

Risk Assessment Guidelines for non-food Consumer Products

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1. INTRODUCTION

Consumer products may cause harm when used, such as a hot flat-iron that causes burns, scissors or knives that cause cuts, or a household cleaner that aggresses the skin. In most cases, such damage does not occur because general knowledge or appropriate use instructions teach how to use consumer products safely. Nevertheless, a risk of damage remains.

Such risk can be assessed in different ways. A range of methods have been used to quantify it for consumer products, such as a nomograph method¹, a matrix method², and the method recommended for the RAPEX rapid alert system of the EU³. While the general principles for risk assessment have always been agreeable, the details on how to quantify risks have been under permanent development. This has led to diverging results and ensuing discussions, as well as considerations on what the best possible practice could be.

The purpose of these Guidelines is therefore to improve the situation and to provide, within the framework of the Directive on General Product Safety⁴, a transparent and practicable method for Member State competent authorities when they assess the risks of non-food consumer products. The Guidelines are based on a risk assessment method developed for other purposes⁵, adapted thoroughly with relevant expertise to the specific requirements of non-food consumer product risk assessment.

Of course some training is needed before the Guidelines can be applied successfully, and expertise in risk assessment will greatly facilitate the task. This will be supported by discussions amongst risk assessors and the fruitful exchange of views, since expertise and experience accumulated through the years is invaluable.

By building up a risk assessment in small, manageable and clearly separated steps, these Guidelines help to focus the attention on the relevant issues of each product, its user(s) and its use(s), and to identify possible divergences of views between risk assessors from the onset, thus avoiding time consuming discussions. The Guidelines should thus lead to consistent and robust risk assessment results based on evidence and science, and

¹ Benis H (1990): A Product Risk Assessment Nomograph, report prepared for the New Zealand Ministry of Consumer Affairs, dated February 1990; Cited in: European Commission (2005) Establishing a Comparative Inventory of Approaches and Methods Used by Enforcement Authorities for the Assessment of the Safety of Consumer Products Covered by Directive 2001/95/EC on General Product Safety and Identification of Best Practices. Report prepared by Risk & Policy Analysts (RPA), Loddon, Norfolk, UK.

² Method used by Belgian authorities. Cited in: European Commission (2005) Establishing a Comparative Inventory of Approaches and Methods Used by Enforcement Authorities for the Assessment of the Safety of Consumer Products Covered by Directive 2001/95/EC on General Product Safety and Identification of Best Practices. Report prepared by Risk & Policy Analysts (RPA), Loddon, Norfolk, UK.

³ Commission Decision 2004/418/EC of 29 April 2004 laying down guidelines for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC. OJ L 208, 10.6.2004, p. 73.

⁴ Directive 2001/95/EC on General Product Safety, OJ L 11, 15.1.2002, p. 4.

⁵ Kinney G, Wiruth AD (1976) Practical risk analysis for safety management. Naval Weapons Center, California, June 1976.

consequently to widely acceptable consensus on the risks that the manifold non-food consumer products may present.

A quick overview and a flow-chart on how to prepare a risk assessment according to these Guidelines is provided in section 5. – "Consumer products" will always mean non-food consumer products throughout these Guidelines.

2. RISK ASSESSMENT - AN OVERVIEW

2.1. Risk – the combination of hazard and probability

Risk is generally understood as something that threatens health or even the lives of people, or that may cause considerable material damage. Nevertheless, people take risks while being aware of the possible damage, because the damage does not always happen. For example:

- Climbing on a ladder always includes the possibility to fall down and be injured. "Falling down" is therefore "built into the ladder", it is intrinsic to the use of the ladder and cannot be excluded. "Falling down" is thus called the intrinsic hazard of the ladder.

This hazard, however, does not always come into effect, since many people climb on ladders and do not fall down, but climb down without being injured. This suggests that there is a certain likelihood (or probability), but no certainty, that the intrinsic hazard comes into effect. Whereas the hazard always exists, the probability can be minimised for example by a prudent behaviour of the person climbing on the ladder;

- Using a household cleaner with sodium hydroxide to free blocked sewage water pipes always bears the possibility of very severe damage of the skin, if the product comes into contact with skin, or even of permanent blindness if drops of the product get into the eye. This is because sodium hydroxide is very corrosive, thus the cleaner is intrinsically hazardous.

Nevertheless, when the cleaner is handled properly, the hazard does not come into effect. Proper handling may include wearing plastic gloves and protective glasses. Skin and eyes are then well protected, and the probability of damage is much reduced.

Risk is thus the combination of the severity of the possible damage to the consumer and the probability that this damage occurs.

To determine the risk, three steps are necessary:

1. Identify the hazard that is intrinsic to the product, and determine how serious it is.

In consumer product risk assessment a yardstick for measuring the hazard is the adverse effect that it can cause to the health of a consumer. It is therefore necessary to consider how the intrinsic hazard of the product can inflict on the consumer's health, namely by describing the different steps that lead to an injury of the consumer. This description is called "injury scenario" (see table 1). In short, the injury scenario describes the accident that the consumer has with the affected product, and the consumer's injury caused by the accident.

An injury can be more or less severe, depending on the hazard of the product, on the way it is used by the consumer, on the type of consumer who uses the product, and many more. The more severe the injury, the more severe is the hazard that caused it, and vice-versa. The "severity of injury" is therefore a means to quantify the hazard in a risk assessment. These Guidelines propose 4 levels of severity, from injuries that are normally completely reversible to very heavy injuries that cause more than about 10% of permanent disability or even death (see table 3).

Note that a single hazard may lead to several injuries in the same scenario. For example, the malfunctioning brakes of a motor cycle could cause an accident with damage to the driver's head, hands and legs, and could cause burns because the petrol could ignite in the accident. In such case, all injuries would belong to the same injury scenario, and the severity of all injuries together would have to be estimated. Of course, these injuries together are very serious;

2. Determine the probability to which the consumer is in practice injured by the intrinsic product hazard.

While the injury scenario describes how the consumer is injured by the hazard, such scenario only happens with a certain probability. The probability can be expressed in terms such as "Almost certain, might well be expected", or "Only remotely possible", and fraction numbers can be attributed to them, such as "> 50 %" or "> 1/1,000", respectively (see table 4).

3. Combine the hazard (in terms of the severity of injury) with the probability (in terms of fraction numbers) to obtain the risk.

Such combination can be made by looking up both values in a suitable table (see table 5), and the table will provide the level of risk in terms of "serious", "high", "significant" and "low" risk.

Note that, when different injury scenarios are reasonably foreseeable, the risk for each of those scenarios should be determined, in order to identify the highest risk as "the risk" of the product. The highest risk is normally decisive because only action on the highest risk can effectively provide a high level of protection.

On the other hand, one of the risks identified may be lower than the highest risk, but require specific risk reduction action. It is then important that also measures against such risk be taken, in order that all risks are effectively reduced.

With this, the risk assessment is basically done.

2.2. Seek information

As can be seen in the above examples, each of the above steps of a risk assessment requires experience of what might happen, since the product under consideration will normally not have caused an accident, and thus the risk will not have materialised (yet). Previous experience with similar products will help in this exercise, as will any other information about the product, such as its construction, its mechanical stability, its chemical composition, its operation, its use instructions, the type of consumers it is intended for (and those for which it is not), test reports, accident statistics, the EU Injury

Data Base (IDB)⁶, information about consumer complaints, about the behaviour of different consumers when they are using the product, and about product recalls. Also product requirements laid down in legislation, in product standards or in checklists such as in ISO 14121 (EN 1050) can be useful sources of information.

Nevertheless, the products to be assessed may be quite specific so that all these sources do not contain the information required. Information collected may also be incomplete, inconsistent, or not fully plausible. This may in particular be the case for accident statistics, when only the product category is registered. Also product-specific statistics have to be considered with great care, since the product may have changed over time, be it in the details of its construction, be it in the composition of the materials it is composed of. In all cases it is very important to critically assess the information.

Particularly useful can be the feedback from expert colleagues, since they can draw from their real-life experience and provide suggestions that are not immediately evident when assessing a product risk. They may also advise to assess the risk for different types of consumers, such as adults and children (see table 2), since the latter may handle a product differently. They may further advise to assess the risk for different injuries that a product may cause, and the way in which those injuries emerge through the use of the product ("injury scenario"). They can also judge whether an injury scenario is "totally unperceived", too unlikely, and then guide the risk assessor towards more realistic assumptions.

Thus, feedback from experienced colleagues can be helpful in several aspects. A risk assessor from an authority could seek advice from colleagues in that same authority, in other authorities, in industry, in other countries, in scientific groupings, and elsewhere. Conversely, any risk assessor in industry could use his contacts to authorities and elsewhere when a new or improved product is to be assessed before it is placed on the market.

2.3. Make a sensitivity analysis of your risk assessment

If all information search and queries to expert colleagues do not provide the required, very specific data, a so-called sensitivity analysis of the risk assessment prepared could help. In such an analysis a lower and a higher value than previously chosen is assumed for each parameter of the risk assessment, and taken through the entire risk assessment procedure. The resulting risk levels will show how sensitive the risk level reacts to the input of lower and higher values. It can thus be estimated in which range the real risk of the product will be.

If the most likely value of each parameter can be estimated, then those most likely values should be taken through the procedure, and the resulting risk level will be the most likely risk.

An illustrative example for a sensitivity analysis is in section 6 further below.

2.4. Check your risk assessment

Feedback from colleagues will also help when finalising the risk assessment. They will be able to provide advice on the assumptions and estimations made during the three steps

⁶ <https://webgate.ec.europa.eu/idbpa/>

above, they will feed in their experience and thus help to generate a more robust, more solid and thus more acceptable risk assessment. It is therefore recommended that, in the ideal case, advice from expert colleagues be sought, possibly in the form of a group discussion, before concluding a risk assessment. Such group, of perhaps 3 to 5 members, should include a combination of expertise appropriate to the product under assessment: engineers, chemists, (micro-) biologists, statisticians, product safety managers, and others. Group discussion will be particularly useful when the product is new on the market, when it has never been assessed before, and in similar situations.

Risk assessments should be solid and realistic. However, since they require some assumptions, different risk assessors may come to different conclusions in view of the data and other evidence they have been able to find or in view of their diverging experience. With the step-by-step risk assessment described in these Guidelines, however, discussions amongst experts should be more productive. Each step will be clearly described and can be considered in the necessary detail. Thus, any point of disagreement can be quickly identified, and consensus can more easily be found. This will make any risk assessment more acceptable.

2.5. Several hazards, several injuries – but only one risk

When several hazards, several injury scenarios or differing severities of injuries or probabilities have been identified, each of those should be carried through the entire risk assessment procedure in order to determine the risk for each. As a result, the product may have several risk levels. The overall risk of the product is then the highest risk level identified, because action on the highest risk level is normally the most effective way of risk reduction. Only in special cases a less-than-highest risk may be considered particularly important since it may require specific risk management measures.

As an example for several risks, a hammer may have a weak head and a weak grip, each of which may break when the hammer is used, and the consumer may be injured. If the relevant scenarios lead to different risk levels, the highest risk is should be reported as "the risk" of the hammer.

It may be argued that

- the apparently most important hazard should be decisive, since it would lead to the most severe injuries. In the above example of the hammer, this could be the breach of the hammer head, since pieces of the broken head could be catapulted into the eye and eventually lead to blindness. On the other hand, a breach of the hammer grip could never provide small pieces that would hit the eye as seriously.

However, this would be a hazard assessment, not a risk assessment. A risk assessment also requires consideration of the probability of an injury to happen. Thus, the "most important hazard" may lead to an injury that is much less likely than a less important hazard, and end up in a lower risk. Conversely, an injury scenario leading to a less severe injury may be much more likely than an injury scenario ending up in death, and the less severe injury may therefore result in a higher risk;

- the highest probability for an injury scenario to happen should be decisive for "the risk" of the product. In the above example of the hammer, if the hammer grip is very weak, the breach of the grip would be the most likely injury scenario, and should therefore be decisive.

However, this would not consider the seriousness of eye injuries that the cracking hammer head could cause. The evaluation of the probability alone would thus provide an incomplete picture.

In conclusion, risk is a balanced combination of both the hazard and the probability of the injury that the hazard can cause. Risk describes neither the hazard, nor the probability, but both at the same time. Taking the highest risk as "the risk" of the product will allow to ensure product safety most effectively (apart from specific cases, as mentioned above).

2.6. Can risks cumulate?

For virtually every product, several injury scenarios can be developed leading to several risks. For example, an angle grinder may present a risk of electric shock, because electric wires may be too easily accessible, and a risk of fire, because during normal use the machine may overheat and ignite. If both risks are considered "moderate", do they add up to an overall "serious risk" of the grinder?

If different independent injury scenarios for a product lead to the same severity level, it is more likely that any of the corresponding risks materialises and causes an injury. The overall likelihood of an injury is therefore increased. For the following reasons, this does not mean however, that the overall risk is automatically higher.

- Calculation of the resulting overall probability is not done by simply adding up probabilities. More complex calculations are necessary. These calculations always result in a probability that is lower than the sum of all probabilities;
- There is a factor 10 of difference between two succeeding probability levels (tables 4 and 5). This means that a lot of different scenarios of the same level would be needed to result in a higher overall probability (and possibly risk) level;
- Probability values are estimations which may not be too precise, they are often set at the "safe" side in order to ensure a high level of protection. It is therefore more useful to look for a more precise estimation of the probability of the scenario leading to the highest risk, than to add up rough estimations of probabilities of all sorts of scenarios;
- With some effort hundreds of injury scenarios could be developed. If risks were simply added, the overall risk would depend on the number of the injury scenarios generated and could increase "endlessly". This does not make sense.

Note that risk assessment is complete when the level of risk has been identified. The follow-up to risk assessment, namely risk management action to reduce or eliminate the risk, is separate. If more than one relevant risk exists, action to manage the risks could be taken more rapidly or could be more pronounced. For example, with two risks, a product may need to be immediately taken off the market and recalled from consumers, whereas with a single risk, halting sales could be sufficient.

Risk management depends on many factors, not only on the number of risks that a product may have concurrently. Therefore, some considerations are given further below about the way from risk to risk management action.

2.7. Compliance with limit values in legislation or in standards

In the practice of market surveillance, consumer products are often tested against limit values laid down in legislation or in product safety standards. If the product complies with the limit value(s) or safety standard(s), it is presumed to be safe (of course only for the safety characteristics covered by the value(s) or standard(s)). This assumption can be made because the risks of a product from intended and reasonably foreseeable use are taken into account when establishing the limit value(s) or standard(s). It is therefore most convenient for the manufacturer to have his product comply with them, because he may then only have to take care of those risks of his product that may not be covered by the limit value(s) or standard(s).

An example for a limit value in

- legislation is the limit of 5 mg/kg benzene in toys which must not be exceeded according to the Directive on restrictions of the marketing and use of certain dangerous substances and preparations⁷;
- a standard is the small parts cylinder: Small parts from a toy have to fit entirely into the cylinder described in the Toys Standard⁸.

If the product does not comply with established limit values, it is not presumed to be safe. For limit values laid down in

- legislation such as on cosmetics or restrictions of marketing and use, the product must then not be made available on the market;
- standards, the manufacturer may nevertheless try to provide the evidence that his product is as safe as if it were compliant with the standard(s)/limit value(s), by providing a fully fledged risk assessment on his specific product. However, this may require more efforts than to manufacture the product in compliance with the limit value(s) or standard(s).

In any case, non-compliance with limit values does not automatically mean that the product presents a "serious risk" (which is the highest risk level offered by these Guidelines). Therefore a risk assessment will be required for those elements of a product that do not comply with or are not covered by a standard.

Furthermore, certain products such as cosmetics require a risk assessment even when they are compliant with the limit values laid down in legislation. Such risk assessment should provide evidence of safety of the whole product.

In conclusion, compliance with limit values in legislation or in standards provides the presumption of safety, but may not be sufficient.

⁷ Directive 76/769/EEC, Annex I, entry n° 5. Consolidated version of Directive 76/769/EEC, CELEX document number 01976L0769-20071003. http://eur-lex.europa.eu/RECH_celex.do.

⁸ Standard EN 71-1:2005, section 8.2.

3. BUILDING A RISK ASSESSMENT STEP BY STEP

This section describes in detail which considerations have to be made and which questions have to be asked when preparing a risk assessment.

3.1. The product

The product should be identified unambiguously. This includes the product name, the brand, the model name, a possible production lot number, and the country of origin. A picture of the product, the packaging and the marking plate (if appropriate) and a test report(s) identifying the product hazard(s) can also be considered parts of the product description.

In particular cases, the hazard may be limited to a distinct part of the product, which can be separated from it and which is also separately available to consumers. In such case it is sufficient to only assess the distinct part of the product. An example are rechargeable batteries of notebook computers which may overheat.

The description of the product includes any label that may be relevant for risk assessment, in particular warning labels. Also the instructions for use may contain relevant information on the risk of the product and how to keep it as low as possible, for example by use of personal protective equipment or by excluding children from using the product. An example for this is a chain saw.

A risk assessment should always consider the entire life time of a product. This is particularly important when a new product has been developed and its risks are assessed: Will age and usage change the type or the extent of the hazard? Will new hazards appear with increasing product age or longer usage? How long is the "time to product failure"? What is the product's lifetime? How long is the product used in practice by the consumer before it becomes waste?

Additional considerations may need to be made when a product becomes unusable after a certain time period although it has never been used. An example are electric heating blankets or pads. The electric cords in the products are usually thin and become fragile after ten years even if the product has never been used. The heating cords may then come in contact with each other and can cause a short-circuit and put the bed clothes on fire.

3.2. The product hazard

Hazard is the intrinsic property of the product that may cause an injury to the consumer who uses the product. It can appear in different forms:

- mechanical hazard, such as sharp edges that may cut fingers, or reduced openings that may squeeze fingers;
- choking hazard, such as from small parts that come loose from a toy;
- suffocation hazard, such as from strangulation with the drawstrings of an anorak's hood;
- electrical hazard, such as from live electrical parts that may cause an electric shock;
- heat or fire hazard, such as a heater fan that overheats and catches fire;
- thermal hazard, such as the hot outer surface of an oven that might cause a burn;

- chemical hazard, such as a toxic substance that poisons a consumer immediately upon ingestion, or a carcinogenic substance that may cause cancer in the long term. Some chemicals may damage the consumer only after repeated exposure;
- microbiological hazard, for example the bacteriological contamination of cosmetics;
- noise hazard, such as ring tones from toy cellular phones that are much too loud;
- other hazards, such as explosion, implosion, sonic and ultrasonic pressure, fluid pressure, or radiation such as from laser sources.

Hazards are often identified and quantified by appropriate tests. Such tests and how to carry them out may be laid down in product standards at European or international level. Compliance of a product with a “harmonised” standard, which is a European standard (“EN ...”) of which the references have been published in the Official Journal, provides the presumption of safety (of course only for the safety characteristics covered by the value(s) or standard(s)). In such a case it can be presumed that the product presents only a minimum risk compatible with a high level of protection with regard to the specific hazard tested.

Nevertheless, there may be cases where the presumption does not hold, and in such cases a particularly well-documented risk assessment will have to be prepared, including a call for amendment of the harmonised standard.

On the other hand, if a product fails the test, a risk can normally be assumed, unless the manufacturer can provide evidence that the product is safe.

For chemicals there are specific instructions on how to prepare a risk assessment^{9,10}, therefore they will not be dealt with in detail in these Guidelines. Nevertheless, they follow the same principles as for "normal" consumer products:

- hazard identification and hazard characterisation. - This corresponds to the determination of the severity of injury mentioned above;
- exposure assessment. In this step, the exposure is expressed as the likely dose of the chemical that the consumer may take up via mouth, lungs or skin when using the product. - This corresponds to the determination of the probability that the injury will indeed occur;
- risk characterisation. This basically consists in a comparison of the dose that the consumer is likely to take up (= exposure) with the derived no-effect levels (DNELs). If the exposure is sufficiently lower than the DNEL for the leading health effect, in other words: if the risk characterisation ration (RCR) is clearly below 1, risk is adequately controlled. – This corresponds to determining the risk level. If the risk level is sufficiently low, risk management measures may not be needed.

⁹ Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006) and guidance documents on REACH, see <http://echa.europa.eu/>

¹⁰ European Chemical Agency (2008) The Guidance on Information Requirements and Chemical Safety Assessment. http://reach.jrc.it/docs/guidance_document/information_requirements_en.htm

For the purpose of these Guidelines, hazards were grouped, linked to the size, shape and surface of a product, to the potential, kinetic or electric energy, to extreme temperatures, and others, as shown in table 1. The table is for orientation, and any risk assessor should adapt it if this is more appropriate for the product under consideration.

Nevertheless, table 1 should assist and stimulate risk assessors to look for and identify any possible hazard of consumer products that are being assessed. If a product has several hazards, each hazard should be taken separately through an own risk assessment in order to identify the highest risk as "the risk" of the product. Of course risks requiring specific risk management measures should also be reported, to ensure that all risks can be appropriately reduced.

In the daily practice of market surveillance, it may be sufficient to assess the risk from even a single hazard. If the risk from that hazard provides for risk management action, that action can be taken without further ado. Nevertheless, the risk assessor should be sure that the risk identified is (one of) the highest risk(s), in order that the risk management action is sufficiently effective. This is always the case when the risk is serious, since this is the highest possible risk level proposed in these Guidelines. In cases of less than serious risk, however, further risk assessments might be necessary, and perhaps specific risk management action later on. In conclusion, experience with risk assessment in market surveillance practice will limit the number of required risk assessments to a minimum.

Products may still present a risk although they do not cause injuries

Products may not be hazardous but can nevertheless cause a risk. Examples for this can be observed in the area of personal protective equipment or life saving equipment, for example warning waistcoats that car drivers put on after an accident. Such waistcoats should raise the attention of the following drivers and traffic participants and warn them of the accident, in particular at night. However, when the coat's reflector stripes are too small or do not reflect sufficiently, recognition is not ensured, and they do not protect users as they should. Such a waistcoat poses a risk although it is not hazardous by itself.

3.3. The consumer

The abilities and behaviour of the consumer using the product may strongly influence the level of risk. It is therefore of prime importance to have a clear view on the type of consumer who is included in the injury scenario.

It may be necessary to generate injury scenarios with different types of consumers in order to identify the highest risk as "the risk" of the product. It would not be sufficient, for example, to consider only the most vulnerable consumer, because the probability of him suffering adverse effects in the scenario may be so low that the risk is lower than in an injury scenario with a non-vulnerable consumer.

Consideration should also be given to people who are not actually using the product, but who may be affected by the vicinity of the user. For example, a chain saw may cause splinters flying around and seriously hitting the eye of a bystander. Thus, although the risk from the chain saw may be appropriately managed by the user him- or herself wearing protective equipment, bystanders may be under serious threat. Consequently, warnings should be given, for example in the chain saw's use instructions, that protective equipment against flying splinters is necessary also in the vicinity of the use.

The following aspects should be considered, with "consumer" also meaning people who are not actually using the product, but being possibly affected when being nearby:

- **Intended/non-intended user:** The intended user of a product may use the product without difficulties because he takes all instructions of use well into account, or because he has used the kind of product since long and is therefore familiar with its handling and use, including any apparent or non-apparent hazard(s). The hazard of the product may then not come into effect, and the product risk could be minor.

The non-intended user may not be familiar with the product and may not recognise any hazard(s). He may therefore be injured by the hazard, he is therefore a consumer for whom the product risk is higher.

Thus, the effect of an intended or non-intended user on the risk may differ according to the product and the way it is used;

- **Vulnerable consumers:** Several categories of vulnerable consumers can be distinguished: Children (0 to 36 months, >36 months to <8 years, 8 to 14 years), vulnerable people and very vulnerable people (see table 2). They all have reduced capacities to recognise a hazard, for example children who, when touching a hot surface, notice the heat only after some 8 seconds (and then are already burnt), whereas adults notice heat immediately.

Vulnerable consumers may also have difficulties to take account of warning labels, or may have difficulties when using a product they have never used before. They may also exhibit specific behaviour that affects their exposure, for example crawling and mouthing of young children. Children may also run around with a product in a way that even increases the risks. Therefore a product that is normally safe for an average adult may not be safe for vulnerable consumers. This has to be taken into account when preparing a risk assessment;

- **Intended and reasonably foreseeable (mis-) use:** Consumers may use a product for other purposes than the product is intended for, although the use instructions are clearly understandable including possible warnings. Therefore, and because warnings may be of limited effectiveness, also other uses than the intended ones have to be considered within a risk assessment. This aspect is particularly important for the manufacturer of a product since he has to ensure that his product is safe under any reasonably foreseeable conditions of use.

Such reasonably foreseeable (mis-) uses may have to be assumed on the basis of experience, because there may be no information available in official accident statistics or other sources of information. Due to such assumption, it may then be difficult to draw the line between "reasonably foreseeable" and "totally unperceived" scenarios. Nevertheless, even "totally unperceived" scenarios can be considered under these Guidelines, even when leading to very severe injuries, because such scenarios will always have a very low probability. This eventually safeguards against too large an influence of such scenarios when concluding on the overall risk of the product;

- **Frequency and duration of use:** Different consumers may use a product more or less often, and for longer or shorter periods of time. This depends also on the attractiveness of the product and the ease with which it can be used. Daily or long-time use could make a consumer entirely familiar with a product and its specificities, including its hazards, its use instructions and warning labels, and the risk would be

minor. On the other hand, daily or long-time use may make the consumer feel too much accustomed to the product, and he may recklessly ignore use instructions and warning labels because he considers mastering the product entirely. This would increase the risk.

Finally, daily or long-time use may accelerate product usage, and any parts not resisting to such use may soon fail and cause a hazard, and eventually an injury to the consumer. Also this increases the risk;

- **Hazard recognition and ensuing protective behaviour and equipment:** Some products are known for their hazard, such as scissors, knives, do-it-yourself drilling machines or chain saws, roller blades, bicycles, motor bikes or cars. In all such cases, the product hazard is clearly known or easily recognisable, and the consumer can apply personal protective equipment such as gloves, helmet or seat-belt, and use the product in a way that minimises the risk.

In other cases, the product hazard may not be as easily recognisable, such as an upcoming short-circuit within an electrical flat-iron, and the consumer will only in rare cases be able to adopt a risk-reducing behaviour upfront.

- **Consumer behaviour in case of an incident:** When the hazard inflicts on the consumer it may cause him an injury. Within a risk assessment, it is then important to consider how the consumer may react. Will he put the product orderly out of action and put it aside, take appropriate risk management action such as combating a fire caused by the product, or will he throw it away in a panic to get rid of it?
- The **consumer's cultural background** and the way a product is used in his home country may influence the risk of a product. Manufacturers in particular have to take account of such cultural differences when launching a new product onto a market, in order to ensure that the product can indeed be used safely.

3.4. Injury scenario: Steps to the injury(ies) that a hazard can cause

In order to develop the injury scenario, it is important to know that most scenarios consist of the following three main steps:

1. The product presents a “defect” or leads to a “dangerous situation” during its foreseeable lifetime;
2. the “defect” or “dangerous situation” results in an accident;
3. the accident results in an injury.

These three main steps can be divided further, if necessary, in order to consider in sufficient detail how the product hazard leads to the injury or adverse effect. These "steps to injury" should nevertheless be clear and concise, without exaggerating the level of detail and thus the number of steps. With some experience, the "shortest path to injury" (or "critical path to injury") will be easily identified.

It is probably easiest to start with a scenario that considers the consumer for whom the product is intended and in which the consumer uses the product in accordance with the use instructions or, if there are none, according to normal handling and use. If such risk assessment provides the highest risk level, there is normally no need to carry out further assessments, and the appropriate risk reduction measures can be taken.

Otherwise, further scenarios could be developed which include vulnerable consumers, in particular children (see table 2), slight or more pronounced deviations from normal use, use under different climate conditions such as very cold or very hot climate, unfavourable conditions of use such as when proper daylight or illumination is missing, use as suggested by the presentation of the product during sale (for instance a lamp sold in a toy shop should also be assessed for its risk when used by a child), use over the entire life-time (thus including wear of the product), etc.: Each scenario should be carried through the entire risk assessment procedure.

From all the scenarios generated the scenario providing the highest risk (= "the risk" of the product) will normally be decisive for the risk reduction measures to be taken, because action on the highest risk reduces the risk most effectively. An exception to the rule may be a specific, less-than-highest risk which could be managed by specific measures which should, of course, also cover the highest risk.

As a rule of thumb, injury scenarios may lead to the highest risk level when

- the injury(ies) considered are at least in severity levels 4 or 3;
- the overall probability of an injury scenario is at least "unusual but possible".

Table 5 offers further orientation in this regard. This might be helpful to limit the number of scenarios.

Of course the number of injury scenarios remains the responsibility of the risk assessor, it depends on all the elements that need to be taken into account when seeking a solid conclusion on the risk. It is therefore not possible to give a firm indication on the number of injury scenarios that may be necessary.

Scenarios should normally be reasonably foreseeable, but sometimes it may be difficult to determine the boundary between "still reasonably foreseeable" scenarios and "totally unperceived" scenarios. Nevertheless, also the latter scenarios may be developed under these Guidelines, since the probability of such scenarios may be so low that the ensuing risk is comparably low. The combination with the probability thus provides for a safeguard against undue influence of "totally unperceived" scenarios.

To assist and stimulate development of appropriate scenarios these Guidelines provide a table with typical injury scenarios (table 1). These should be adapted, as appropriate, to the specific product, consumer type and other circumstances under consideration, in order to provide for the specific scenario(s) required for the risk assessment.

3.5. Severity of injury

The injury that a hazard can cause to the consumer can have different degrees of severity. The severity of injury thus reflects the effect of the hazard on the consumer under the conditions of use described in the injury scenario.

The severity of injury depends on:

- the type of the hazard (see list of hazards above and table 1). A mechanical hazard, such as sharp edges, may cause cuts in fingers which are immediately noticed, and the consumer will take action to heal these injuries. On the other hand, a chemical hazard may cause cancer. Such hazard normally passes unnoticed, and the injury may appear only after many years, and is considered to be very severe since cancer is very difficult to remedy, if at all;

- how powerful the hazard is. For example, a surface heated at 50 °C may cause slight burns, whereas a surface at 180 °C will cause severe burns;
- the duration that the hazard inflicts on the consumer. A short contact time with an abrasion hazard may scratch the consumer's skin only superficially, whereas a longer time may take off large parts of the skin;
- the body part that is injured. For example, penetration by a sharp point of the skin of the arm is painful, but penetration of an eye is a more serious and perhaps life-affecting injury;
- the impact of the hazard on one or several body parts. An electrical hazard may cause an electric shock with unconsciousness and, subsequently, a fire which may damage the lungs of the consumer when inhaling the smoke;
- the type and behaviour of the consumer. A product labelled with a warning message may well be used, without doing harm, by an adult consumer, because the consumer adapts his behaviour when using the product. On the other hand, a child or other vulnerable consumer (see table 2) unable to read or understand the warning label may be injured very seriously.

To quantify the severity of injury(ies) identified in the injury scenario, these Guidelines provide table 3 as an orientation on how to classify injuries into four categories, depending on the reversibility of an injury, respectively whether recovery from an injury is possible and to which extent. Of course this categorisation is indicative, and a risk assessor should change category if this is more appropriate.

If several injury scenarios are considered for the risk assessment, the severity of each injury should be classified separately, and taken through to the entire risk assessment process.

An example: A consumer uses a hammer to knock a nail into the wall. Since the hammer head is too weak (due to inappropriate material), it breaks, and one of the pieces flying around hits the eye of the consumer so vigorously that it causes blindness. The injury is thus “Eye injury, foreign body in eye: Permanent loss of sight (one eye)”, which is a level 3 injury according to table 3.

3.6. Probability of injury

The probability of injury is the second core parameter which determines the risk, together with the severity of injury. It is the probability that an injury scenario may indeed take place during the expected lifetime of the product.

Such probability is relatively easy to calculate when a scenario is described in distinct steps. Each step is given the appropriate probability, and the multiplication of these partial probabilities gives the overall probability of the scenario. If several scenarios have been developed, each scenario requires its own overall probability.

These Guidelines distinguish between 8 levels of probability: From “(Virtually) Impossible (<1/1,000,000)” to “Almost certain, might well be expected (>50%)” (see table 4). The following example of a hammer head that breaks when the user knocks on a nail should illustrate how to assign levels of probability to the different steps of an injury scenario:

- Step 1: The hammer head breaks when the user tries to knock a nail into the wall, because the material of the hammer head is too weak. The weakness was determined in a test, and with the reported weakness it is estimated that the probability for the hammer head to break during lifetime is 1/10;
- Step 2: One of the pieces of the breaking hammer hits the user. The probability for this is estimated as 1/10, since the surface that the user's upper body part offers to the pieces flying around is considered to be 1/10 in relation to the half-sphere in front of the wall. Of course, if the user were standing very close to the wall, his body would take a larger share of the half-sphere, and the probability would be higher;
- Step 3: The piece hits the head of the user. The head is roughly estimated to be about 1/3 of the upper body part, the probability is therefore 1/3;
- Step 4: The piece hits an eye of the user. The eyes are considered to be about 1/20 of the head's surface offered to the piece flying around, therefore the probability is 1/20.

Multiplying the probabilities of the above steps provides an overall probability for the scenario of $1/10 * 1/10 * 1/3 * 1/20 = 1/6,000$. This translates into "Conceivable, but highly unlikely" according to table 4.

When the overall probability has been calculated for an injury scenario, it should be checked for plausibility. This check requires quite some experience, and the assistance of persons experienced in risk assessment is suggested (see higher above in section "Check your risk assessment"). Furthermore, with ongoing experience with these Guidelines the estimation of probabilities should become easier, and an increasing number of examples will become available to facilitate such task.

Assigning probabilities to different injury scenarios for the same product may lead to the following:

- When the product is used by more vulnerable consumers, the probability may in general have to be raised because more vulnerable consumers may be damaged more easily. This applies in particular to children, since children do not normally have the experience that could induce a risk-reducing behaviour, on the contrary their behaviour could even increase risks (see also "Vulnerable consumers" in section 3.3);
- When the risk is easily recognisable, including by warning labels, the probability may have to be lowered because the user will use the product more carefully in order to avoid an injury as far as possible. Of course this may not be applicable to an injury scenario with a young child or other vulnerable user (see table 2) who cannot read, or a scenario with a consumer who uses the product for the first time;
- When accidents have been reported that fit into the injury scenario, the probability for that scenario could be increased. In cases where accidents have only rarely be reported, or are not known at all, it may be useful to ask the manufacturer of the product whether he is aware of any accident or adverse effect caused by the product;
- When a larger number of conditions is necessary for the injury to occur, the overall probability of the scenario would normally be lower;

- When the conditions necessary for the injury to occur are easily met, this may increase the probability of the scenario;
- When the test results of the product show a large difference to the limit values required (by the relevant standard or legislation), the probability for the injury (scenario) to occur or the severity of injury may be higher than if the product performed close to the limit values.

3.7. Determination of the risk

When the severity of injury and the probability have been thoroughly determined, possibly for several injury scenarios, the risk level just needs to be looked up in table 5. Table 5 combines both the severity of injury and the probability, and eventually the highest risk is "the risk" of the product. Of course risks requiring specific risk management measures should also be reported, to ensure that all risks are appropriately reduced.

These Guidelines distinguish between 4 levels of risk: Serious, high, significant, low. Note that, between neighbouring severities of injury or probabilities, the risk level normally changes by 1 level. This is consistent with the general experience that risk does not increase incrementally when input factors change gradually. However, where the severity of injury decreases from level 2 to level 1 (at the right hand side of the table 5), some changes comprise 2 levels, namely from serious to significant risk and from high to low risk. This is due to the fact that these Guidelines include 4 graduations of severity of injury, whereas the original method (see Introduction) included 5. Nevertheless, 4 graduations are considered appropriate for consumer products, since they allow for a sufficiently robust estimation of severity; 5 levels would be too sophisticated since neither the severity of injury nor the probability can be determined with very high precision.

At the end of the risk assessment, be it for an individual injury scenario, be it for the overall risk of the product, the plausibility of the risk level and the uncertainties in the estimates should be considered.

In this regard, a sensitivity analysis can be very valuable: How does the risk level change when the severity of injury or the probability are changed by 1 level? If the risk level does not change at all, it is quite plausible that it has been appropriately estimated. If it changes, however, the risk level may be considered borderline. It is then necessary to reconsider the injury scenarios and the assigned severity of injury(ies) and of probabilities. At the end of the sensitivity analysis the risk assessor should be confident that, in view of all efforts made, the risk level is sufficiently plausible, and that he can communicate it further on.

4. FROM RISK TO ACTION

Once the risk assessment is complete, it will normally be used to decide whether measures or action are necessary to reduce the risk and thus avoid harm to consumer's health. Although such action(s) is separate from risk assessment, some considerations will be given here to illustrate the possible follow-up of identified risks.

With a serious risk in a consumer product, appropriate measures to reduce the risk may include withdrawal from the market or recall from consumers. Lower levels of risk

normally lead to less rigorous measures. It may then be sufficient to add warning labels on the product or to improve the use instructions to make the product safe. Nevertheless, when the product shows several less-than-serious risks, and its overall risk is thus not serious, urgent action may be necessary since any of the risks may materialise quite swiftly. Moreover, the pattern of risks in the product may indicate a lack of quality control in production.

For the timing and strictness of risk management measures it is also important to take into account the exposure of the population as a whole. If a product is used by a large number of consumers, even a less-than-serious risk may require quick action to avoid adverse effects on the health of those consumers.

Less-than-serious risks may also require action when the concerned product could cause fatal accidents, although such accidents may be extremely unlikely. This could be the case for a specific closure of milk packs which, when coming loose, could be swallowed by a child and lead to death through choking. A simple change of design of the lid could avoid the risk, and no further action might be required. Even a selling-off period may be conceded if the risk of a fatal accident were indeed extremely small.

Other aspects when acting on risk may be the public perception of the risk and its likely consequences, cultural and political sensitivities and its representation in the media. These aspects may be especially relevant when the concerned consumers are vulnerable, in particular children. It will then be up to the national market surveillance authority(ies) to determine which measures are appropriate.

Taking action on a risk may also depend on the product itself and the "minimum risk compatible with the product's use, considered to be acceptable and consistent with a high level of protection".¹¹ Such minimum risk will probably be much lower for the use of a toy, where children are involved, than for the use of a chain-saw, which is known to cause risks so high that solid protective equipment is required to keep the risk at a manageable level.

Finally, even if there is no risk, action may be necessary, for example when a product is non-compliant with the applicable regulation (e.g. incomplete markings).

In conclusion, there is no automatic link from risk to action. Surveillance authorities will take into account a range of factors such as those indicated above. In all cases, the principle of proportionality has to be considered, and actions or measures have to be sufficiently effective.

5. HOW TO PREPARE A RISK ASSESSMENT - IN BRIEF

- (1) Describe the product and its hazard.

Describe the product unambiguously. Does the hazard concern the entire product or only a (separable) part of a product?

¹¹ Taken from the definition of "safe product" in Article 2 (b) of Directive 2001/95/EC on General Product Safety; OJEU L11, 5.1.2002, p. 4.

Is there only one hazard within the product? Are there several hazards? See table 1 for orientation.

Identify the standard(s) or legislation applicable to the product.

- (2) Identify the consumer type whom you would like to include in the injury scenario with the hazardous product.

Start with the intended user and the intended use of the product.

- (3) Describe an injury scenario, in which the product hazard(s) you selected causes an injury(ies) (or adverse health effect(s)) to the consumer you selected.

Describe the subsequent steps to the injury(ies) clearly and concisely, without exaggerating the level of detail ("shortest path to injury", "critical path to injury"). If there are several concurrent injuries in your scenario, include them all in that same scenario.

When you describe your injury scenario, consider frequency and duration of use, hazard recognition by the consumer, whether the consumer is vulnerable (in particular children, if appropriate), his protective equipment, the consumer's behaviour in case of an accident, the consumer's cultural background, and other elements that you consider important for the risk assessment.

See section 3.3 and table 1 for orientation.

- (4) Determine the severity of the injury.

Determine the level of severity (1 to 4) of the injury caused to the consumer. See table 3 for orientation. If the consumer suffers from several injuries in your injury scenario, estimate the severity of all those injuries together.

- (5) Determine the probability of the injury scenario.

Assign a probability to each step of your injury scenario. See table 4 for orientation. Multiply the probabilities to calculate the overall probability of your injury scenario.

- (6) Determine the risk level.

Combine the severity of injury and the overall probability of your injury scenario by looking up table 5; read the risk level from that table.

- (7) Check whether the risk level is plausible.

If the risk level is not plausible to you, or if you are uncertain about the severity of injury(ies) or about the probability(ies), modify them by one level and calculate the risk anew. This "sensitivity analysis" will show you whether your risk changes when your input changes.

If your risk level remains the same, you can be quite confident about your risk assessment. If it changes easily, you may want to err on the safe side and take the higher risk level as "the risk" of the consumer product.

You could also discuss with experienced colleagues about your risk assessment, in order to get further views on the plausibility of the risk level.

- (8) Make further risk assessments, if necessary, to identify the highest risk of the product.

If in your first injury scenario you identify a risk level below the highest risk level offered by these Guidelines, and if you consider that the product may cause a higher risk than the one identified,

- select other consumers (including vulnerable consumers, in particular children, if appropriate);
- identify other uses (including reasonably foreseeable uses),

in order to determine in which injury scenario the product has its highest risk.

The highest risk is normally "the risk" of the product, which will allow for the most effective risk management measures. In specific cases, a particular hazard may lead to a less-than-highest risk requiring specific risk management measures. This has to be taken into account appropriately.

As a rule of thumb, injury scenarios may lead to the highest risk level offered by these Guidelines when

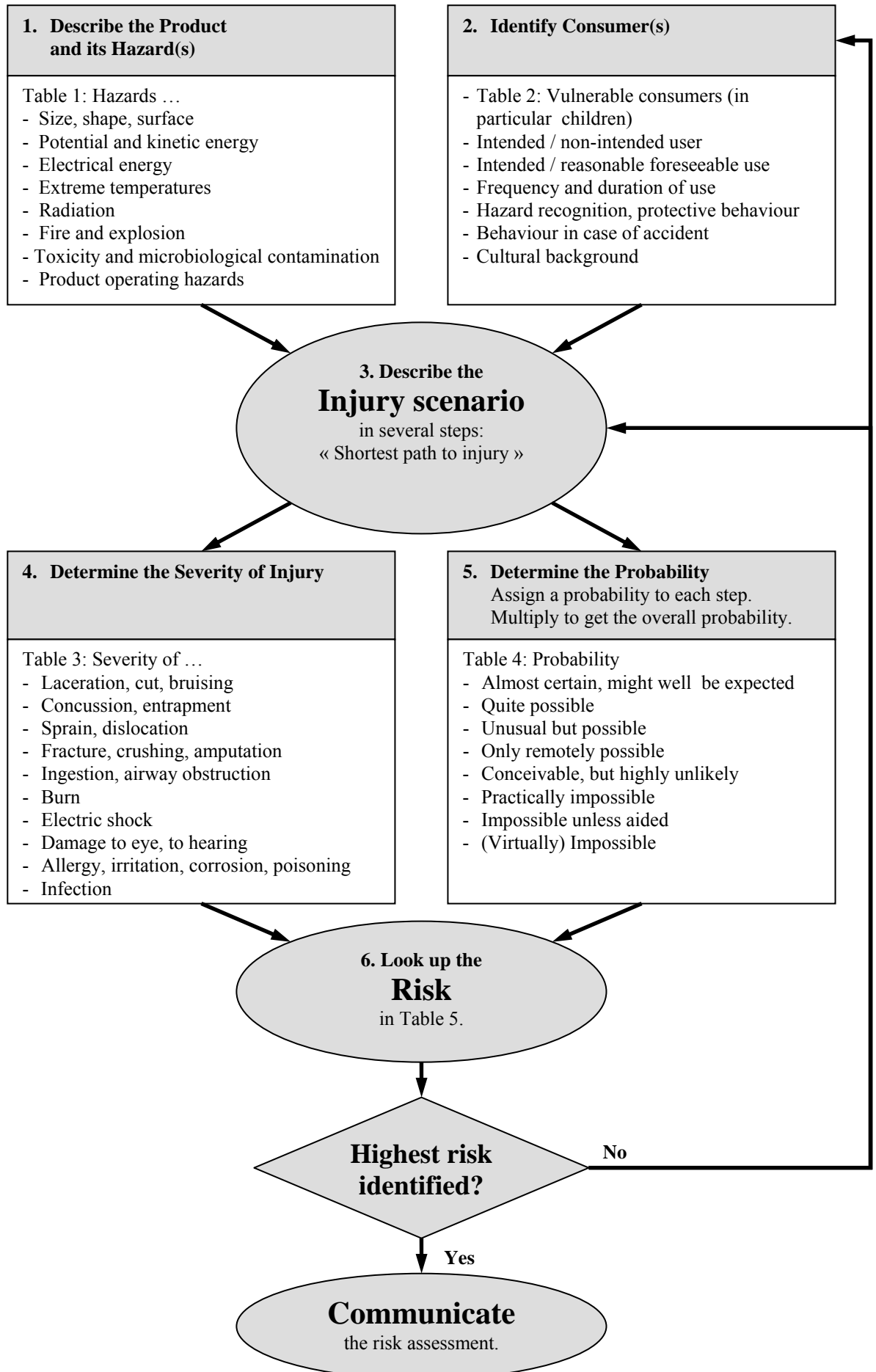
- the injury(ies) considered are at least at levels 4 or 3;
- the overall probability of an injury scenario is at least "unusual but possible".

See table 5 for orientation.

- (9) Communicate your risk assessment(s).

Examples for reporting your risk assessment(s) are given in the examples in section 6 of these Guidelines.

Schematic flow of risk assessment



6. EXAMPLES

6.1. Folding chair

A folding chair has a folding mechanism constructed in such a way that the user's fingers can get entrapped between the seat and the folding mechanism. This can lead to fractures or even loss of one or more fingers.



Determination of the risk(s)

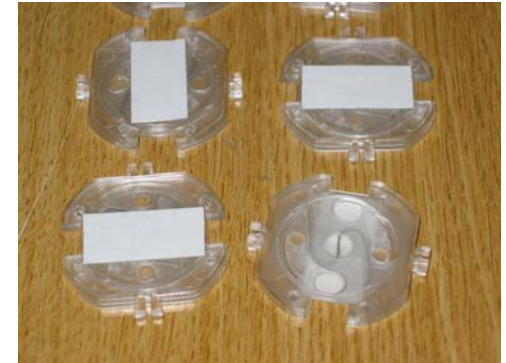
| Injury scenario | Injury type and location | Severity of injury | Probability of injury | Overall probability | Risk |
|--|--------------------------|--------------------|---|---------------------------|-----------|
| Person unfolds the chair, grips seat close to the back corner by mistake (Person inattentive/distracted), finger gets caught between seat and backrest | Minor pinching of finger | 1 | Unfolding the chair: 1 Gripping the seat at back corner while unfolding: 1/50 Finger gets caught 1/10 Minor pinching: 1 | 1/500 >1/1000 | Low risk |
| Person unfolds the chair, grips seat at the side by mistake (Person inattentive/distracted), finger gets caught between seat and link | Minor pinching of finger | 1 | Unfolding the chair: 1 Gripping the seat at the side while unfolding: 1/50 Finger gets caught 1/10 Minor pinching: 1 | 1/500 >1/1000 | Low risk |
| Person unfolds the chair, chair is clamped, Person tries to push down the seat and grips seat close to the corner by mistake (Person inattentive/distracted), finger gets caught between seat and backrest | Fracture of finger | 2 | Unfolding the chair: 1 Chair clamps: 1/1,000 Gripping the seat at corners while unfolding: 1/50 Finger gets caught 1/10 Fracture of finger: 1 | 1/500,00 >1/1,000,000 | Low risk |
| Person unfolds the chair, chair is clamped, Person tries to push down the seat and grips seat at the side by mistake (Person inattentive/distracted), finger gets caught between seat and link | Fracture of finger | 2 | Unfolding the chair: 1 Chair clamps: 1/1,000 Gripping the seat at the side while unfolding: 1/50 Finger gets caught 1/10 Fracture of finger: 1 | 1/500,000 >1/1,000,000 | Low risk |
| Person is sitting on chair, wants to move the chair and tries to lift it by gripping the chair at the rear part of the seat, finger gets caught between seat and backrest | Loss of digit | 3 | Sitting on chair: 1 Moves the chair while sitting: 1/2 Grips chair at rear part while moving: 1/2 Chair partially folds, creating a gap between the backrest and seat 1/3 Finger is between backrest and seat 1/5 Finger gets caught: 1/10 Loss of (part of) finger: 1/10 | 1/6,000 > 1/10,000 | High risk |

| Injury scenario | Injury type and location | Severity of injury | Probability of injury | Overall probability | Risk |
|---|--------------------------|--------------------|---|----------------------|-----------|
| Person is sitting on chair, wants to move the chair and tries to lift it by gripping the chair at the rear part of the seat, finger gets caught between seat and link | Loss of digit | 3 | Sitting on chair: 1 Moves the chair while sitting: 1/2 Grips chair at rear part while moving: 1/2 Chair partially folds, creating a gap between the backrest and seat: 1/3 Finger is between backrest and seat: 1/5 Finger gets caught: 1/10 Loss of (part of) finger: 1/10 | 1/6,000 >1/10,000 | High risk |

The overall risk of the folding chair is thus "high risk".

6.2. Socket protectors

This case deals with socket protectors. These are devices that users (parents) put into the electrical socket outlets to avoid that small children access live parts by putting long metal object into one of the holes in the outlet and getting a (fatal) electric shock. The holes in this particular protector (where the pins of the plug go trough) are so narrow that the pins might get stuck. This would most likely mean that the user will pull the protector off the outlet when the plug is pulled out. It may occur that the user does not recognize this event.



Determination of the risk(s)

| Injury scenario | Injury type and location | Severity of injury | Probability of injury | Overall probability | Risk |
|--|--------------------------|--------------------|--|--------------------------|--------------|
| Protector is removed from the plug, which becomes unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and is electrocuted. | Electrocution | 4 | Removal of protector: 9/10 Not noticing the removal of protector: 1/10 Child is playing with thin conductible object: 1/10 Child is unattended when playing: 1/2 Child inserts the object into the socket: 3/10 Access to voltage: 1/2 Electrocution due to voltage (without circuit interrupter): 1/4 | 27/160,000 > 1/10,000 | Serious risk |
| Protector is removed from the plug, which becomes unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and sustains shock. | Burns 2nd degree | 1 | Removal of protector: 9/10 Not noticing the removal of protector: 1/10 Child is playing with thin conductible object: 1/10 Child inserts the object into the socket: 3/10 Access to voltage: 1/2 Child is unattended when playing: 1/2 Burn due to electric current (without circuit interrupter): 3/4 | 81/160.000 > 1/10,000 | Low risk |
| Socket unprotected. Child is playing with thin conductible object which can be inserted into the socket, access high voltage and is electrocuted. | Electrocution | 4 | Child is playing with thin conductible object: 1/10 Child is unattended when playing: 1/100 Child inserts the object into the socket: 3/10 Access to voltage: 1/2 Electrocution due to voltage (without circuit interrupter): 1/4 | 3/80,000 > 1/100,000 | High risk |

The overall risk of the socket protectors is thus "serious risk".

6.3. Sensitivity analysis

The factors used to calculate the risk of an injury scenario, namely the severity of injury and the probability, often have to be estimated. This causes uncertainty in the numbers. In particular, the probability can be difficult to estimate, since for example the behaviour of consumers can be difficult to predict: does someone perform a certain action often or only occasionally?

It is therefore important to consider the level of uncertainty of the two factors and to make a sensitivity analysis. The purpose of such analysis is to clarify how much the risk level varies when the estimated factors vary. The example below only shows the variation of the probability, since the severity of injury is usually predicted with more certainty.

A practical way of doing the sensitivity analysis is to repeat the risk assessment for a certain scenario, but to use a different probability for one or more steps in the scenario. For example, a candle containing seeds could cause a fire, because the seeds catch fire and generate high flames. Furniture or curtains catch fire and persons that are not in the room could inhale toxic fumes and suffer fatal poisoning:

| Injury scenario | Injury type and location | Severity of injury | Probability of injury | Resulting probability | Risk |
|--|--------------------------|--------------------|---|-------------------------|---------|
| Seeds or beans catch fire generating high flames. Furniture or curtains catch fire. Persons are not in room, but inhale toxic fumes. | Fatal poisoning | 4 | <ul style="list-style-type: none"> Seeds or beans catch fire: 90% (0.9). People not in the room for some time: 30% (0.3). Furniture or curtains catch fire: 50% (0.5) (depends on surface on which candle is placed) Persons inhale toxic fumes: 5% (0.05). | 0.00675 >1/1,000 | Serious |

Probabilities for the steps in the scenario were estimated as shown in the table.

The overall probability is 0.00675, which is in the category "Only remotely possible >1/1,000" of Table 4. This leads to the conclusion "serious risk". Note that the exact probability is closer to 1/100 than to 1/1,000, which already gives some confidence in the risk level because it is a little deeper in the serious risk area of table 5 than the "> 1/1.000" row suggests.

Suppose we are uncertain about the 5% probability that persons inhale the toxic fumes. We could then estimate it much lower at 0.1% (0.001 = 1 in a thousand). If we recalculate with that assumption, the overall probability is 0.000135, which is in the category "Conceivable, but highly unlikely >1/10.000". Nevertheless, the risk is still serious. Even if for some reason the probability would be again a factor of 10 lower, the risk would still be high. Therefore, although the probability may vary 10- or 100-fold, we still find a serious or high risk (the latter being quite close to "serious"). Thus, this sensitivity analysis provides quite some confidence that the risk is indeed serious.

In general, however, risk assessment should be based on "reasonable worst cases": Not too pessimistic about every factor, but certainly not too optimistic.

Table 1. Hazards, typical injury scenario and typical injury

| Hazard group | Hazard (product property) | Typical injury scenario | Typical injury |
|-------------------------|---|--|---|
| Size, shape and surface | Product is obstacle | Person trips over product, falls and hits the floor; or person bumps into product | Bruising; fracture |
| | Product is impermeable to air | Product covers mouth and/or nose of a person (typically a child) | Suffocation |
| | Product is or contains small part | Person (child) swallows small part; the part gets stuck in larynx and blocks airways | Internal airway obstruction |
| | Possibility to bite off small part from product | Person (child) swallows small part; the part gets stuck in the digestive tract | Digestive tract obstruction |
| | Sharp corner or point | Person hits sharp corner or is hit by moving sharp object; this causes a puncture or penetration injury | Puncture; blinding, foreign body in eye; hearing, foreign body in ear |
| | Sharp edge | Person touches sharp edge; this lacerates skin or cuts through tissues | Laceration, cut; amputation |
| | Slippery surface | Person walks on surface, slips and falls hitting the floor | Bruising; fracture |
| | Rough surface | Person slides along rough surface; this causes friction and/or abrasion | Abrasion |
| Potential energy | Gap or opening between elements | Person puts a limb or body in opening and is trapped with finger, arm, neck, head, body or clothing; injury occurs due to gravity or movement | Crushing, fracture, amputation, strangulation |
| | Low mechanical stability | Product tips; person on top of product falls from height, or person near product is hit by the product; electrical product tips, breaks and gives access to live parts, or continues to work heating nearby surfaces | Bruising; dislocation; sprain; fracture; crushing; electric shock; burns |
| | Low mechanical strength | Product collapses by overloading; person on top of product falls from height, or person near product is hit by the product; electrical product tips, breaks and gives access to live parts, or continues to work heating nearby surfaces | Bruising; dislocation; fracture; crushing; electric shock; burns |
| | High position of user | Person at high position on the product loses balance, has no support to hold on to and falls from height | Bruising; dislocation; fracture; crushing |
| | Elastic element or spring | Elastic element or spring under tension is suddenly released; person in the line of movement is hit by the product | Bruising; dislocation; fracture; crushing |
| Kinetic energy | Pressurised liquid or gas, or vacuum | Liquid or gas under pressure is suddenly released; person in the vicinity is hit; or implosion of the product produces flying objects | Dislocation; fracture; crushing; cuts (see also under fire and explosion) |
| | Moving product | Person in the line of movement of the product is being hit by the product or run over | Bruising; sprain; fracture; crushing |
| | Parts moving against one another | Person puts a body part between the moving parts while they move together; the body part gets trapped and put under pressure (crushed) | Bruising; dislocation; fracture; crushing |

| Hazard group | Hazard (product property) | Typical injury scenario | Typical injury |
|----------------------|-------------------------------------|---|--|
| | Parts moving past one another | Person puts a body part between the moving parts while they move close by (scissor movement); the body part gets trapped between the moving parts and put under pressure (shearing) | Laceration, cut; amputation |
| | Rotating parts | A body part, hair or clothing of a person is entangled by the rotating part; this causes a pulling force | Bruising; fracture; laceration (skin of the head); strangulation |
| | Rotating parts close to one another | A body part, hair or clothing of a person is drawn in by the rotating parts; this causes a pulling force and pressure on the body part | Crushing, fracture, amputation, strangulation |
| | Acceleration | Person on the accelerating product loses balance, has no support to hold on to and falls with some speed | Dislocation; fracture; crushing |
| | Flying objects | Person is hit by the flying object and depending on the energy sustains injuries | Bruising; dislocation; fracture; crushing |
| | Vibration | Person holding the product loses balance and falls; or prolonged contact with vibrating product causes neurological disorders, osteo-articular disorder, trauma of the spine, vascular disorder | Bruising; dislocation; fracture; crushing |
| | Noise | Person is exposed to noise from the product. Tinnitus and hearing loss may occur depending on sound level and distance | Hearing injury |
| Electrical energy | High/low voltage | Person can touch part of the product that is at high voltage; the person receives an electric shock and may be electrocuted | Electric shock |
| | Heat production | Product becomes hot; a person touching it may sustain burns; or the product may emit molten particles, steam etc. that hits a person | Burn, scald |
| | Live parts too close | Electric arc or sparks occur between the live parts. This may cause a fire and intense radiation | Eye injury; burn, scald |
| Extreme temperatures | Open flames | A person near the flames may sustain burns, possibly after clothing catches fire | Burn, scald |
| | Hot surfaces | Person does not recognise the hot surface and touches it; the person sustains burns | Burn |
| | Hot liquids | Person handling a container of liquid spills some of it; the liquid falls on the skin and causes scalds | Scald |
| | Hot gases | Person breathes in the hot gases emitted from a product; this causes lung burn; or prolonged exposure to hot air causes dehydration | Burn |
| | Cold surfaces | Person does not recognise the cold surface and touches it; the person sustains frostbite | Burn |
| Radiation | Ultraviolet radiation, laser | Skin or eyes of a person are exposed to radiation emitted by the product | Burn, scald; neurological disorders; eye injury; skin cancer, mutation |

| Hazard group | Hazard (product property) | Typical injury scenario | Typical injury |
|-------------------------------|--|--|---|
| | High intensity EMF source; low frequency or high frequency (microwave) | Person is close to the EMF source, body (central nervous system) is exposed | Neurological (brain) damage, Leukemia (children) |
| Fire and explosion | Flammable substances Explosive mixtures Ignition sources Overheating | Person is near the flammable substance; an ignition source sets the substance to fire; this causes injuries to the person Person is near the explosive mixture; an ignition source causes an explosion; the person is hit by the shock wave, burning material and/or flames The ignition source causes a fire; a person is injured by flames, or intoxicated by gases from the house fire Product overheats; fire, explosion | Burn Burn, scald; eye injury, foreign body in eye; hearing injury, foreign body in ear Burn; poisoning Burn, scald; eye injury, foreign body in eye; hearing, foreign body in ear |
| Toxicity | Toxic solid or fluid Toxic gas, vapour or dust Sensitising substance Irritating or corrosive solid or fluid Irritating or corrosive gas or vapour CMR substance | Person ingests substance from product, e.g. by mouthing; and/or substance gets onto skin Person aspirates (breathes in) solid, fluid or emetic mass (pulmonary aspiration) Person inhales substance from product; and/or substance gets onto skin Person ingests substance from product, e.g. by mouthing; and/or substance gets onto skin; and/or person inhales gas, vapour or dust Person ingests substance from product, e.g. by mouthing; and/or substance gets onto skin or in eyes Person inhales substance from product; and/or substance gets onto skin or in eyes Person ingests substance from product, e.g. by mouthing; and/or substance gets onto skin; and/or person inhales substance as gas, vapour or dust | Acute poisoning; irritation, dermatitis, Acute poisoning in lungs (aspiration pneumonia); infection Acute poisoning in lungs; irritation, dermatitis Sensitisation; allergic reaction Irritation, dermatitis; skin burn; eye injury, foreign body in eye Irritation, dermatitis; skin burn; acute poisoning or corrosive effect in lungs or in eyes Cancer, mutation, reproductive toxicity |
| Microbiological contamination | Microbiological contamination | Person gets into contact with contaminated product by ingestion, inhalation or skin contact | Infection, local or systemic |

| Hazard group | Hazard (product property) | Typical injury scenario | Typical injury |
|------------------------------|--|--|---|
| Product operating hazards | Unhealthy posture | Design causes unhealthy posture of person when operating the product | Strain; musculoskeletal disorder |
| | Overexertion | Design requires use of considerable force when operating the product | Sprain or strain; musculoskeletal disorder |
| | Anatomical unsuitability | Design is not adapted to human anatomy which makes it difficult or impossible to operate | Sprain or strain |
| | Ignoring personal protection | Design makes it difficult for a person wearing protection to handle or operate the product | Various injuries |
| | Inadvertent (de)activation | Person can easily (de)activate product which leads to unwanted operation | Various injuries |
| | Operational inadequacy | Design provokes faulty operation by a person; or product with a protective function does not provide expected protection | Various injuries |
| | Failure to stop | Person wants to stop the product, but it continues to operate in situation where this is unwanted | Various injuries |
| | Unexpected start | Product shuts down during a power failure, but resumes operation in a hazardous way | Various injuries |
| | Inability to stop | In an emergency situation, person is not able to stop operation of the product | Various injuries |
| | Inadequately fitting parts | Person tries to fit a part, needs too much force to fit, product breaks; or part is too loosely fitted and gets loose during use | Sprain or strain; laceration, cut; bruising; entrapment |
| | Missing or incorrectly fitted protection | Hazardous parts are reachable for a person | Various injuries |
| | Insufficient warning texts and symbols | User does not notice warning texts and/or does not understand symbols | Various injuries |
| Insufficient warning signals | User does not see or hear warning signal (optical or auditive) causing dangerous operation | Various injuries | |

Table 2. Vulnerable consumers

| Vulnerable consumer | Definition |
|----------------------------|---|
| Very young children | 0 to 36 months |
| Young children | Older than 36 months and younger than 8 years |
| Older children | 8 to 14 years |
| Children | Includes all the three above definitions |
| Vulnerable people | Persons having reduced physical, sensory or mental capabilities (e.g. partially disabled, elderly having some reduction in their physical and mental capabilities), or lack of experience and knowledge (e.g. older children) |
| Very vulnerable people | Persons having very extensive and complex disabilities |

Table 3. Severity of injury

Introduction

In these Risk Assessment Guidelines, four levels of injury severity are distinguished. It is important to realise that severity should be assessed in a rather objective way. The aim is to **compare** the severity of different scenarios and to set priorities, not to judge the **acceptability** of a single injury at this stage. Any injury that could easily have been avoided will be difficult to accept for a consumer; however, it seems justified that authorities spend more effort on avoiding irreversible consequences than on preventing a temporary discomfort.

In order to assess the severity of consequences (acute injury or other damage to health), objective criteria can be found on the one hand in the level of medical intervention, and on the other hand in the consequences on the further functioning of the victim. Both could be expressed as cost, but the costs of consequences of health damage may be difficult to quantify.

Combining these criteria, the four levels may be defined as follows:

- 1 Injury or consequence that after a basic treatment (first aid, normally not by a doctor) does not substantially hamper the functioning or cause excessive pain; usually the consequences are completely reversible.
- 2 Injury or consequence for which a visit to the Emergency Room may be necessary, but in general hospitalisation is not required. The functioning may be affected for a limited time, not more than about 6 months, and recovery is more or less complete.
- 3 Injury or consequence that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function.
- 4 Injury or consequence that is or could be fatal, including brain death; consequences that affect reproduction or offspring; severe/grievous loss of limbs and/or function, leading to more than about 10% of disability.

The following table provides examples of injuries in all four levels.

| Type of injury | Severity of injury | | | |
|--|---|--|--|---|
| | 1 | 2 | 3 | 4 |
| Laceration, Cut | Superficial | External (deep) (>10cm long on body) (>5cm long on face) requiring stitches Tendon or into joint White of eye or Cornea | Optic nerve Neck artery Trachea Internal organs | Bronchial tube Oesophagus Aorta Spinal cord (low) Deep laceration of internal organs Severed high spinal cord Brain (severe lesion/dysfunction) |
| Bruising (abrasion/ contusion, swelling, oedema) | Superficial ≤25 cm ² on face ≤50 cm ² on body | Major >25 cm ² on face >50 cm ² on body | Trachea Internal organs (minor) Heart Brain Lung, with blood or air in chest | Brain stem Spinal cord causing paralysis |
| Concussion | | Very short unconsciousness (minutes) | Prolonged unconsciousness | Coma |
| Entrapment/ pinching | Minor pinching | -- | (refer to the final outcomes bruising, crushing, fracture, dislocation, amputation, as applicable) | (Refer to Suffocation / Strangulation) |
| Sprain, strain, musculoskeletal disorder | Extremities Joints Spine (no dislocation or fracture) | Knee ligaments strain | Ligament or tendon rupture/ tear Muscle tear Whiplash | - |
| Dislocation | -- | Extremities (finger, toe, hand, foot) Elbow Jaw Loosening of tooth | Ankle Wrist Shoulder Hip Knee Spine | Spinal column |
| Fracture | -- | Extremities (finger, toe, hand, foot) Wrist Arm Rib Sternum Nose Tooth Jaw Bones around eye | Ankle Leg [femur and lower leg] Hip Thigh Skull Spine (minor compression fracture) Jaw (severe) Larynx Multiple rib fractures Blood or air in chest | Neck Spinal column |

| Type of injury | Severity of injury | | | |
|-----------------------------|--|---|---|--|
| | 1 | 2 | 3 | 4 |
| Crushing | -- | -- | Extremities (fingers, toe, hand, foot) Elbow Ankle Wrist Forearm Leg Shoulder Trachea Larynx Pelvis | Spinal cord Mid-low neck Chest (massive crushing) Brain stem |
| Amputation | -- | -- | Finger(s) Toe(s) Hand Foot (Part of) Arm Leg Eye | Both extremities |
| Piercing, puncturing | Limited depth, only skin involved | Deeper than skin Abdominal wall (no organ involvement) | Eye Internal organs Chest wall | Aorta Heart Bronchial tube Abdominal Organs (liver, kidney, bowel, etc) deep |
| Ingestion | -- | -- | Internal organ injury (refer also to internal airway obstruction in case the ingested object gets stuck high in the oesophagus) | Permanent damage to internal organ |
| Internal airway obstruction | -- | -- | Oxygen flow to brain blocked without permanent consequences | Oxygen flow to brain blocked with permanent consequences |
| Suffocation / Strangulation | -- | -- | Oxygen flow to brain blocked without permanent consequences | Fatal suffocation / strangulation |
| Submersion / Drowning | -- | -- | - | Fatal drowning |
| Burn/ Scald | 1°, up to 100% of body surface 2°, <6% of body surface | 2°, 6-15% of body surface | 2°, 16-35% of body surface, or 3°, up to 35% of body surface Inhalation burn | 2° or 3°, >35% of body surface Inhalation burn requiring respiratory assistance |
| Electric shock | (see also under burns as electric current can cause burns) | Local effects (temporary cramp or muscle paralysis) | - | Electrocution |
| Neurological disorders | - | - | Triggered epileptic seizure Neurological effects of EMF | - |

| Type of injury | Severity of injury | | | |
|---|--|---|--|--|
| | 1 | 2 | 3 | 4 |
| Eye injury, foreign body in eye | - | - | Partial loss of sight Permanent loss of sight (one eye) | Permanent loss of sight (both eyes) |
| Hearing injury, foreign body in ear | - | - | Partial loss of hearing Complete loss of hearing (one ear) | Complete loss of hearing (both ears) |
| Poisoning from substances (ingestion, inhalation, dermal) | Diarrhoea, vomiting, local symptoms | Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia | Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nerve system | Irreversible damage to nerve system Fatality |
| Irritation, dermatitis, inflammation or corrosive effect of substances (inhalation, dermal) | Local slight irritation, | Reversible eye damage Reversible systemic effects Inflammatory effects | Lungs, respiratory insufficiency, chemical pneumonia Irreversible systemic effects Partial loss of sight Corrosive effects | Lungs, requiring respiratory assistance Asphyxia |
| Allergic reaction or sensitisation | Allergic contact dermatitis, Superficial and local | Sensitisation, widespread allergic contact dermatitis | Strong sensitisation, provoking allergies to multiple substances | Anaphylactic reaction, shock Fatality |
| Long-term damage from contact with substances or from exposure to radiation | Diarrhoea, vomiting, local symptoms | Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia | Damage to nerve system (e.g. OPS), Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nerve system | Cancer (leukaemia) Effects on reproduction Effects on offspring CNS depression |
| Microbiological Infection | | Reversible damage | Irreversible effects | Infection requiring prolonged hospitalisation, antibiotics resistant organisms Fatality |

Table 4. Probability of injury

| Probability of damage during the foreseeable lifetime of the product | |
|--|---------------|
| Almost certain, might well be expected | > 50 % |
| Quite possible | > 1/10 |
| Unusual but possible | > 1/100 |
| Only remotely possible | > 1/1,000 |
| Conceivable, but highly unlikely | > 1/10,000 |
| Practically impossible | > 1/100,000 |
| Impossible unless aided | > 1/1,000,000 |
| (Virtually) Impossible | < 1/1,000,000 |

Table 5. Risk level from the combination of the severity of injury and the probability

| Probability of damage during the foreseeable lifetime of the product | | Severity of Injury | | | |
|--|---------------|--------------------|-----|-----|-----|
| | | 4 | 3 | 2 | 1 |
| Almost certain, might well be expected | > 50 % | S | S | S | H |
| Quite possible | > 1/10 | S | S | S | Sig |
| Unusual but possible | > 1/100 | S | S | S | Sig |
| Only remotely possible | > 1/1,000 | S | S | H | L |
| Conceivable, but highly unlikely | > 1/10,000 | S | H | Sig | L |
| Practically impossible | > 1/100,000 | H | Sig | L | L |
| Impossible unless aided | > 1/1,000,000 | Sig | L | L | L |
| (Virtually) Impossible | < 1/1,000,000 | L | L | L | L |

| | |
|-------|------------------|
| S – | Serious Risk |
| H – | High risk |
| Sig – | Significant risk |
| L – | Low risk |

Glossary of terms

Hazard: Source of danger evoking a chance of being injured or harmed. A means for quantifying the hazard in a risk assessment according to this guideline is the severity of a possible injury or harm.

Product hazard: Hazard raised by the properties of a product.

Risk: Balanced combination of a hazard and the probability that a damage occurs. Risk describes neither the hazard, nor the probability, but both at the same time.

Risk assessment: Procedure of identifying and assessing hazards, consisting of three steps:

- Identification of the seriousness of a hazard;
- Determination of the probability that a consumer is injured by that hazard;
- Combination of the hazard with the probability.

Risk-level: Degree of a risk which may result in "serious", "high", "significant" and "low". When the (highest) level of risk has been identified, risk assessment is complete.

Risk management: Follow-up action which is separate from risk assessment and that aims at reduction or elimination of a risk.