However, the often-limited availability of genuinely comparable data does restrict the circumstances in which risk benchmarking can be applied, and caution must be exercised to ensure that 'apples are being compared with apples'. Also, the degree to which benchmarking should influence decision making does require careful consideration[52].
- **The potential for multiple casualties:** this issue will have been considered at stage (v) of the risk assessment. An incident in which numerous people are injured is obviously a more serious outcome than a single person being injured, other things being equal, particularly where fatal injuries are involved. Some products will clearly have the potential to cause harm to multiple subjects in a single incident and, where available, injury statistics can provide an indication of likelihood simply by dividing the number of injuries by the number of incidents involving an injury (the higher the resulting figure, the higher the likelihood).

  Where the potential for multiple casualties exists, and depending upon the extent of that potential, the assessor should take this into account in making decisions on risk management. The potential for multiple casualties, particularly where there is potential for fatal injuries, is also relevant to risk perception and tolerability (see under 'nature of the risk' in the 'Factors relating to perception and tolerability of the risk' section below).
- **The risk differential:** for many if not most products, the level of risk they present when fully compliant will be very low or negligible. Other products, even when fully compliant, may still involve a substantive level of risk when used, for example trampolines and ladders. Careful use of such products can ensure the level of risk is not excessive, but an element of risk will remain. In the context of a risk assessment outcome, two non-compliant products could present the same level of risk – say 'high' – but if one of those products when fully compliant would involve only a negligible or very low risk, but the other would involve a more substantive – perhaps medium – level of risk, then the risk differential (the gap between the level of risk presented by the non-compliant product and the level of risk it would present if it was fully compliant) is very different in the two cases.

[52] In defining a 'safe product', Regulation 2 of the General Product Safety Regulations 2005 states that "the feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be a dangerous product". That said, if the product under consideration appears to be causing injuries at a rate significantly higher than the average rate for that type of product, it is likely that this is something the assessor will wish to take into account.

The risk evaluation should consider the risk differential and highlight any circumstances where the differential is likely to be significant (in general where there is a differential of two or more levels of risk), because it is here that risk management action can potentially have the most impact in terms of risk reduction.

- **People at increased risk:** the risk assessment (see Section 2, stages (iii) and (iv)) may have identified people that will foreseeably be exposed to a higher level of risk than the general population. This could mean, for example, that while the level of risk for the product is low, for some people their level of risk will be at a higher level. Where the assessment indicates that certain people will be at increased risk, this should be noted because it could mean that bespoke risk management action will be required to specifically target and protect those people.
- **Action taking place elsewhere:** it may be the case that other MSAs or other organisations with an interest in the particular risk are taking or planning to take risk management action to address it. Where this is the case, the implications should be considered within the risk evaluation because it could influence the extent to which action is required, where any action is best targeted, and whether there would be benefit in a joint approach involving a number of organisations working collectively to produce and implement a risk management strategy.

3.2 Factors related to perception and tolerability of the risk

In some cases it will be clear to the assessor that there is already a degree of public concern relevant to the risk under consideration. This may have been expressed, for example, within media outlets, by lobbying or pressure groups, or by politicians. Irrespective of the outcome of the risk assessment, such concerns cannot be ignored and must be considered and noted as part of the risk evaluation. Such concerns are very often (but by no means exclusively) expressed where risks have the potential to harm vulnerable people, such as children.

In other cases, there may currently be no significant public concern but it is foreseeable that, in the event of harm occurring or continuing to occur, such concern is likely to arise. An understanding of the factors that influence how people perceive risks can assist in predicting the likelihood of public concern arising. These factors have been and continue to be extensively researched, and are described in Part 2(7) ‘A summary of the factors that influence how risks are perceived’.

The assessor should come to a conclusion as to whether the risk presented by the non-compliant product is tolerable[53] to the public. Societal tolerance signals that, overall, the benefits derived from a product outweigh the perceived risks associated with it. Both the level of risk presented and how it is perceived will be of relevance, however:

[53] “Risk tolerability” is defined in section 1.3

- A serious or high level of risk will normally equate to an intolerable risk[54] [55].
- A medium level of risk is likely to equate to an intolerable risk[56].
- A low level of risk is unlikely to equate to an intolerable risk[57].

It is particularly important to be aware of factors that could lead to a low level of risk being viewed as intolerable. These include:

- The overall risk presented by the product: where the hazard under consideration is assessed as presenting a low risk, but there are other hazards associated with the product that can and do cause harm (even if such harm does not necessarily arise in the context of non-compliance) the risk is more likely to be intolerable. This can also apply where there are unrelated causes of the same type of harm. For example in circumstances where there is a defect in a product that can result in a fire, but there are also other unrelated causes of fire associated with the product, the assessor should consider assessing the overall fire risk associated with the product as well as the risk presented by the defect.
- Nature of the risk: high severity low likelihood risks (in particular those where there is the potential for fatalities) tend to be less tolerable than low severity high likelihood risks, particularly where there is clear scope for risk management action to be taken that would reduce the probability of harm still further.
- Risks to non-users: risks that can cause harm to people who are not the users of the product are more likely to be seen as intolerable.
- Risks to vulnerable users: there is generally a low tolerance towards any risks presented by products aimed at vulnerable users.
- Risks associated with defective protective products: certain products are designed to provide a protective function when certain circumstances arise, such as child car seats in the event of an accident, smoke alarms in the event of a fire, and many types of personal protective equipment where the protective function is only called upon in specific circumstances. The risk presented by defective examples of such products tends to be low when assessed in the usual way, because the harm scenario will initially require consideration of, for example, the probability of a fire or an accident occurring and this will typically be low.

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54 Article 20 of the Regulation on Accreditation and Market Surveillance (765/2008) as it has effect in Great Britain ('GB RAMS') places an obligation on Market Surveillance Authorities to ensure that products that present a serious risk requiring rapid intervention are recalled, withdrawn or prohibited from being made available on the UK market.

55 "***Intolerable risks*** are those which exceed a socially negotiated norm (e.g. the availability of clean drinking water) or a value (e.g. continuity of a way of life) *despite adaptive action*." (pp. 385) Dow, K., Berkhout, F., & Preston, B. L. (2013). Limits to adaptation to climate change: a risk approach. *Current Opinion in Environmental Sustainability*, *5*(3-4), 384-391.

56 For example, some evidence in support comes from work examining "unacceptable risk" Basketter, D. A., Angelini, G., Ingber, A., Kern, P. S., & Menné, T. (2003). Nickel, chromium and cobalt in consumer products: revisiting safe levels in the new millennium. *Contact dermatitis*, *49*(1), 1-7.

57 Gupta, N., Fischer, A. R. H., & Frewer, L. J. (2015). Ethics, risk and benefits associated with different applications of nanotechnology: a comparison of expert and consumer perceptions of drivers of societal acceptance. *NanoEthics*, *9*(2), 93-108.

However, there is generally a low tolerability of defects in protective products, given that their function is to prevent harm and increase safety to the consumer. In such cases, it may prove insightful to conduct a risk assessment with a harm scenario that starts from the point that a fire or accident has occurred – further information on how to achieve this is provided in Part 2(6), 'Relative risk'.

- Inability to control: risks over which people cannot exercise any control, on becoming aware that the risk exists, are more likely to be intolerable than those over which there is opportunity to exercise a degree of control.
- Deliberate or knowing non-compliance: risks arising in contexts where businesses knew their products were non-compliant but continued to market them are more likely to be intolerable than risks arising in the context of error or oversight.
- Media influence: risks that feature heavily in the media, whether mainstream or social media, are as a result more likely to be seen as intolerable.

The assessor should state whether they believe the risk to be tolerable or intolerable, and the basis for that view. It may be the case that further investigative work is required to enable a more informed position to be taken on tolerability, and that assessor should make clear where that is the case. The tolerable / intolerable distinction is important because:

For intolerable risks: risk management action will normally be required to reduce the risk to a tolerable level and to comply with the law.

For tolerable risks: risk management action is not normally required, however action may still be needed to address any relevant non-compliance.

Section 4: Quality Assurance and Recording / Reporting

4.1 Quality assurance

Once the risk assessment and risk evaluation are complete, the assessor may wish their findings to be checked by a colleague or other third party who has not until this point been involved in the process. This 'fresh pair of eyes' can in some circumstances bring new perspectives and observations, and provides an opportunity for checking of calculations made and judgements applied.

4.2 Recording and reporting

The risk assessment and evaluation should be recorded in sufficient detail to capture the key findings and form a point of reference for future use. In some circumstances the resulting document may need to be produced in legal proceedings and therefore the details recorded should be suitable for this purpose.

The findings should also be notified to the OPSS Product Safety Database in all circumstances where the product that has been assessed is non-compliant[58]. A tool has been developed for this purpose.

Access the PRISM toolkit.

4.3 Monitoring and review

New information and evidence can subsequently come to light that impacts on the findings of the risk assessment. In such circumstances the assessor should review the assessment, refine it as necessary, and where the outcome is a change to the level of risk or to other significant aspects of the assessment then the implications for risk management should be considered and communicated.

[58] For guidance on how to make notifications see: https://www.gov.uk/guidance/notification-of-unsafe-and-noncompliant-products.

Section 5: Risk Management

The risk assessment and evaluation will have identified whether the level of risk presented by the relevant product is tolerable or intolerable. It is at the risk management stage that decisions are made to:

- confirm that risk management action is required;
- identify the nature of the action needed; and
- implement the action.

As noted in section 3, risk management action will normally be required where an intolerable risk has been identified, to reduce the risk to a tolerable level. A wide range of risk management options are available, formal and informal, and the action taken should be both proportionate and effective in achieving the required reduction in risk and in remedying the non-compliance giving rise to the risk, both within an appropriate timescale.

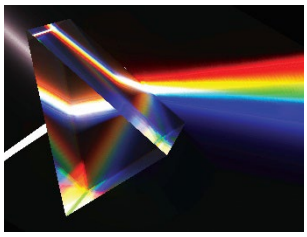
Although the level of risk involved will be fundamental in determining the nature of the action required (and the urgency), there is no direct link between particular levels of risk and particular types of action. The action taken, whether directly by the MSA, voluntarily by the relevant business, or by the business acting upon advice or instruction by the MSA, should be what will be proportionate and effective in the circumstances.

In some cases, the risk management action will be general in nature, with the aim of reducing the level of risk to all those people (or other subjects) that are or might be exposed to it. However, in cases where the level of risk to the general population is low, but for certain sections of the population is higher, then specific, targeted risk management action may be required with the aim of protecting those people at increased risk.

There may also be a need to consider whether the non-compliance highlights more systemic failings that need to be addressed in relation to how the business manages product safety, and whether similar products supplied by different producers could also be non-compliant (for example other manufacturers may use an identical defective component in their products).

Further information on risk management can be found in PAS 7100:2022 *Supporting better product recalls. Code of practice on consumer product safety related recalls and other corrective actions.*

Part Two – Additional Guidance, Resources and Useful Information

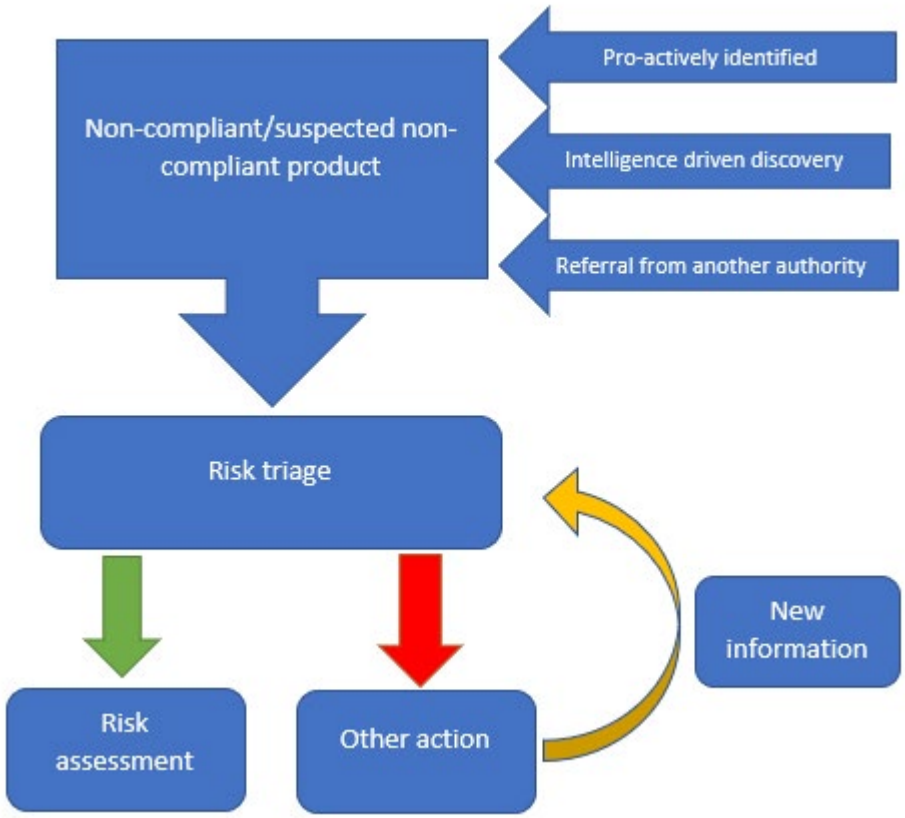


1. Risk Triage

A risk assessment usually occurs after non-compliance has been identified in a product. The hazard associated with the non-compliance may be suspected[59], identified by the assessor or identified by a third-party test house commissioned to examine the product – either because the hazard is potentially giving rise to non-compliance or for a proactive examination.

Robust, detailed risk assessments can take time to produce. The purpose of risk triage is to sense check whether a detailed risk assessment is required and give an early indication of what the risk level is likely to be and, accordingly, the degree of urgency with which the issue under consideration needs to be progressed. Figure 2 below shows where risk triage normally occurs within a product safety investigation, and the process typically starts with suspected non-compliance. However, another possibility is project work in relation to a particular product type where several products are test purchased to establish a baseline of compliance. In this scenario all products will be assessed irrespective of whether there is suspected non-compliance or the level of risk the hazard may present.

Figure 2: The risk triage process



[59] Suspected is used here to describe a hazard that may require technical qualification, for example establishing the exact strength of a magnet.

Where a full risk assessment is not required, further action may nevertheless be needed. ‘Other action’ may include reporting the product to the product safety database (PSD), further investigation such as the commissioning of formal testing, and the gathering of additional evidence and/or intelligence. This new information may then form part of a new risk triage to assess whether, based on the new information, it is now appropriate to perform a full risk assessment.

There are other benefits to an MSA employing a risk triage system as part of the overall approach to product safety regulation. As well as helping to focus resource on the products that merit a full risk assessment, it can provide a means of articulating why a matter was not prioritised for action. In addition, risk triage can be used as a training tool to introduce basic concepts of product safety risk assessment to less experienced staff.

An effective risk triaging approach will enable triage to be performed in the following circumstances:

- Limited availability of information.
- Limited time to make a judgement (depending on the context of the screening).
- Where assessors have little or no experience in performing risk assessments.

A purely qualitative approach is generally easier to apply but is likely to have greater subjectivity.

The triage process

As triage may be the start of a process that leads to formal enforcement action, a record should be kept. This might include, for example, the absence of labelling on the product, the presence of several apparent hazards, and whether the product was part of a much larger batch.

The triage process should cover the following key aspects:

1. Background: this sets the context for the process, making clear, for example, how the assessor first became aware of the product and the suspected non-compliance;
2. An estimate of the foreseeable harm: this will establish the harm severity and is an estimation of the type of harm that can arise from the relevant hazard/s; and
3. An estimate of the probability that the hazard will cause harm.

Additional factors that may require consideration during triage include the presence of multiple hazards and the total number of product items estimated to be in use.

1. Background

The first component of a triaging system is capturing why the assessor is investigating the non-compliance / suspected non-compliance. This can also help explain why other products might have been excluded from further investigation at the time of the screening.

Product safety practitioners receive intelligence and referrals from numerous sources including open and closed intelligence sources, information derived from exploratory projects, seasonal/recurring projects (such as fireworks compliance), referrals from other parts of the organisation, and referrals from other regulators and MSAs.

Queries from politicians, reports in the media, complaints from the public, Coroners' Letters of Concern, and NGOs/consumer groups/trade association campaigns etc. can also act as initial triggers for action.

Much can be inferred from the product's history of use, including an indication of the risk it presents in circumstances where harm has already occurred. Where there is as yet no corroborating information, such as test results, the product's history will help inform a risk-based decision on the extent to which further investigation is required, including whether it is appropriate to undertake a full and detailed risk assessment.

2. Estimating the severity and probability of harm

Assessing the harm *severity* should be a similar process to that taken during the full assessment, but generally without needing to have regard to the same level of evidence. Asking a colleague to perform a sense check on the conclusions can help identify any potential errors.

Likewise, given the normally limited information and time pressures that often apply at triage, it may be helpful to consider *probability* using a qualitative approach. The labels shown in Table 5 below are one example of such an approach.

Table 5: Triage labels

Qualitative label	Approximate quantitative equivalent
Common – a greater than 50% chance	>50%
Often – a less than 50% chance, but still quite probable	>1/10
Occasional – it would not be surprising if the event occurred	>1/100
Unusual – an unlikely event	>1/1,000
Rare – a highly unlikely event	>1/10,000
Very rare – an extremely unlikely event	>1/100,000
Hardly ever – the event hardly ever occurs	>1/1,000,000
Almost entirely unlikely – while possible, the event will almost certainly not occur	<1/1,000,000

Qualitative descriptions are less precise but are intended to articulate a reasoned probability that will be qualified by more detailed research if the product is subject to a full assessment.

Multiple hazards

The guidance on risk assessing multiple hazards (see Part 2(2)) explains how multiple hazards that are suspected sources of non-compliance can be assessed to arrive at a more holistic view of the product's overall risk level. In the context of triage, the key issue is whether the fact that multiple hazards exist in itself warrants a full risk assessment.

Some products by their nature appear to more commonly present hazards that may be sources of non-compliance, such as electrical appliances that may have issues with their insulation, fuse, construction of the plug, control of ignition and fuel sources, etc.

Total number of product items in use

The prevalence of a product does not affect the product's *actual* risk to an individual user, and instead reflects the overall risk to the population (see Part (1) section 2.2(vii)). To estimate the total number of product items in use, the assessor may wish to consider how the product is being supplied, for example whether it is being supplied by a major, regional or local retailer and, if the latter, how feasible it might be that the product may be stocked by multiple different retailers or is 'branded' to a store. For some types of product, the same model might be branded for different sellers who then become the producer. However, the product can be of identical construction, so if a defect is present in one brand it is likely to be present in others.

Finally, the outcome of triage should be seen as informative but not definitive. It should indicate the extent to which a full risk assessment is needed, however the final decision on whether a full assessment is required is a matter for the assessor.

Triage tools

OPSS has developed a product risk assessment triage tool.

Access the triage tool in the PRISM toolkit.

2. Risk Assessing Multiple Hazards

As explained in Part 1 of this guidance (under stage (vii) of section 2), where a risk assessment has involved consideration of the risk presented by more than one hazard, the overall level of risk associated with the product will usually be determined by the hazard that creates the greatest risk. However, in some circumstances there may be value in the risk assessor explicitly flagging the fact that there is more than one hazard of concern associated with the product, which might be the case where a product is of generally low quality with a number of issues of concern consequentially arising. In such circumstances there can be value in taking a broader view, to enable the tolerability two or more risks presented by such a product to be considered.

Two approaches to combining the risks presented by multiple hazards are:

1. Combining risk level outcomes produced by the different hazards to generate a revised risk level.
2. Adding the label ‘risk level plus’ to the risk level.

These approaches are explained below.

1. Combining risk probabilities

This method is useful when a product has at least two independent hazards that involve the same level of injury severity. Adding the probabilities of harm presented by the two hazards would generate a greater overall probability of harm. Note that adding probabilities will not necessarily result in a change in risk level.

For example, a power tool lacking a guard for the dangerous moving parts and having inadequate protection from contact with live electrical conductors. If the absence of the guard involves a 1/2,000 probability of a level three injury, and exposure to live conductors involves a 1/3,000 probability of a level three injury, then the risk level is ‘high’ in both cases – see Table 3 in Part 1 section 2.2(vii). Combining the probabilities produces a new probability of harm from the product as 0.8/1000. This is close to the threshold limit of greater than 1/1,000, compared to 1/2000 and certainly 1/3000. However as it does not fall within the >1/1000 threshold, overall the product remains within the high risk category.

However, in circumstances where two hazards had the potential to produce severity level three injuries, and the probability of occurrence for each was 1/1500, the combined probability of a level three injury would be 1.3/1000 and therefore a serious risk.

The difference between the two scenarios is where the probabilities sit within the risk band and how close they are to taking the level of risk into the next level of seriousness. In circumstances where there is no change to the risk level, the ‘risk level plus’ method may be more appropriate.

2. Risk level plus

This approach is most suited to scenarios where a product has multiple independent hazards that involve risks with different injury severity levels. The risk associated with the product would, as normal, be derived from the hazard creating the greatest level of risk, but here the risk (whether low, medium high or serious) would be referred to as low risk plus, medium risk plus, high risk plus or serious risk plus.

The risk level plus label can be attached to any non-compliant product where more than one hazard is creating risk. For example, a product with two hazards where each is assessed as creating a high risk would be “high risk plus”, as would a product with one hazard creating a high risk and another creating a medium risk. The supporting narrative would explain the hazards identified and how the risk level plus classification has arisen, and any risk level plus classification should be taken into account as part of the risk evaluation.

Summary

In circumstances where more than one hazard has been assessed, consideration should be given to how the overall product risk is best expressed. In most cases, this will involve the normal PRISM approach whereby the risk level of the product is defined by the hazard that creates the highest level of risk. However in some circumstances the assessor may wish to take account of there being more than one hazard of concern. Of the two options for doing so presented above, the risk level plus method is basic but straightforward to apply; in contrast the option of combining risk probabilities provides a more informative assessment of risk but is not suitable in all circumstances. The assessor should be able to justify whichever approach is taken.

3. Use of Data

Risk assessment can be a complex and demanding task, which is often made easier where the assessor is able to make use of data that is relevant to the issues under consideration. Data can assist the assessor when considering, for example, which people might use particular products, how they might use them, harm types and severities, harm scenarios and probabilities of harm. Data can also prove insightful for risk evaluation purposes. Fundamentally, the use of data can bring greater certainty to the risk assessment process. Data can also allow for more informed risk evaluation.

Data should be used with caution, however. Comprehensive injury statistics, for example, can appear to offer valuable insights when undertaking risk modelling (and in some cases they do), however the basis upon which such statistics have been derived must be understood. For example, such statistics will not differentiate between injuries caused by or associated with products which were legally safe, and those caused by dangerous products. Such data may still be useful for risk assessment purposes, but should be used with appropriate caveats, adjustments and recognition of uncertainty. Further, injury statistics can only ever account for those injuries that (a) have been reported and recorded within a dataset, and not those which have not been reported (in general the more severe an injury, the more likely it is to be reported), and (b) have happened, and not those which are yet to happen. Also the assessor should take into account the age of a particular dataset which may impact on its accuracy and relevance to the issue under consideration and, similarly, data gathered in other countries, while potentially useful, should nevertheless be used with caution as there may be factors such as cultural differences that make the data less relevant to the UK context.

Injury data can therefore potentially provide a useful baseline but is very unlikely to provide an absolute and reliable probability of a particular type of injury occurring. Accordingly, while data can reduce the need for estimation on behalf of the risk assessor, some degree of estimation will almost always be required.

Data can be placed into one of three broad categories:

1. Primary data (directly relevant to the harm scenario under consideration): this would be the case where the data relates to the same product type which is used in the same way by the user and which presents the same type of hazard. An example of where this could apply is the Home Office's fire statistics, which differentiate various severities of injury caused by fires originating from particular types of products (in circumstances where there was Fire and Rescue Service attendance at the scene). These statistics can be used to estimate, in the event of a fire originating from a particular type of product, the probability of that fire resulting in injuries at various levels of severity.

2. **Secondary data (partially relevant to the harm scenario under consideration)**: such data would typically have some commonality with the product type, user behaviour, or hazard under consideration, but that commonality would not be sufficient for the data to be used directly in estimating injury types or probabilities. While such data can be persuasive, such estimations would need to take other factors into account.

An example is aggregate statistics relating to deaths resulting from a small object becoming lodged in a child's trachea. While such data can be useful for risk assessment purposes it should be recognised that it does not relate to the type of product being assessed, and factors such as the size and shape of the product that may impact on the likelihood of serious rather than minor injury would need to be considered.

3. Tertiary data (not relevant to the harm scenario under consideration but may be informative): this would include injury data relevant to the product under consideration, but not to the particular hazard, such as electric shock injury data when the hazard under consideration relates to fire risk. While such data might appear irrelevant in such a scenario, it may offer some insight into who is using the product or how it is used. It might also highlight an additional hazard requiring assessment under the triage process or help with the identification of multiple hazards in a product.

It is important that the assessor, when considering available data, is able to recognise in which of the three categories the data sits. Clearly it is primary data that will offer the most utility within the risk assessment process and has the greatest potential to achieve certainty, particularly where it relates to a large population size and/or covers a long time period. If primary data is unavailable, the use of secondary or tertiary data, where available, should be considered. Because, for the majority of risk assessments, data sets containing relevant primary data will not exist or, where they do exist, will not cover all stages of the risk assessment, the assessor will usually need to consider the availability of other data sets and how they might be used to inform the assessment. It may be the case that minimal or no data, whether primary, secondary or tertiary is available, and the assessor is obliged to rely entirely upon considered estimation. Such an approach is perfectly justified although the assessor should ensure that reasonable efforts have been made to confirm the unavailability of relevant data.

Access open source data sets to support risk assessment.

There is another potentially important source of data that should be considered as part of any risk assessment, namely that held by the relevant business. Such data should in theory be directly relevant to the product being assessed (including the exact batch and model, where applicable), and businesses have certain legal obligations[60] with regard to holding data on complaints concerning the safety of their products and taking measures to inform themselves of risks their products might pose. However, an appropriate degree of caution should be exercised when considering the reliability of information provided by a business that is under investigation.

[60] In particular the General Product Safety Regulations 2005, regulation 7

4. People at Increased Risk

The process of product safety risk assessment involves predicting the perceptions, behaviours, and decisions of the product user, linking this to how they will typically engage with the product and making a forecast on whether this all taken together will lead to harm.

In relation to the user, this will typically focus on their perception of the risk and how the risk might be mitigated by the user, if at all. Some product users will have less refined risk perception skills, either through inexperience of the risk or because of individual characteristics that reduce their ability to identify risk before harm occurs. Some users, such as those with a high risk tolerance, might choose not to exercise caution, for example by ignoring safety warnings. Note, however, that some product risks, by their nature, will not be apparent to the majority of people, for example most chemical risks. Also, exposure to some types of risk can for some people result in more severe harm and/or longer recovery times from harm caused.

Identifying people at increased risk of harm should be determined on a case-by-case basis. This is to avoid ‘template’ assessments that may wrongly assume that in all cases hazard x will always harm user y in circumstances z. For example, products with small parts that are not correctly labelled with the prescribed age warnings may foreseeably be given to a child under 36 months, resulting in the child choking on the small part without a supervising adult becoming aware. However, depending upon the nature of the toy and its intended use, very different levels of supervision can be anticipated, for example a toy intended to be left in a child’s cot or bed compared to a toy intended for use in a bath. Also, consideration should also be given to the possibility of certain people experiencing greater harm because of their individual circumstances, for example a product with a microbiological hazard that has severe implications for immunocompromised people.

With regard to products that present a fire risk, there are scenarios where the risk is increased because of people’s characteristics and/or circumstances. Factors in relation to buildings where people live are pertinent, for example whether the building is a residential block and thus, if occupants residing in units within the block own an unsafe product the resulting risk may affect other residents, depending on the nature of the building and how a fire might spread between demised dwellings. As well as an occupant being in possession of an unsafe product, in some ‘new builds’, or residential blocks subject to wholesale refurbishment, the same integrated appliances and devices maybe fitted in all units. If these appliances or devices are found to be dangerous, the fire risk is substantially increased.

Identifying risk factors

Assertions relating to users at increased risk should be based on research and evidence. Where there is uncertainty, this should be flagged. The evidence can potentially be drawn from a range of sources, including:

- Data and evidence held by non-governmental organisations, consumer groups and other organisations representing the interests of users who may be at risk.
- Experiences reported by consumers.

- Evidence and guidance from other authorities and regulators.
- Advice from organisational staff networks, such as networks that represent the interests and experiences of BAME staff, or neurodiverse staff members.
- Media reports (noting these will be focused on issues of the greatest public interest and may not represent the experiences of all people who are at increased risk).
- Any other evidence sources which shed light on increased levels of risk which some groups of people may experience.

Linking to the risk assessment

When undertaking risk assessment of products aimed at the general population (rather than particular groups) balanced consideration needs to be given to the risks to the majority and to the higher levels of risk to which some people may be exposed. For products in general use that involve a fire risk, (i.e. the building fire scenario above), the risk assessment would focus on the risk to the general population. However, the assessment narrative should consider whether such products might present an increased risk for certain people. Where a product is targeted at users who would be at increased risk, the risk assessment should focus on those users, for example products intended for very young children, for people with disabilities, or products specifically intended for use in residential blocks.

Where people at increased risk are identified, this should be flagged within the risk evaluation. It could mean, for example, that while the overall level of risk presented to the general population by a particular hazard is low, specific corrective action may be required for the purpose of protecting those people who are at increased risk and for whom the risk is not low.

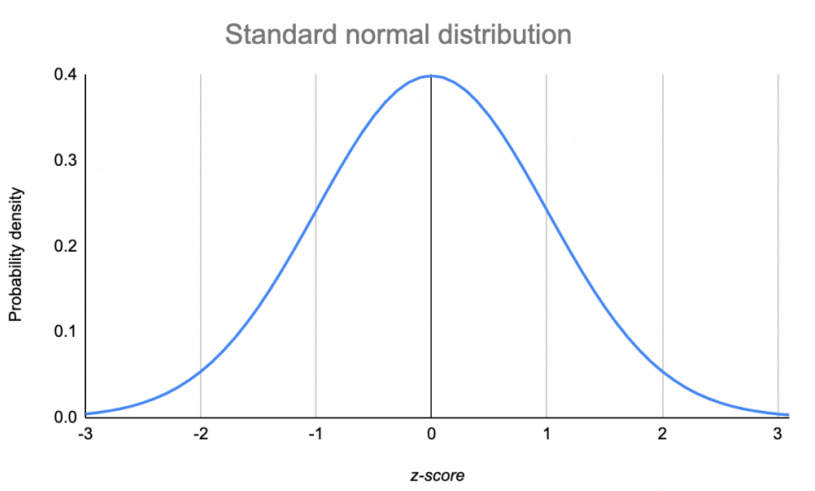
5. Testing and Product Homogeneity

Testing and product homogeneity are important risk assessment considerations that are sometimes overlooked. Hazards are often quantified by product sampling and testing, the results of which are detailed in a test report which provides a useful starting point to consider the probability of the hazard causing harm/s.

However, single test results do not always indicate or quantify hazards comprehensively. All mass production (mass manufacturing) systems have controls on inputs, processes, and outputs to ensure consistency of the finished product. It is important to consider the impact the variability of these controls has on that consistency to ensure manufactured products will be the same as other products produced in any given batch.

Taking the standard distribution (bell) curve shown below, it is highly likely (but not guaranteed) that if a random product drawn from the population of products of that type is tested, it will be at the '0' point (or close to the '0' point) on the x axis (the mean, median and mode of the distribution) as this represents the largest number of products available.

Figure 4: Standard normal distribution curve



Also, outliers would be expected that fall in both directions either side of the '0' point on the x-axis but within the confines of the bell curve.

This variation is typical and is caused by the variability of multiple factors in production, for example:

- Sourcing of parts and materials
- Production processes
- The dexterity and skill of production line operatives
- Environmental conditions
- Calibration of production line equipment
- Workload
- Etc.

These variations should be kept “in control” by the quality management system operated by the manufacturer, for example by following the ISO 9000 series standards (note: the ISO 9000 standards are not usually mandatory and therefore other quality management systems may be employed). The degree to which the quality management system is “in control” will determine the amount of product attributes either side of the ‘0’ point and the spread of these attributes. Lower levels of control will result in a flatter curve and a larger proportion of product either side of the ‘0’ point. Essentially, effective control of production is required to ensure that what is produced is consistent with the design and production parameters.

The expected “norm” should be set out and described in the conformity assessment documentation for the product/s and it is important that any variations that produce data points outside of the expected “norm”, i.e., outside of the bell curve, are considered during the risk assessment process as they are a potential cause for concern.

A good example is the tensile strength test for toys as described in EN 71-1 (*Safety of toys, Part 1: Mechanical and physical properties*). If the following data set was obtained:

Test no.	Sample no.	Tensile test results (N)[61]	Limit (N)
1	1	83	90
2	2	80	90
3	3	78	90

These test results and the variability can be considered the ‘norm’ and as such are representative of the entire batch of products. In this case, the results indicate a failure, because every product in a production batch should meet (at least) the 90N pull test. Thus the actual specification would need to be higher (than 90N) to ensure that this minimum is met when all the variations described above are considered.

If further tests were conducted and additional data points obtained:

Test no.	Sample no.	Tensile test results (N)	Limit (N)
1	1	83	90
2	2	80	90
3	3	78	90
4	4	45	90
5	5	126	90

[61] Newton, absolute unit of force in the International System of Units (SI units), abbreviated N. It is defined as that force necessary to provide a mass of one kilogram with an acceleration of one metre per second per second.

These additional data points are outside of the expected ‘norm’ and suggest that the manufacturer’s processes are out of control.

It is important to note that numerical test data is required to assist in these considerations. Test results are often reported as a “pass” or “fail” without necessarily indicating the failure rate. It is also conceivable that testing may be performed on a single sample only and not on multiple samples as in the example considered above.

A commonly used example of this variability is given below:

A manufacturer’s products rely on a gluing process. The glue is tested, verified, and validated and if used correctly, the secured parts are adequately fixed resulting in safe products being produced. However, complaints were received about hazards arising from small parts becoming detached. An investigation concluded that one batch was affected, and these were produced over several days where the ambient temperature had dropped in the factory due to extreme cold weather outside. It transpired that temperature was a critical part of the gluing process and that low temperatures adversely affected that process.

This example demonstrates how easily production processes can go out of control and how single test results do not always identify problems.

If products with test results outside of the expected norm are present within a batch, and these products are not readily identifiable, then that variability must be considered for the whole batch in terms of the risk assessment (and going forward the risk management action required). This is quite different from hazards arising from the design or specification of the product.

Considerations for risk assessors

1. Products should not be assumed to be homogeneous across all production in all cases unless there is adequate documentation / evidence to demonstrate homogeneity is being achieved (the scale and significance of any differences will depend upon how effective the manufacturer is at change management and production control).
2. The parameters of the conformity assessment documentation should be considered as part of the risk assessment documentation for the product. This will provide the assessor with an understanding of the adequacy of the production controls the manufacturer has in place and therefore the likely spread of the characteristics of the hazard.
3. Consideration should be given to increasing the probability of harm to allow for exceptional outliers. For example, a marginal failure within the expected norm that results in a low or medium level of risk may have to be re-considered as a significant failure resulting in a high or serious risk for the entire batch, if those test results exist outside the expected norm/s. The exception here is if the manufacturer can adequately demonstrate why that should not be the case. The potential for harm depends on how many products are out of specification and how serious the deviations are.

4. This variability can occur across all product types, for example creepage (the distance between conductive parts measured along the surface of an insulating material) and clearance (distance between conductive parts measured through air) on electrical products, flammability testing for combustible products, etc.
5. The risk assessor should always explain and document their rationale and associated decisions in the narrative accompanying the risk assessment.

6. Relative Risk

The outcome of a product risk assessment undertaken by MSAs is generally expressed in terms of an absolute level of risk[62]. This can be defined as the risk presented by one or more of the product's hazards over the lifetime of the product. The steps to harm are a conjunctive sequence of plausible events that once set in motion can result in harm.

Harm can occur in circumstances where a protective product fails to provide the expected level of protection. Sometimes the protection is required only after an unexpected initiating event has occurred, such as the protection provided by a carbon monoxide detector after a carbon monoxide leak from a domestic boiler, by a child's car seat in the event of a car accident, and by safety shoes in the event of a heavy object dropping onto a person's foot.

When assessing the risk presented by defects in such products, the assessor has to decide the point at which to start the harm scenario, and essentially there are two options: either before or after the initiating event. Clearly, a harm scenario that includes the likelihood of the initiating event happening within the steps to harm will produce a lower level of risk that one which starts from the point of the initiating event having taken place. The approach to risk assessment set out in Part 1 of this document would involve taking the former approach, however it is relevant that (as explained in Part 1, section 3 'Factors relating to perception and tolerability of the risk') the public in general has a low tolerability of defects in protective products[63]. It should be noted that certain types of protective products provide their protection regularly or constantly, rather than following an unexpected initiating event, such as cricket pads, hearing protection from loud noise, respiratory protection worn in dusty environments, climbing harnesses, etc. The risk presented by defects in such products can usually be assessed in the same way as the generality of products, i.e. by assessing the absolute risk.

Defects in products whose protective qualities are only required following an unexpected event can nevertheless have serious consequences if the event occurs. Accordingly, because of the low tolerability of such incidents, it can be useful and insightful for assessors to consider the 'relative risk' presented by such products as well as the absolute risk. Two examples are given below; the first relates to a defective smoke detector, and the second to a defective child car seat. For both, a precise set of circumstances need to occur first before the products' protective qualities are required:

- A working smoke detector reduces the likelihood of the occupants of a dwelling being unaware of a fire. If a fire started while the occupants were out or able to detect the fire through other means, the defective smoke detector may have limited or no consequence.

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62 For examples of different impacts of using relative and absolute expressions of risk see Stone, E. R., Yates, J. F., & Parker, A. M. (1994). Risk communication: Absolute versus relative expressions of low-probability risks. *Organizational Behavior and Human Decision Processes*, *60*(3), 387-408

63 The work here shows that where products are marketed as increasing safety the consumer shows greater concern and likely to take stronger punitive actions compared to the same products marketed to increase efficiency. Therefore, the function of the product and how it is marketed is an important determination of consumer tolerance of risk, if the product is then found to be faulty.
See: https://www.gov.uk/government/publications/public-perceptions-of-smart-products-summary-report

- Children’s car seats are designed to protect against certain impacts. A minor impact would probably mean the protective qualities of the car-seat would not be required, and at the other extreme a very severe impact might render the seat’s protective qualities irrelevant.

In both examples the risk assessor should set out a harm scenario in the normal way, factoring in the probability of the initiating event taking place. It is likely (but not inevitable) that this will produce a low level of risk. This will nevertheless be the risk associated with the product. However for the purposes of risk evaluation and tolerability, further insight can be gained by repeating the assessment on the basis of relative risk, i.e. with the harm scenario starting from the point that the fire (example 1) or accident (example 2) has occurred. The higher the resulting level of risk, the more likely it is that the risk will be intolerable.

Both harm scenarios (absolute risk and relative risk), and the corresponding risk outcomes for each, should be presented in the overall assessment. Essentially, the risk assessment will then be transparent in acknowledging a lower absolute risk, but potentially with a basis for risk management action according to the relative risk.

Using relative risk is an option available to assessors as a tool to best inform the question of tolerability. It is not a default approach for assessing certain product categories and should be justified when applied. When it is applied, the relative risk should always be presented alongside the absolute risk.

7. A Summary of the Factors That Influence How Risks are Perceived

Of the many factors that influence the perception of risk, two that are critical are:

a. familiarity with the hazard, with more direct experience raising the perception of risk beyond what the objective value might be; and

b. the extent to which the hazard is considered controllable, where the more uncontrollable it is the more "dreaded" it is perceived to be beyond what the objective value might be.

Considerable work has been carried out in behavioural sciences research to examine the types of factors that inform the way risk assessors carry out assessments, the psychological pitfalls they face (e.g. biases) and how they depart from the kind of biases that lay people recruit when they interpret the risks they face[64]. In this regard, the work shows that representing risk information in the form of point estimates in combination with verbal expressions (e.g. low risk, 10%) leads to less biased perceptions and more accurate interpretations of risk, than verbal expressions alone[65].

Perceptions of risk are dynamic because they are socially and culturally informed. This also means that at a public level the perceptions of risks associated with hazards historically change over time[66]. The typical stages of public risk perceptions start with a novel hazard which is judged as highly dreaded. During this stage public perceptions of the risk presented by the hazard are liable to amplification (e.g. via news media, social media, word of mouth)[67]. In the latter stages when the public has developed experience of the hazard over time, and scientific knowledge has increased, the perceptions of risk reduce and the hazard is perceived as tolerable, to a point in time where the population remains mindful of the perceived risk rather than being alarmed by it. Moreover, other factors that inform risk perceptions are causal factors, where people relate their understanding of risk to the causes that might bring them about. For this reason, new approaches to understanding expert and lay perceptions of risk have been proposed, that take into account the causal attributions that people use to interpret levels of risk[68].

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8. Applying the Precautionary Principle[69]

The precautionary principle provides a basis for undertaking risk management action in circumstances where there is uncertainty in the evidence currently available concerning the nature of a risk (which could be because, for example, evidence is lacking or contradictory, and so no obvious consensus in the findings can be determined), but there is reason to believe that any harm caused could be significant. A risk management plan could therefore be implemented in advance of the risk being fully understood and assessed. Thus, to evoke the precautionary principle, the test is twofold:

1. There is significant uncertainty on the extent of the risk posed which cannot be resolved within a reasonable timescale; and
2. If realised, the harm caused could be significant.

The principle's origin lies within risks relating to environmental harms where, for example, a failure to act may result in significant harm such as the entire loss of a key species or areas of inhabited land becoming uninhabitable. It was described as "when an activity raises threats of harm to environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically"[70].

The precautionary principle is not intended for scenarios where the extent of the risk is understandable but not yet understood by the risk assessor, i.e. if evidence relating to the nature of the risk exists, the assessor must obtain and review it before seeking to rely on the principle. For example, relying on the precautionary principle in relation to a product with a choking hazard where there is some uncertainty around the likelihood of the child mouthing the product is unlikely to be justifiable, because the probabilities could be established with the input of relevant expertise. Because evoking the precautionary principle can itself create risk, such as preventing a potentially beneficial product from coming to market, it must be deployed with caution and only after careful consideration of the available evidence.

Where it is believed that the precautionary principle may be applicable, the following is advised:

- Capture as much information that can reasonably be gathered to understand the risk and why the precautionary principle is applicable.
- Identify the regulated entity.
- Alert OPSS early. OPSS can provide risk assessment support and subject matter technical assistance, and can assist in identifying relevant stakeholders and affected regulated entities.

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69 See definition in Part 1, section 1.3

70 Bergen Ministerial Conference on Sustainable Development as cited in Tickner, J. (1998). The precautionary principle: A framework for sustainable business decision-making. Corporate Environmental Strategy, 5(4), 75–82.

9. Psychological Harm

Product safety risk assessments typically focus on physical harm to people, including both injuries and ill health. However, product-related incidents can also impact on a person's mental health, for example as a result of the trauma experienced following an injury. This is often referred to as psychological harm.

Psychological harm can also occur in other circumstances, for example:

- Where a person has come close to suffering severe physical harm, for example after escaping from a burning house.
- After witnessing severe physical harm occurring to another person, which might include having to assist or treat the injured person, such as dealing with a child choking on an inhaled small object.
- As a result of the severe damage and associated disruption that can occur following a house fire, which might also include the death of a family pet.

When undertaking a risk assessment, the assessor should consider the potential for psychological harm. Where such potential exists, and could be significant, this should be noted as part of the risk evaluation. Reported incidents, data relating to comparable products / hazards, information and guidance relating to mental health conditions, and the expected user and whether this might include people at increased risk are all relevant factors in determining the potential for psychological harm.

Office for Product Safety and Standards
Department for Business, Energy and Industrial Strategy
4th Floor, Cannon House, 18 The Priory Queensway, Birmingham B4 6BS