Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System ‘RAPEX’ established under Article 12 of Directive 2001/95/EC on general product safety and its notification system (notified under document C(2018) 7334)

ANNEX U.K.

RISK ASSESSMENT GUIDELINES FOR CONSUMER PRODUCTS[1]

1. *Introduction* U.K.

Consumer products may cause harm when used, e.g. a hot flat-iron that can cause burns, scissors or knives that can cause cuts, or a household cleaner that can damage the skin. This kind of damage is not a usual occurrence because general knowledge or instructions teach how to use consumer products safely. Nevertheless, the risk of damage remains.

This risk can be assessed in different ways. A range of methods have been used to quantify risk for consumer products, such as a nomograph method[2], a matrix method[3], and the method previously recommended for the EU's RAPEX rapid alert system[4]. While the general principles for risk assessment have always been agreed, how to quantify risks has been under permanent development. This has led to diverging results and ensuing discussions, as well as to consideration of what the best possible practice might be.

The purpose of these risk assessment guidelines is therefore to improve the situation and, within the framework of the Directive on General Product Safety[5], 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. These guidelines are based on a risk assessment method developed for other purposes, adapted to the specific requirements of non-food consumer products.

A certain amount of training will of course be needed before these guidelines can be put into practice, but expertise in risk assessment will greatly facilitate this task. This will be backed by exchanges of views between risk assessors, since expertise and experience accumulated through the years is invaluable.

In building up a risk assessment method in small, manageable steps, these guidelines help to focus on the relevant issues of a 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. They should thus lead to consistent and robust risk assessment results based on evidence and science, and consequently to widely acceptable consensus on the risks that the many non-food consumer products may present.

A quick overview and a flow chart on how to prepare a risk assessment pursuant to these guidelines is provided in section 5 — ‘Consumer products’ mean non-food consumer products throughout these guidelines.

These guidelines do not set out to replace other guidelines that may address very specific products or may be specifically provided for in legislation, such as in the area of chemicals, cosmetics, pharmaceuticals or medical devices. It is highly recommended to use this specific guidance, since it is tailor-made, but it will always be for the risk assessor to decide how best to assess the risks of a product.

Nor are these guidelines to be used by manufacturers ‘just to avoid serious risks’ when designing and manufacturing products. Consumer products have to be safe, and these guidelines aim at helping authorities to identify serious risks when, despite the best efforts of the manufacturer, a product is not safe.

2. *Risk assessment — an overview* U.K.

2.1. Risk — Combination of hazard and probability U.K.

Risk is generally understood as something that threatens the 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 a ladder always includes the possibility of falling off and injuring oneself. 'Falling off' is therefore 'built into the ladder'; it is an intrinsic part of using a ladder and cannot be excluded. 'Falling off' is thus called the intrinsic hazard of a ladder.

— This hazard, however, does not always materialise, since many people climb ladders without falling off and injuring themselves. This suggests that there is a certain likelihood (or probability), but no certainty, of the intrinsic hazard materialising. Whereas the hazard always exists, the probability of it materialising can be minimised, for example by the person climbing the ladder being careful.

— Using a household cleaner with sodium hydroxide to free blocked sewage water pipes always entails the possibility of very severe damage to 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, meaning that the cleaner is intrinsically hazardous.

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

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

2.2. **A risk assessment in three steps** U.K.

It takes three steps to determine the risk:

1. Anticipate an injury scenario in which the intrinsic product hazard harms the consumer (see table 1). Determine how severe the consumer's injury is.

   A yardstick for quantifying the intrinsic product hazard is the extent of the adverse effect that it can cause to the health of a consumer. The risk assessor therefore anticipates an 'injury scenario' that describes step by step how the hazard leads to the injury of a consumer (see table 2). In short, the injury scenario describes the accident that the consumer has with the product in question, and the severity of the consumer's injury caused by that accident.

   An injury can vary in severity, depending on the hazard of the product, on the way the product is used by the consumer, on the type of consumer who uses the product, and much more (see section 3). The more severe the injury, the more severe the hazard that caused it, and vice versa. The 'severity of the injury' is therefore a means of quantifying the hazard. These guidelines propose 4 levels of severity, from injuries that are normally completely reversible to very serious injuries that cause more than approximately 10 % of permanent disability or even death (see table 3).

2. Determine the probability of the consumer being injured in practice by the intrinsic product hazard.

   While the injury scenario describes how the consumer is injured by the hazard, the scenario only happens with a certain probability. The probability can be expressed as a fraction, such as '> 50 %' or '> 1/1 000' (see left-hand side of table 4).

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

This combination can be made by looking up both values in the appropriate table (see table 4); the table will provide the level of risk in terms of 'serious', 'high', 'medium' and 'low' risk.

Where different injury scenarios are foreseeable, the risk for each of those scenarios should be determined the highest risk being labelled as 'the risk' of the product. The highest risk is normally crucial because only action on the highest risk can effectively provide a high level of protection.

On the other hand, an identified risk may be lower than the highest risk, but require specific risk reduction action. It is then important also to take measures against that risk so that all risks are effectively reduced.

Once the three steps have been carried out, the risk assessment is basically complete. A flow chart on building a risk assessment is at the end of section 5.

2.3. Some useful tips U.K.

Seek information

As can be seen from the examples of Chapter 2.1, each of the three steps of a risk assessment (see point 2.2) requires anticipation of what might happen and how likely it is to 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 design, mechanical stability, chemical composition, operation, instructions for use, including possible risk management advice, type of consumers it is intended for (and those for which it is not), test reports, accident statistics, the EU Injury Database (IDB)[6], information about consumer complaints, about the behaviour of different consumers when they are using the product, and about product recalls. Product requirements laid down in legislation, in product standards or in checklists (such as in ISO 14121: Safety of machinery — Risk assessment) can also be useful sources of information.

Nevertheless, the products to be assessed may be quite specific and thus these sources may not contain the information required. The information collected may also be incomplete, inconsistent, or not fully plausible. This may be the case in particular for accident statistics, when only the product category is registered. The absence of an accident history, a small number of accidents or low severity of accidents should not be taken as a presumption of low risk. Product-specific statistics also have to be viewed with great care, since the product may have changed over time, be it in design or composition. The information must always be critically assessed.

Feedback from expert colleagues can be particularly useful, since they can draw from their real-life experience and pro vide suggestions that are not immediately obvious when assessing a product risk. They may also give advice when assessing the risk for different types of consumers, including vulnerable consumers such as children (see table 1), since the latter may handle a product differently. They may also help 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. 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, although not an obligation, 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 with authorities and others when a new or improved product is to be assessed before it is placed on the market.

New information obtained should of course be used to update any existing risk assessment.

Make a sensitivity analysis of your risk assessment

If all information searches and queries to expert colleagues do not provide the required, very specific data, a so-called sensitivity analysis might help. In this 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. In this way the range in which the real risk of the product will be can be estimated.

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 example of a sensitivity analysis is illustrated in section 6.

Let others 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 referred to in point 2.2. They will feed in their experience and thus help to generate a more robust, more solid, more transparent and ultimately more acceptable risk assessment. It is therefore recommended that, ideally, advice be sought from expert colleagues, possibly in the form of a group discussion, before concluding a risk assessment. These groups, 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 a product is new on the market and has never been assessed before.

Risk assessments should be solid and realistic. However, since they require a number of assumptions, different risk assessors may come to different conclusions in view of the data and other evidence they have been able to find or because of their diverging experience. It is thus necessary for risk assessors to talk to one another in order to reach agreement or, at least, consensus. The step-by-step risk assessment described in these guidelines, however, should make such discussions more productive. Each step in a risk assessment must be clearly described in detail. Thus, any point of disagreement can be quickly identified, and consensus can more easily be reached. This will make risk assessments more acceptable.

Document your risk assessment

It is important to document your risk assessment, describing the product and all the parameters that you chose while developing it, such as test results, the type(s) of consumers you chose for your injury scenario(s), and the probabilities with the underlying data and assumptions. This will enable you to demonstrate unambiguously how you estimated the level of risk, and it will also help you to update your assessment while keeping track of all changes.

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 may a less-than-highest risk be considered particularly important, since it may require specific risk management measures.

As an example of 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 should be reported as ‘the risk’ of the hammer.

It could be argued that:

— the apparently most significant hazard should be decisive, since it would lead to the most severe injuries. In the example of the hammer in point 2.1, this could be the hammer head breaking, since pieces of the broken head could fly into one's eye, possibly blinding the user. The hammer grip breaking, on the other hand, would never split into small pieces that could do as much damage to the eyes;

— However, this would be a hazard assessment, not a risk assessment. A risk assessment also looks at the probability of an injury actually happening. Thus, the 'most significant hazard' might cause an injury that is much less likely than a lesser hazard, and therefore present a lower risk. Conversely, a scenario leading to a less severe injury may be much more likely than a scenario resulting in death, and the less severe injury may therefore present a higher risk;

— the highest probability for an injury scenario to happen should be the decisive factor for 'the risk' of the product. In the example of the hammer in point 2.1, if the hammer grip is very weak, the most likely injury scenario would be from the grip breaking, and that should therefore be decisive.

However, this would not consider the seriousness of eye injuries that the hammer head breaking could cause. Looking at probability alone would not therefore give the whole 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 ensure the most effective product safety (apart from specific risks requiring specific risk management, as referred to at the beginning of this section.

Can risks cumulate?

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

Where several risks are linked to the same product, one of them is obviously more likely to materialise and causes an injury. The overall likelihood of an injury is therefore greater. This does not mean that the overall risk is automatically higher, however:

— The overall probability is not calculated by simply adding up probabilities. More complex calculations are necessary, and these always result in a probability that is lower than the sum of all probabilities.

— There is difference of a factor of 10 between two succeeding probability levels (table 4). This means that a lot of different scenarios of the same level would be needed to result in higher overall probability (and possibly risk).

— Probability values are estimations which may not be totally accurate, as they often err on the 'safe' side in order to ensure a high level of protection. It is therefore more useful to look at a more accurate estimation of the probability of a scenario leading to the highest risk than to add up rough estimations of probabilities of all sorts of scenarios.

— With a little effort hundreds of injury scenarios could be developed. If risks were simply added together, the overall risk would depend on the number of injury scenarios generated and could increase 'endlessly'. This does not make sense.

Thus, risks are not simply cumulated. However, if more than one relevant risk exists, action to manage the risks may need to be taken more rapidly or may need to be more pronounced. For example, with two risks, a product may need to be immediately taken off the market and recalled, 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 present at one and the same time. Thus, consideration is given to the link between risk and risk management (section 4).

Compliance with limit values in legislation and standards

In market surveillance, consumer products are often tested against limit values or requirements laid down in legislation and in product safety standards. A product that complies with the limit value(s) or requirement(s)[(7)] is presumed to be safe in terms of the safety characteristics covered by those value(s) or requirement(s). This assumption can be made because the risks of a product from its intended and reasonably foreseeable use are taken into account when establishing the limit value(s) or requirement(s). Manufacturers thus need their products to comply with these values or requirements, because they then only have to look at risks with their products that are not be covered by those limit value(s) or requirement(s).

An example of a limit value in:

— legislation is the limit of 5 mg/kg benzene in toys which must not be exceeded, as per point 5 of Annex XVII, to the REACH Regulation[(8)], as amended by Commission Regulation (EC) No 552/2009[(9)];

— a standard is the small parts cylinder: small parts of a toy for children under 36 months must not fit entirely into the cylinder described in the Toys Standard[(10)]. If they do, they present a risk;

— The product is presumed not to be safe where it fails to comply with established limit values. For limit values laid down in:

— legislation, such as on cosmetics or restrictions on marketing and use, the product must not be made available on the market;

— standards, the manufacturer may nevertheless try to provide evidence that his product is as safe as if it were compliant with the standard's limit value by way of a fully-fledged risk assessment on his product. However, this may require more effort, and may be impossible in cases such as the small parts cylinder referred to in the first bullet of this list, than actually manufacturing the product in compliance with the standard's limit value.

Non-compliance with limit values does not automatically mean that the product presents a ‘serious risk’ (which is the highest risk level covered by these guidelines). Therefore, to ensure appropriate risk reduction measures, a risk assessment will be required for those parts of a product that do not comply with or are not covered by legislation or a standard.

Furthermore, some products, such as cosmetics, require a risk assessment even when they are compliant with the limit values laid down in legislation. This risk assessment should provide evidence of the safety of the whole product[(11)].

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

Specific risk assessment guidelines in specific cases

For chemicals there are specific instructions on how to prepare a risk assessment[(12)], and therefore they are not dealt with in detail in these guidelines. Nevertheless, they follow the same principles as for ‘normal’ consumer products:

— hazard identification and assessment — this is the same as determining the severity of the injury, as described in section 2.2;

— exposure assessment — in this step, exposure is expressed as the likely dose of the chemical that the consumer may take up via oral, inhalation or dermal routes,

separately or jointly, when using the product as anticipated in the injury scenario. This step is the same as determining the probability that the injury will indeed occur;

— risk characterisation — this step basically consists of comparing the dose of the chemical that the consumer is likely to take up (= exposure) with the derived no-effect level (DNEL) of that chemical. Should the exposure be sufficiently lower than the DNEL, in other words, should the risk characterisation ratio (RCR) be clearly below 1, risk is considered to be adequately controlled. This is the same as determining the risk level. Risk management measures may not be needed if the level of risk is sufficiently low.

Since a chemical may possess several hazards, risk is normally determined for the 'leading health effect', which is the health effect (or 'endpoint' such as acute toxicity, irritation, sensitisation, carcinogenicity, mutagenicity, toxicity for reproduction) considered to be the most important.

For cosmetics, there is also specific guidance[13], and there may be specific guidance for other products or purposes.

It is highly recommended to use such specific guidance, since it is tailored to the specific cases in question. Nevertheless, where the data required by the specific guidance do not exist or cannot be estimated the present guidelines may be used for a preliminary risk assessment. This risk assessment will have to be carried out with due care and attention in order to avoid any misinterpretation.

3. *Building a risk assessment step by step* U.K.

This section describes in detail what points have to be taken into account and what questions have to be asked when preparing a risk assessment.

3.1. **The product** U.K.

The product should be identified unambiguously. This includes the product name, the brand, the model name, the type number, a possible production lot number, any certificate that may come with the product, a child-resistant fastening if there is one, the identity of the person who placed it on the market, 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 to be part of the product description.

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

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

Products may also need to be self-assembled by consumers before use, such as self-assembled furniture. Are the assembly instructions clear enough for the ready-to-use product to meet all the relevant safety requirements? Or could consumers make mistakes when putting the product together that could lead to unforeseen risks?

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 perhaps through reasonably foreseeable inappropriate use? How long is the ‘time to product failure’? What is the product's lifetime, including shelf life? How long is the product used in practice by the consumer before it becomes waste?

Additional considerations may need to be taken into account when a product becomes unusable after a certain time period, even though it has never been used. Examples are electric blankets or heating 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 can come into contact with each other, can cause a short-circuit and set the bedclothes on fire.

Finally, the packaging of the product should also be included in any risk assessment.

3.2. **The product hazard** U.K.

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 can cut fingers, or tight openings in which someone can trap their fingers;
— choking hazard, such as from small parts that come loose from a toy, which may be swallowed by a child and make the child choke;
— suffocation hazard, such as from the drawstrings of an anorak hood which may lead to strangulation;
— electrical hazard, such as from live electrical parts that can cause an electric shock;
— heat or fire hazard, such as a heater fan that overheats, catches fire and causes burns;
— thermal hazard, such as the hot outer surface of an oven that can cause a burn;
— chemical hazard, such as a toxic substance that can poison a consumer immediately upon ingestion, or a carcinogenic substance that can cause cancer in the long term. Some chemicals may damage the consumer only after repeated exposure;
— microbiological hazard, such as a bacteriological contamination of cosmetics which may cause a skin infection;
— noise hazard, such as ring tones from toy mobile phones that are much too loud and can damage children's hearing capacity;
— other hazards, such as explosion, implosion, sonic and ultrasonic pressure, fluid pressure, or radiation from laser sources.

For the purpose of these guidelines, hazards have been grouped, linked to the size, shape and surface of a product, to potential, kinetic or electric energy, to extreme temperatures, and others, as shown in table 2. The table is for guidance only, and any risk assessor should adapt the scenario to the product under consideration. Of course not every type of hazard applies to every product.

Nevertheless, table 2 should help risk assessors to look for and identify all possible hazards in consumer products that are being assessed. Where a product has several hazards, each hazard should be taken separately with its own risk assessment and the highest risk identified 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 reduced.

Note that a single hazard may lead to several injuries in the same scenario. For example, malfunctioning brakes on a motor cycle could cause an accident and result in damage to the driver's head, hands and legs, and could even cause burns if the petrol bursts into flames in the accident. In this 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. Several injuries in different scenarios should, however, not be added.

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), to ensure 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 possibly specific risk management at a later stage. In conclusion, experience with risk assessment in market surveillance practice will limit the number of required risk assessments to a minimum.

Hazard identification by tests and standards

Hazards are often identified and quantified by tests. These tests and how to carry them out may be laid down in European or international product standards. Compliance of a product with a 'harmonised' European standard ('EN …'), of which the references have been published in the Official Journal, provides presumption of safety (albeit only for the safety characteristics covered by the value(s) or standard(s)). It can be presumed in such cases that the product presents only a minimum risk and a high level of protection with regard to the specific hazard tested.

Nevertheless, there may be instances where presumption of safety is not the case, and in such cases a particularly well-documented risk assessment will have to be prepared, including a call for amendment to 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.

Products may still present a risk even though they do not cause injuries

Products may not be hazardous but can nevertheless cause a risk, due to not being fit for their intended use. Examples of this can be observed in the area of personal protective equipment or life-saving equipment, such as reflective jackets that car drivers put on after an accident. These jackets are meant to get the attention of oncoming drivers and traffic participants to warn them of the accident, in particular at night. However, they might not be seen if the reflector stripes are too small or do not reflect sufficiently, and do not therefore protect users as they should. These jackets therefore pose a risk even though they are not hazardous in themselves. Another example is a sunscreen product which displays 'high protection' (sun protection factor of 30) on the label but provides only 'low protection' (factor of 6). This can lead to severe sunburn.

3.3. **The consumer** U.K.

The abilities and behaviour of the consumer using the product may greatly influence the level of risk. It is therefore of prime importance to have a clear idea of the type of consumer pictured in the injury scenario.

It may be necessary to generate injury scenarios with different types of consumers in order to identify the highest risk and thus 'the risk' of the product. It is not enough, for example, to consider only the most vulnerable consumers, because the probability of their 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 in the vicinity of the user. For example, a chain saw may cause splinters to fly around and hit a bystander in the eye. Thus, although the risk from the chain saw may be effectively managed by the user him- or herself wearing protective equipment and complying with any other risk management measures specified by the manufacturer, bystanders may be under serious threat. Consequently, warnings should be given, for example in the chain saw instructions for use, about the risks to bystanders and how to minimise such risks.

Thus, when developing an injury scenario, the following aspects should be taken into account regarding the type of consumer and how they use the product. This is not a complete list, but it should encourage risk assessors to describe their injury scenarios with the necessary level of detail. It should be noted that 'consumer' also means people who are not actually using the product, but who may be affected by virtue of being nearby:

— Intended/non-intended user: The intended user of a product may use the product with ease because he goes by the instructions or because he is familiar with this kind of product, including its apparent and non-apparent hazard(s). The hazard of the product may not then materialise, and the product risk could be minor.

  The non-intended user may not be familiar with the product and may not recognise the hazard(s). He therefore runs the risk of injury, and the consumer risk is thus higher.

  Thus, the risk may be different for an intended and a non-intended user, depending on the product and the way it is used.

— Vulnerable consumers: Several categories of vulnerable and very vulnerable consumers can be distinguished: children (0 to 36 months, > 36 months to < 8 years, 8 to 14 years) and others such as the elderly (see table 1). They all have less capacity 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 problems taking account of warning labels, or may have particular problems using a product they have never used before. They may also act in a way that makes them more exposed, for example young children crawling and mouthing. Children may also be attracted to products because of their appeal, which makes them a high risk in the hands of children. On the other hand, supervision by parents or other adults should normally prevent children from running straight into trouble.

  Furthermore, consumers who are not usually vulnerable may become vulnerable in specific situations, for example when the instructions or warnings on a product are in a foreign language that the consumer does not understand.

  Finally, in the particular case of chemicals, children may be more susceptible to the toxicity of chemicals than the average adult. Therefore, children should not be treated as if they were 'small adults'.

  In conclusion, 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 determining the severity and probability of an injury (see section 3.5) and thus the risk.

— Intended and reasonably foreseeable use: Consumers may use a product for other purposes than the one for which it is intended, although the instructions are clearly understandable, including any warnings. Therefore, as warnings may not be fully effective, other uses than the intended ones also have to be taken into account in a risk assessment. This aspect is particularly important for the manufacturer of a product, since he has to ensure that the product is safe under any reasonably foreseeable conditions of use.

  Reasonably foreseeable use may have to be based on experience, because there may be no information available in official accident statistics or other sources of information. 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 they lead to very severe injuries, because such scenarios will always have very low probability. This possibly

safeguards against such scenarios having too much of an influence in determining the overall risk of the product.

— Frequency and duration of use: Different consumers may use a product often or not so often, and for longer or shorter periods of time. This depends on the attractiveness of the product and the ease with which it can be used. Daily or long-term use could make a consumer entirely familiar with a product and its specifics, including its hazards, instructions and warning labels, thus making the risk minor. On the other hand, daily or long-term use may make the consumer too used to the product and lead to user fatigue where he recklessly ignores instructions and warnings, thus increasing the risk.

  Finally, daily or long-term use may also accelerate product ageing, and any parts that cannot withstand such frequent use may quickly fail and cause a hazard, and possibly an injury, which also increases the risk.

— Hazard recognition and protective behaviour and equipment: Some products are known for their hazards, such as scissors, knives, do-it-yourself drilling machines, chain saws, roller blades, bicycles, motor bikes and cars. In all these cases, the product hazard is clearly known or readily recognisable, or described in the instructions, which will include risk management measures. The consumer can then act carefully or use personal protective equipment such as gloves, helmets or seat-belts, thereby using the product in a way that minimises the risk.

  In other cases, the product hazard may not be so readily recognisable, such as a short-circuit within an electric iron, warning labels may be overlooked or misunderstood, and consumers will only rarely be able to take preventive measures.

— Consumer behaviour in the event of an incident: Where the hazard impinges on the consumer it may cause injury. It is thus important for a risk assessment to consider how the consumer may react. Will he put the product to one side calmly and take preventive action, such as combating a fire caused by the product, or will he throw it away in a panic? Vulnerable consumers, especially children, may after all not behave the same as other, non-vulnerable consumers.

— 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 these cultural differences when launching a new product on a market. Manufacturers' experience in this area can thus be a valuable source of information for authorities preparing a risk assessment.

3.4. **Injury scenario: Steps leading to injury(ies)** U.K.

Most injury scenarios consist of the following three main steps:

1. the product has a ‘defect’ or can lead 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 into further steps to show how the product hazard can lead to injury and the like. Nevertheless, these ‘steps to injury’ have to be clear and concise, and not exaggerate the detail or the number of steps. With experience, it will be increasingly easier to identify the conditions for the occurrence of any given injury and the ‘shortest path to injury’ (or ‘critical path to injury’).

It is probably easiest to start with a scenario with the consumer for whom the product is intended where the consumer uses the product as per the instructions or, if there are none,

according to normal handling and use. If this assessment produces the highest risk level, there is normally no need to carry out further assessments, and appropriate risk reduction measures can be taken. Similarly, where an incident is reported in a specific consumer complaint, a single injury scenario may be sufficient to conclude as to appropriate risk reduction measures.

Otherwise, further scenarios could be developed to include vulnerable consumers, in particular children (see table 1), slight or more pronounced deviations from normal use, use under different climate conditions, such as very cold or very hot, unfavourable conditions of use, such as without proper daylight or illumination, use as suggested when the product was sold (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 (including wear and tear), etc. Each scenario should be considered through the entire risk assessment procedure.

Where the product displays several hazards, injury and thus risk scenarios should be developed for each of them. Nevertheless, a plausibility check as to whether an injury scenario might lead to a risk requiring action can limit the number of injury scenarios.

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 might be a specific, less-than-highest risk stemming from a different hazard, which could be managed by specific measures and should, of course, also cover the highest risk.

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

— the injury(ies) considered are in the highest severity levels (levels 4 or 3);

— the overall probability of an injury scenario is quite high (at least > 1/100).

Table 4 provides further guidance in this respect. This might help to limit the number of scenarios.

Of course, the number of injury scenarios remains the responsibility of the risk assessor, and it depends on the number of factors that need to be taken into account when determining 'the risk' of the product. It is therefore impossible to give a specific number of injury scenarios that may be necessary in a specific case.

To help develop a suitable number of scenarios, these guidelines provide a table with typical injury scenarios (table 2). These should be adapted to the specific product, consumer type and other circumstances.

3.5. **Severity of injury** U.K.

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

The severity of the injury can depend on:

— the type of hazard (see list of hazards of section 3.2 in table 2). A mechanical hazard, such as sharp edges, can cause cuts to the fingers; these are immediately noticed, and the consumer will take action to heal his injuries. On the other hand, a chemical hazard may cause cancer. This normally passes unnoticed, and the illness may appear only after many years, and is considered to be very severe since cancer is very difficult to cure, if at all;

— how powerful the hazard is. For example, a surface heated to 50 °C may cause slight burns, whereas a surface at 180 °C will cause severe burns;

— how long the hazard impinges 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;
— what body part is injured. For example, penetration by a sharp point into the skin of the arm is painful, but penetration into an eye is a more serious and perhaps a life-affecting injury;
— what impact the hazard has 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 when the unconscious person inhales the smoke;
— the type and behaviour of the consumer. A product labelled with a warning message can be used, without harm, by an adult consumer, because the consumer adjusts to using the product. On the other hand, a child or other vulnerable consumer (see table 1) who cannot read or understand the warning label may be very seriously injured.

To quantify the severity of injury(ies), table 3 in these guidelines shows how to classify injuries into four categories, depending on the reversibility of an injury, i.e. whether recovery from an injury is possible and to what extent. This categorisation is for guidance only, and a risk assessor should change the category if necessary, and report it in the risk assessment.

Where several injury scenarios are considered in the risk assessment, the severity of each injury should be classified separately, and considered throughout the entire risk assessment process.

An example: A consumer uses a hammer to knock a nail into a wall. The hammer head is too weak (due to incorrect material) and it breaks, one of the pieces flying into the eye of the consumer so hard that it causes blindness. The injury is thus an ‘eye injury, foreign body in eye: permanent loss of sight (one eye)’, which is a level 3 injury in table 3.

3.6. **Probability of injury** U.K.

The ‘probability of injury’ is the probability that injury scenario may indeed materialise during the expected lifetime of the product.

This probability is not easy to estimate; but when a scenario is described in distinct steps, each step can be given a certain probability, and multiplying these partial probabilities together gives the overall probability of the scenario. This stepwise approach should make it easier to estimate the overall probability. Of course, where several scenarios are developed, each scenario requires its own overall probability.

Where an injury scenario is nevertheless described in a single step, the probability of the scenario can also only be determined in a single overall step. This would only be a ‘guesstimate’, however, which could be severely criticised and thus call the entire risk assessment into question. A more transparent assignment of probabilities to a several-step scenario is therefore preferable, especially as the partial probabilities can be built on undisputable evidence.

These guidelines distinguish between 8 levels of probability to classify overall probability: from < 1/1 000 000 to > 50 % (see left-hand side of table 4). The following example of a hammer head that breaks when the user knocks a nail into a wall should illustrate how to assign a probability to each step, and how to classify overall probability:

Step 1:	The hammer head breaks when the user tries to knock a nail into a wall because the material of the hammer head is too weak. The weakness was determined in a test, and with the reported weakness the probability of the hammer head breaking during the

	otherwise expected lifetime of the hammer is put at 1/10.
Step 2:	One of the pieces of the hammer hits the user when it breaks. The probability of this happening is put at 1/10, since the area of upper body exposed to the pieces flying off is considered to be 1/10 of 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 user on the head. The head is estimated to be about 1/3 of the upper body, and the probability is therefore 1/3.
Step 4:	The piece hits the user in the eye. The eyes are considered to be about 1/20 of the area of the head, and therefore the probability is 1/20.

Multiplying the probabilities of these steps together gives an overall probability for the scenario of 1/10 × 1/10 × 1/3 × 1/20 = 1/6 000. This translates into > 1/10 000 (see left-hand side of table 4).

Once the overall probability has been calculated for an injury scenario, it should be checked for plausibility. This requires rather a lot of experience, thus suggesting that the assistance of persons experienced in risk assessment should be sought (see section ‘Let others check your risk assessment’). As experience is gained with these guidelines estimating probability should become easier, and an increasing number of examples will become available to facilitate this 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 in a scenario, the probability may have to be raised in general because more vulnerable consumers can be injured more easily. This applies in particular to children, since children do not normally have the experience to take preventive action, on the contrary (see also ‘Vulnerable consumers’ in section 3.3).

— When the risk is readily recognisable, including through warning labels, the probability may have to be lowered because the user will use the product more carefully in order to avoid injury as far as possible. This may not apply to an injury scenario with a (young) child or other vulnerable user (see table 1) who cannot read.

— When accidents have been reported that fit into the injury scenario, the probability for that scenario could increase. In cases where accidents have only rarely been 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 fairly large number of conditions are needed for the injury to occur, the overall probability of the scenario would normally be lower.

— When the conditions needed for the injury to occur are easily met, this may increase the probability.

— When the test results of the product fail by a large margin to come within the limit values required (by the relevant standard or legislation), the probability of the injury

(scenario) occurring may be higher than if the product performed close to the limit values.

The 'probability of injury' in this instance is the probability that the injury scenario may actually happen. Probability does not therefore describe the general exposure of the population to the product, calculated, for example, by considering the millions of product items sold on the market and then considering that a few of them might fail. Considerations of this kind do, however, play a role when determining the appropriate risk reduction measures (see section 4).

Also, accident statistics, even if product-specific, have to be considered with care when used for to estimate probability. The circumstances of the accident may not be reported in sufficient detail, the product may have changed over time, or the manufacturer may be different, and so on. In addition, light accidents may not have been reported to those collecting the data for the statistics. None the less, accident statistics can shed light on injury scenarios and their probability.

3.7. Determination of risk U.K.

Once the severity of the injury and the probability have been determined, if possible for several injury scenarios, the risk level then needs to be looked up in table 4. Table 4 combines both the severity of the injury and the probability, and the highest risk is 'the risk' of the product. Risks requiring specific risk management measures should also be reported, to ensure that all risks are reduced to a minimum.

These guidelines distinguish between 4 levels of risk: serious, high, medium and low. The risk level between neighbouring severities of injury or probability 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 increases from level 1 to level 2 (on the right-hand side of table 4), some risk levels increase by 2 levels, namely from medium to serious and from low to high. 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 normal for consumer products, since they make for a sufficiently robust estimation of severity; 5 levels would be too sophisticated since neither the severity of the 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 or for the overall risk of the product, the plausibility of the risk level and uncertainties in the estimates should be considered. This may mean verifying that the risk assessor has used the best information available to make his estimations and assumptions. Feedback from colleagues and other experts can also be helpful.

A sensitivity analysis can also be very valuable (see example in section 6.3). How does the risk level change when the severity of injury or probability changes by 1 level up or down? If the risk level does not change at all, it is quite plausible that it has been estimated correctly. If it changes, however, the risk level may be borderline. It is then necessary to reconsider the injury scenarios and the assigned severity of injury(ies) and probability(ies). At the end of the sensitivity analysis the risk assessor should be confident that the risk level is sufficiently plausible and that he can document it and pass the information on.

4. *From risk to action: how to manage risk responsibly* U.K.

Once the risk assessment is complete it will normally be used to decide whether action needs to be taken to reduce the risk and thus prevent harm to a consumer's health. Although action is separate from risk assessment, some points are raised here to illustrate the possible follow-up of identified risks.

Within market surveillance, action will often be taken in contact between the authority and the manufacturer, importer or distributor. This can help the authority to determine the most effective and efficient way of managing the risk.

With a serious risk in a consumer product, measures to reduce the risk may include withdrawal from the market or recall. 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 instructions to make the product safe. Thus, whatever the level of risk, the authority should consider whether to take action, and if so, what action.

Nevertheless, there is no automatic link from risk to action. When a 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 quickly. The pattern of risks in the product may indicate a lack of quality control in production[(14)].

It is also important to take account of exposure of the population as a whole. Where there are a large number of products on the market and the product is therefore used by a large number of consumers, even a single less-than-serious risk may require quick action to avoid adverse effects to the health of consumers.

Less-than-serious risks may also require action when the product concerned could cause fatal accidents, even though such accidents may be extremely unlikely. This could be the case with a fastening on a beverage container, which could come loose and be swallowed by a child, causing the child to choke to death. A simple change of design to the lid could eliminate the risk, and no further action might be required. Even a selling-off period may be granted if the risk of a fatal accident were indeed extremely small.

Other risk-related aspects may be the public perception of risk and its likely consequences, cultural and political sensitivities and how it is portrayed in the media. These aspects may be especially relevant when the consumers concerned are vulnerable, in particular children. It will be up to the national market surveillance authority(ies) to determine what measures are required.

Taking action to counteract a risk may also depend on the product itself and the ‘minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection’[(15)]. This minimum risk will probably be much lower for toys, where children are involved, than for a chain-saw, which is known to be so high-risk 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/legislation (e.g. incomplete markings).

In conclusion, there is no automatic link from risk to action. Surveillance authorities will take account of a range of factors such as those indicated in section 3.3. The principle of proportionality always has to be considered, and action has to be effective.

5. ***How to prepare a risk assessment — in brief*** U.K.

1. Describe the product and its hazard. U.K.

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

Is there only one hazard within the product? Are there several hazards? See table 2 for guidance. Identify the standard(s) or legislation applicable to the product.

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

2. Identify the type of consumer you want to include in your injury scenario with the hazardous product. U.K.

Start with the intended user and the intended use of the product for your first injury scenario. Take other consumers (See table 1) and uses for further scenarios.

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

Describe the steps to the injury(ies) clearly and concisely, without exaggerating the details (‘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 the injury scenario, consider the frequency and duration of use, hazard recognition by the consumer, whether the consumer is vulnerable (in particular children), protective equipment, the consumer's behaviour in the case of an accident, the consumer's cultural background, and other factors that you consider important for the risk assessment.

See section 3.3 and table 2 for guidance.

4. Determine the severity of the injury. U.K.

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

See table 3 for guidance.

5. Determine the probability of the injury scenario. U.K.

Assign a probability to each step of your injury scenario. Multiply the probabilities to calculate the overall probability of your injury scenario.

See left-hand side of table 4 for guidance.

6. Determine the risk level. U.K.

Combine the severity of the injury and the overall probability of the injury scenario and check the risk level in table 4.

7. Check whether the risk level is plausible. U.K.

If the risk level does not seem plausible, or if you are uncertain about the severity of injury(ies) or about the probability(ies), move them one level up and down and recalculate the risk. This ‘sensitivity analysis’ will show you whether the risk changes when your input changes.

If the risk level remains the same, you can be quite confident of 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 the plausibility of the risk level with experienced colleagues.

8. Develop several injury scenarios to identify the highest risk of the product. U.K.

If your first injury scenario identifies a risk level below the highest risk level set out in these guidelines, and if you think that the product may pose a higher risk than the one identified,

— select other consumers (including vulnerable consumers, in particular children);

— identify other uses (including reasonably foreseeable uses),

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

The highest risk is normally 'the risk' of the product that allows the most effective risk management measures. In specific cases, a particular hazard may lead to a less-than-highest risk and require specific risk management measures. This has to be taken duly into account.

As a rule of thumb, injury scenarios may lead to the highest risk level set out in these guidelines where:

— the injury(ies) considered are at least at levels 3 or 4; —

— the overall probability of an injury scenario is at least > 1/100.

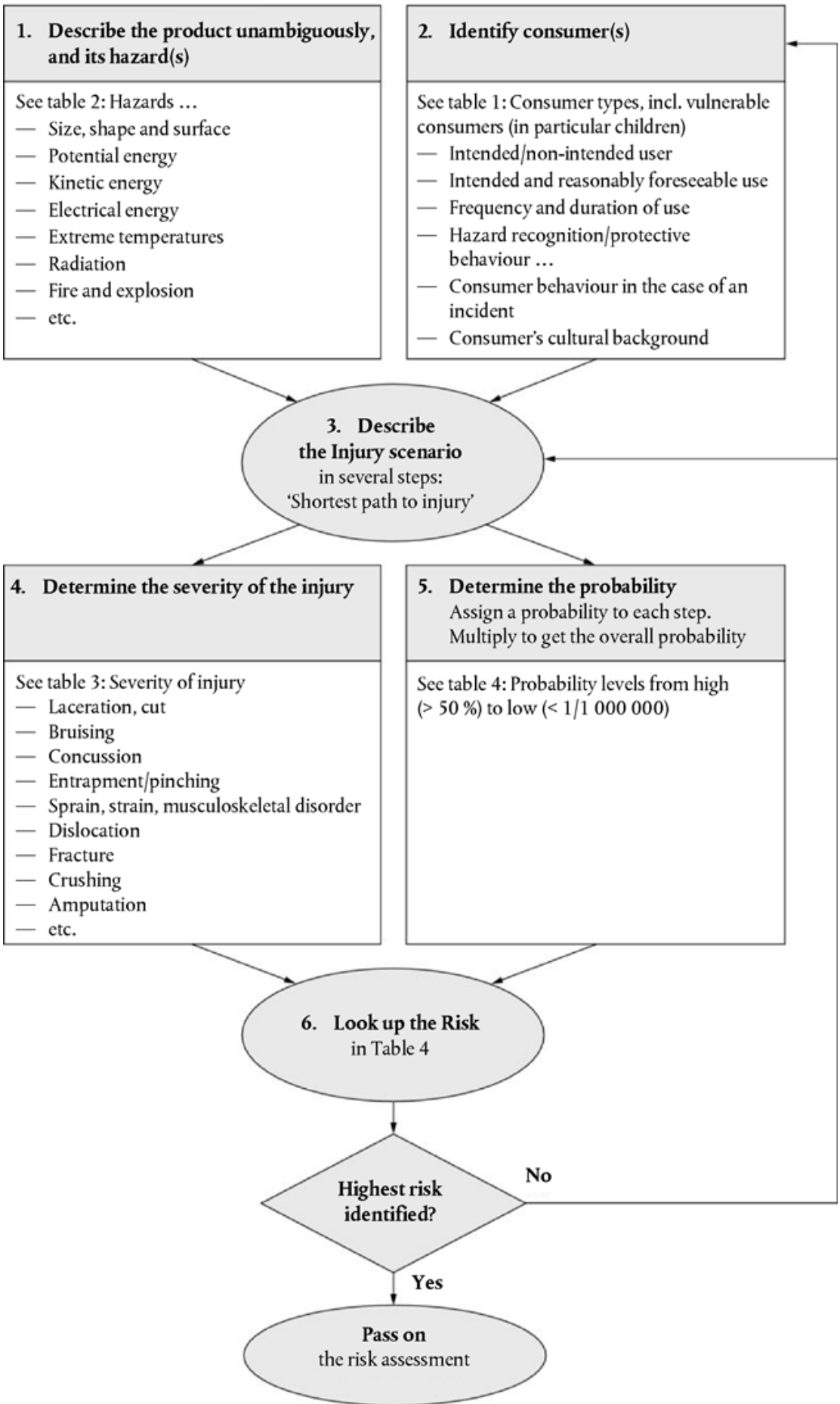
See table 4 for guidance.

9. Document and pass on your risk assessment. U.K.

Be transparent and also set out all the uncertainties that you encountered when making your risk assessment.

Examples for reporting risk assessments are provided in section 6 of these guidelines.

Schematic flow of risk assessment



6. *Examples* U.K.

6.1. Folding chair U.K.

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

DETERMINATION OF 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	1/500	Low risk
			Gripping the seat at back corner while unfolding	1/50		
			Finger gets caught	1/10	> 1/1 000	
			Minor pinching	1		
Person unfolds the chair, grips seat at the side by mistake (Person inattentive/	Minor pinching of finger	1	Unfolding the chair	1	1/500	Low risk
			Gripping the seat at the side while unfolding	1/50		

distracted), finger gets caught between seat and link			Finger gets caught	1/10	> 1/1 000	
			Minor pinching	1		
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	1/500 000	Low risk
			Chair clamps	1/1 000		
			Gripping the seat at corners while unfolding	1/50		
			Finger gets caught	1/10	> 1/1 000 000	
			Fracture of finger	1		
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	1/500 000	Low risk
			Chair clamps	1/1 000		
			Gripping the seat at the side while unfolding	1/50		
			Finger gets caught	1/10	> 1/1 000 000	
			Fracture of finger	1		
Person is sitting on chair, wants to move the chair and tries	Loss of digit	3	Sitting on chair	1	1/6 000	High risk
			Moves the chair while sitting	1/2		

to lift it by gripping the chair at the rear part of the seat, finger gets caught between seat and backrest			Grips chair at rear part while moving	1/2		
			Chair partially folds, creating a gap between the backrest and seat	1/3	> 1/10 000	
			Finger is between backrest and seat	1/5		
			Finger gets caught	1/10		
			Loss of (part of) finger	1/10		
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	1/6 000	High risk
			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	> 1/10 000	
			Finger is between backrest and seat	1/5		
			Finger gets caught	1/10		

			Loss of (part of) finger	1/10		

The overall risk of the folding chair is thus ‘high risk’.

6.2. Socket protectors U.K.

This case deals with socket protectors. These are devices that users (parents) put into the electrical socket outlets to stop small children from accessing live parts by putting a 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 through) are so narrow that the pins can get stuck. This means that the user may pull the protector off the outlet when the plug is pulled out. The user may not notice this happening.

DETERMINATION OF RISK(S)

Injury scenario	**Injury type and location**	**Severity of injury**	**Probability of injury**		**Overall probability**	**Risk**
Protector is removed from the socket, which becomes unprotected. Child is playing with thin conductible object, which can be inserted into the socket, accessing	Electrocution	4	Removal of protector	9/10	27/160 000	Serious risk
			Not noticing the removal of protector	1/10		
			Child is playing with thin conductible object	1/10		
			Child is unattended when playing	1/2	> 1/10 000	

high voltage and is electrocuted.			Child inserts the object into the socket	3/10		
			Access to voltage	1/2		
			Electrocution due to voltage (without circuit interrupter)	1/4		
Protector is removed from the socket, which becomes unprotected. Child is playing with thin conductible object, which can be inserted into the socket, accessing high voltage and sustains shock.	Burns 2nd degree	1	Removal of protector	9/10	81/160 000	Low risk
			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	> 1/10 000	
			Child is unattended when playing	1/2		
			Burn due to electric current (without circuit interrupter)	3/4		
Socket unprotected. Child is playing with thin conductible object, which can	Electrocution	4	Child is playing with thin conductible object	1/10	3/80 000	High risk
			Child is unattended	1/100		

be inserted into the socket, accessing high voltage and is electrocuted.			when playing			
			Child inserts the object into the socket	3/10		
			Access to voltage	1/2	> 1/100 000	
			Electrocution due to voltage (without circuit interrupter)	1/4		

The overall risk of the socket protectors is thus ‘serious’.

6.3. **Sensitivity analysis** U.K.

The factors used to calculate the risk of an injury scenario, namely the severity of the injury and the probability, often have to be estimated. This creates uncertainty. Probability in particular can be difficult to estimate, since the behaviour of consumers, for example, can be difficult to predict. Does a person 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 this analysis is to establish how much the risk level varies when the estimated factors vary. The example provided on the table below only shows the variation of probability, since the severity of the injury is usually predicted with more certainty.

A practical way of performing 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 can catch fire and generate high flames. Furniture or curtains can catch fire and persons 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	— Seeds or beans catch fire: 90 % (0,9) — People not in the room for	0 00675 > 1/1 000	Serious

			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)	

The probability levels for the steps in the scenario were estimated as shown in the table.

The overall probability is 0,00675, which corresponds to > 1/1 000 in table 4. This leads to the conclusion of '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 4 than the > 1/1 000 row suggests.

Suppose we are uncertain about the 5 % probability that persons inhale the toxic fumes. We could put it at a much lower 0,1 % (0 001 = 1 in a thousand). If we recalculate with that assumption, the overall probability is 0,000135, which translates into > 1/10 000. Nevertheless, the risk is still serious. Even if for some reason the probability were to be 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 lets us confidently assess the risk as serious.

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

TABLE 1

Consumers

Consumers	Description
Very vulnerable consumers	Very young children: 0 to 36 months Others: Persons with extensive and complex disabilities

Vulnerable consumers	Young children: Children older than 36 months and younger than 8 years. Older children: Children 8 to 14 years Others: Persons with reduced physical, sensory or mental capabilities (e.g. partially disabled, elderly, including those over 65, with some reduction in their physical and mental capabilities), or lack of experience and knowledge
Other consumers	Consumers other than very vulnerable or vulnerable consumers

TABLE 2

Hazards, typical injury scenarios and typical injuries

Hazard group	Hazard(product property)	Typical injury scenario	Typical injury
Size, shape and surface	Product is obstacle	Person trips over product and falls; or person bumps into product	Bruising; fracture, concussion
	Product is impermeable to air	Product covers mouth and/or nose of a person (typically a child), or covers internal airway	Suffocation
	Product is or contains small part	Person (child) swallows small part; the part gets stuck in larynx and blocks airways	Choking, internal airway obstruction
	Possible 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 bumps into 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 the skin or cuts through tissues	Laceration, cut; amputation

NB: This table is for guidance only; the typical injury scenarios should be adapted when preparing a risk assessment. There is specific risk assessment guidance for chemicals, cosmetics and possibly others. It is highly recommended to use this specific guidance when assessing such products. See section 3.2.

	Slippery surface	Person walks on surface, slips and falls	Bruising; fracture, concussion
	Rough surface	Person slides along rough surface; this causes friction and/or abrasion	Abrasion
	Gap or opening between parts	Person puts a limb or body in opening and finger, arm, neck, head, body or clothing is trapped; injury occurs due to gravity or movement	Crushing, fracture, amputation, strangulation
Potential energy	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, concussion; 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, concussion; 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, concussion; crushing
	Elastic element or spring	Elastic element or spring under tension is suddenly released;	Bruising; dislocation; fracture, concussion; crushing

NB: This table is for guidance only; the typical injury scenarios should be adapted when preparing a risk assessment. There is specific risk assessment guidance for chemicals, cosmetics and possibly others. It is highly recommended to use this specific guidance when assessing such products. See section 3.2.

		person in the line of movement is hit by the product	
	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, concussion; crushing; cuts (see also under fire and explosion)
Kinetic Energy	Moving product	Person in the line of movement of the product is hit by the product or run over	Bruising; sprain; fracture, concussion; 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
	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	Dislocation; fracture, concussion; crushing

NB: This table is for guidance only; the typical injury scenarios should be adapted when preparing a risk assessment. There is specific risk assessment guidance for chemicals, cosmetics and possibly others. It is highly recommended to use this specific guidance when assessing such products. See section 3.2.

		support to hold on to and falls with some speed	
	Flying objects	Person is hit by the flying object and depending on the energy sustains injuries	Bruising; dislocation; fracture, concussion; crushing
	Vibration	Person holding the product loses balance and falls; or prolonged contact with vibrating product causes neurological disorders, osteoarticular 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 touches 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

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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
	High intensity electromagnetic field (EMF) source; low frequency or high frequency (microwave)	Person is close to the electromagnetic field (EMF) source, body (central nervous system) is exposed	Neurological (brain) damage, leukaemia (children)
Fire and explosion	Flammable sub stances	Person is near the flammable substance; an ignition source sets the substance on fire; this causes injuries to the person	Burn
	Explosive mixtures	Person is near the explosive mixture;	Burn, scald; eye injury, foreign body

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		an ignition source causes an explosion; the person is hit by the shock wave, burning material and/or flames	in eye; hearing injury, foreign body in ear
	Ignition sources	The ignition source causes a fire; a person is injured by flames, or intoxicated by gases from the house fire	Burn; poisoning
	Overheating	Product overheats; fire, explosion	Burn, scald; eye injury, foreign body in eye; hearing injury, foreign body in ear
Toxicity	Toxic solid or fluid	Person ingests substance from product, e.g. by putting it in mouth, and/or substance gets on skin	Acute poisoning; irritation, dermatitis
		Person breathes in solid or fluid, for example vomited material (pulmonary aspiration)	Acute poisoning in lungs (aspiration pneumonia); infection
	Toxic gas, vapour or dust	Person inhales substance from product; and/or substance gets on skin	Acute poisoning in lungs; irritation, dermatitis
	Sensitising substance	Person ingests substance from product, e.g. by putting it in mouth; and/or substance gets on skin; and/or person inhales gas, vapour or dust	Sensitisation; allergic reaction
	Irritating or corrosive solid or fluid	Person ingests substance from product,	Irritation, dermatitis; skin burn; eye injury, foreign body in eye

NB: This table is for guidance only; the typical injury scenarios should be adapted when preparing a risk assessment. There is specific risk assessment guidance for chemicals, cosmetics and possibly others. It is highly recommended to use this specific guidance when assessing such products. See section 3.2.

		e.g. by putting it in mouth, and/or substance gets on skin or in eyes	
	Irritating or corrosive gas or vapour	Person inhales substance from product, and/or substance gets on skin or in eyes	Irritation, dermatitis; skin burn; acute poisoning or corrosive effect in lungs or in eyes
	CMR substance	Person ingests substance from product, e.g. by putting it in mouth, and/or substance gets onto skin; and/or person inhales substance as gas, vapour or dust	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
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,	Various injuries

NB: This table is for guidance only; the typical injury scenarios should be adapted when preparing a risk assessment. There is specific risk assessment guidance for chemicals, cosmetics and possibly others. It is highly recommended to use this specific guidance when assessing such products. See section 3.2.

	which leads to unwanted operation	
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 becomes loose during use	Sprain or strain; laceration, cut; bruising; entrapment
Missing or incorrectly fitted protection	Hazardous parts are reachable for a per son	Various injuries
Insufficient warning instructions, signs and symbols	User does not notice warning instructions signs and/or does not understand symbols	Various injuries
Insufficient warning signals	User does not see or hear warning signal (optical or audio), causing dangerous operation	Various injuries

NB: This table is for guidance only; the typical injury scenarios should be adapted when preparing a risk assessment. There is specific risk assessment guidance for chemicals, cosmetics and possibly others. It is highly recommended to use this specific guidance when assessing such products. See section 3.2.

Table 3 **Severity of injury** U.K.

Introduction

These risk assessment guidelines distinguish between four levels of injury harm severity. It is important to realise that severity should be assessed completely objectively. 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 harm that could easily have been avoided will be difficult to accept for a consumer. However, authorities can justifiably invest more effort into avoiding irreversible consequences than into preventing temporary discomfort.

In order to assess the severity of the 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 to 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. Harm or consequence 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.

2. Harm or consequence 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.

3. Harm or consequence that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function.

4. Harm or consequence that is or could be fatal, including brain death; consequences that affect reproduction or offspring; severe loss of limbs and/or function, leading to more than approximately 10 % of disability.

The following table, which should be considered as a guide rather than prescriptive or complete, provides examples of injuries at all four levels. National differences may exist, either cultural or caused by different systems of health care and financial arrangements. However, deviating from the proposed classification in the table will affect uniform assessment of risks in the EU; this should be clearly stated and explained in the risk assessment report, and reasons should be given.

Type of injury	**Severity of injury**			
	1	**2**	**3**	**4**
Laceration, cut	Superficial	External (deep) (> 10 cm long on body) (> 5 cm 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/	Superficial ≤ 25 cm^2 on face	Major > 25 cm^2 on face	Trachea	Brain stem

contusion, swelling, oedema)	≤ 50 cm^2 on body	> 50 cm^2 on body	Internal organs (minor) Heart Brain Lung, with blood or air in chest	Spinal cord causing paralysis
Concussion	—	Very short unconsciousness (minutes)	Prolonged unconsciousness	Coma
Entrapment/ pinching	Minor pinching	—	(Use as appropriate the final outcomes of bruising, crushing, fracture, dislocation, amputation, as applicable.)	(Same outcome as for 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
Crushing	—	—	Extremities (fingers, toe, hand, foot) Elbow Ankle Wrist	Spinal cord Mid-low neck Chest (massive crushing) Brain stem

			Forearm Leg Shoulder Trachea Larynx Pelvis	
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 Deep injuries in organs (liver, kidney, bowel, etc.)
Ingestion	—	—	Internal organ injury (Refer also to internal airway obstruction where the ingested object gets stuck high in the oesophagus.)	Permanent damage to internal organ
Internal air way 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 (by heat, cold, or chemical substance)	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	—
Eye injury, foreign body in eye	Temporary pain in eye without need for treatment	Temporary loss of sight	Partial loss of sight Permanent loss of sight (one eye)	Permanent loss of sight (both eyes)
Hearing injury, foreign body in ear	Temporary pain in ear without need for treatment	Temporary impairment of hearing	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	Mild or local allergic reaction	Allergic reaction, 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 nervous system, e.g. Organic Psycho Syndrome (OPS; also called Chronic Toxic	Cancer (leukaemia) Effects on reproduction Effects on offspring CNS depression

			Encephalopathy, also known as 'painters' disease'). Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nervous system	
Microbiological infection		Reversible damage	Irreversible effects	Infection requiring prolonged hospitalisation, antibiotics-resistant organisms Fatality

TABLE 4

Risk level from the combination of the severity of injury and probability

Probability of damage during foreseeable lifetime of the product		**Severity of injury**			
		1	**2**	**3**	**4**
High	>50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1 000	L	H	S	S
	> 1/10 000	L	M	H	S
	> 1/100 000	L	L	M	H
	> 1/1 000 000	L	L	L	M
Low	< 1/1 000 000	L	L	L	L

S — Serious Risk

H — High risk

M — Medium risk

L — Low risk
Glossary of terms

Hazard	:	Source of danger involving the chance of being injured or harmed. A means of quantifying the hazard in a risk assessment is the severity of the possible injury or harm.
Product hazard	:	Hazard created by the properties of a product.
Risk	:	Balanced combination of a hazard and the probability that damage will occur. Risk describes neither the hazard, nor the probability, but both at the same time.
Risk assessment	:	Procedure for identifying and assessing hazards, consisting of three steps: 1. identification of the seriousness of a hazard; 2. determination of the probability that a consumer will be injured by that hazard; 3. combination of the hazard with the probability.
Risk level	:	Degree of risk, which may be ‘serious’, ‘high’, ‘medium’ and ‘low’. When the (highest) level of risk has been identified, the risk assessment is complete.
Risk management	:	Follow-up action, which is separate from risk assessment and aims to reduce or eliminate a risk.

(**1**) If you need more information on the Risk Assessment method for harmonised products (both consumer and professional products) in relation to broader categories of public risks protected under EU harmonisation legislation, please refer to Part I, Chapter 5.3.

(**2**) Benis HG (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.

(**3**) Method used by the 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.

(**4**) Commission Decision 2004/418/EC of 29 April 2004 laying down guidelines for the management of the EU Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC (OJ L 151, 30.4.2004, p. 83).

(**5**) Directive 2001/95/EC.

(**6**) https://webgate.ec.europa.eu/idbpa/.

(**7**) NB: uncertainty always has to be taken into account when comparing a test result with a limit. See, for example:

- the 'Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation …' https://ec.europa.eu/food/safety/chemical_safety/contaminants/catalogue_en
- the Summary report on the 'Preparation of a working document in support of the uniform interpretation of legislative standards and the laboratory quality standards prescribed under Directive 93/99/EEC'. http://ec.europa.eu/food/fs/scoop/9.1_sr_en.pdf

(**8**) 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, p. 1).

(**9**) OJ L 164, 26.6.2009, p. 7.

(**10**) Standard EN 71-1:2005, section 8.2 +A6:2008.

(**11**) Article 10 of Regulation (EC) No 1223/2009 (OJ L 342, 22.12.2009, p. 59).

(**12**) REACH Regulation and guidance documents on REACH, see http://echa.europa.eu/ European Chemicals Agency (2008). The Guidance on Information Requirements and Chemical Safety Assessment: http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm

(**13**) Commission Implementing Decision 2013/674/EU of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 315, 26.11.2013, p. 82); SCCS (Scientific Committee on Consumer Safety), SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 9th revision, 29 September 2015, SCCS/1564/15, revision of 25 April 2016: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_190.pdf

(**14**) See Part I Chapter 1.1, penultimate paragraph.

(**15**) This is taken from the definition of 'safe product' in Article 2(b) of Directive 2001/95/EC.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2019/417, RISK ASSESSMENT GUIDELINES FOR CONSUMER PRODUCTS.