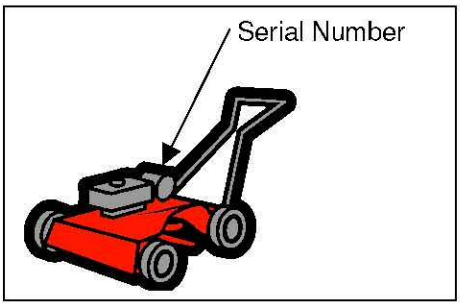
Annex A - Example of a good Corrective Action announcement

The following example has been created to illustrate the main features that should be incorporated into a good Corrective Action announcement. **The information in this example is not intended to refer to any real product or company.**

- A suitable heading → **IMPORTANT SAFETY WARNING**
- Product type → GREENGRASS LAWN MOWERS
- Model → Model – GG 123
- Picture → 

- Location of serial number →
- Details of problem and when batch was sold → We have become aware that some GG123 lawnmowers, sold between 1 March 2002 and 30 July 2002 have a manufacturing defect.
- Hazard → This defect may cause the handle to break under heavy load, at the joint with the frame, possibly leading to serious injury
- How to check for affected product → If you own a GG123 mower, please check the serial number as shown in the diagram.
- Identification → The models affected have serial numbers from X5761 to X5874 or Z2376 to Z3199 (inclusive) and were sold in **Smiths Homestores**, **Barney's Gardenware** and also through the **GreenGrass** Mail Order Catalogue.
- Sales outlets → **Gardenware** and also through the **GreenGrass** Mail Order Catalogue.
- Further action to take → If you have an affected mower please **stop using it immediately.** Please return it to the retailer it was purchased from for a replacement mower or a full refund of the purchase price.
- Redress offered → return it to the retailer it was purchased from for a replacement mower or a full refund of the purchase price.
- Free Helpline → If you have any queries please do not hesitate to contact GreenGrass on **Freephone 0800 1234 5678 (24 hrs)**
- Apologies (if appropriate) → We wish to thank you for your co-operation and apologise for any inconvenience.
- Company responsible for recall → **GreenGrass & Co, 10 Central Rd, Europa Trading Estate, Newchester, United Kingdom WW1 2GG**
- Contact details → **www.greengrassmowers.com/productrecall**

In some non European Countries, e.g. Australia, the law foresees that a specific form is to be used for recalls.

The recall form foreseen by the Australian law can be found under the following link: *http://www.recalls.gov.au/content/index.phtml/itemId/952922*

Annex B - European Information Sources

Task D Note: all references will be verified before final draft for printing is prepared.

All references and web addresses to be verified and confirmed before the final draft is made.

DIRECTIVES

General Product Safety

- 2001/95/EC - General Product Safety Directive (GPSD)

  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0095:EN:NOT

- Guidelines for the notification of dangerous consumer products by producers and distributors to the competent authorities in the Member States under the Directive on general product safety: DG SANCO 3/04

  http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/notification_dang_en.pdf

- Guidance Document on the relationship between the General Product Safety Directive (GPSD) and certain sector Directives with provisions on product safety. DG SANCO 11/03.

  http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/gpsd_2ndchapiter_en.pdf

- Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive)

  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:022:0001:0064:EN:PDF

SECTOR-SPECIFIC DIRECTIVES

- http://ec.europa.eu/enterprise/sectors/toys/safety/
- http://ec.europa.eu/consumers/sectors/cosmetics/
- http://ec.europa.eu/enterprise/sectors/maritime/recreational-craft/
- http://ec.europa.eu/enterprise/sectors/mechanical/personal-protective-equipment/
- http://ec.europa.eu/enterprise/sectors/electrical/lvd/
- http://ec.europa.eu/enterprise/sectors/mechanical/machinery/index_en.htm

Note: For some of the above mentioned sectors (e.g. Machinery or LVD) there may be Guides developed by the relevant Unit to help the reader to understand better the contents of the legislative tool.

SAFETY STANDARDS

For information about standards that are applicable to your products reference should be made to national/European standards organisations. Contact details are given on the following websites:

- http://www.iso.org
- http://www.cen.eu
- http://www.iec.ch
- http://www.cenelec.eu

PRODUCT SAFETY GUIDELINES

- Guide to the implementation of directives based on the New Approach or the Global Approach. European Commission 2000

  http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf

BEST PRACTICES IN MARKET SURVEILLANCE

- Guidelines on the best practices adopted for the market Surveillance by Authorities in Europe

  http://www.prosafe.org/default.asp?itemID=16&itemTitle=undefined

RISK ASSESSMENT

- ISO Guide 73:2009 Risk management - Vocabulary
- ISO 31000:2009 Risk management — Guidelines on principles and implementation of risk management
- ISO/IEC 31010:2009 Risk management - Risk assessment techniques
- ISO/IEC Guide 116:2008 - Guidelines for safety related risk assessment and risk reduction for low voltage equipment
- EN-ISO 12100:2010 - Safety of machinery - General principles for design - Risk assessment and risk reduction ;
- ISO/TR 14121-2 Safety of machinery - Risk assessment - Part 2: Practical guidance and examples of methods

QUALITY MANAGEMENT

- EN ISO 9001:2008 - Quality Management Systems- Requirements
- BS 8600:1999 – Complaints Management Systems. Guide to design and implementation

INFORMATION SOURCES at the European Commission

- European Union legislation

  http://eur-lex.europa.eu/en/index.htm
- DG Enterprise

  http://ec.europa.eu/enterprise/
- Enterprise Europe Network

  http://www.enterprise-europe-network.ec.europa.eu/index_en.htm
- DG Health and Consumer Protection

  http://ec.europa.eu/dgs/health_consumer/index_en.htm
- DG Trade

  http://ec.europa.eu/trade/
- New Approach Standardisation in the Internal Market

  www.newapproach.org
- New Legislative framework

  http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common rules-for-products/new-legislative-framework/index_en.htm

Annex C - National Market Surveillance Authorities

Task D Note: all references will be verified before final draft for printing is prepared

The organisations below mentioned are the main contacts for market surveillance in each of the countries concerned. In some countries, the responsibility for some aspects of market surveillance is delegated to the regional organisations.

An up to date list of contacts can be found under the following link:
http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/index_en.htm

The EU Commission keeps the information listed updated.

The coordination of the Market surveillance activity is done by the bodies listed in the following table:

Country	Body	Contact data
AUSTRIA	Bundesministerium für Wirtschaft und Arbeit www.bmwa.gv.at	
BELGIUM	FOD Economie, KMO, Middenstand en Energie www.mineco.fgov.be	
CYPRUS	Ministry of Commerce, Industry & Tourism http://www.mcit.gov.cy/	
CZECH REPUBLIC	Česká obchodní Inspekce www.coi.cz	
DENMARK	Sikkerhedsstyrelsen www.sikkerhedsstyrelsen.dk	
ESTONIA	www.consumer.ee	
FINLAND	• Kuluttajavirasto -www.kuluttajavirasto.fi • TUKES – Turvatekniikan keskus www.tukes.fi	
FRANCE	• Ministère de l'Economie, des Finances et de l'Industrie (MINEFI) www.minefi.gouv.fr • Direction générale de la concurrence, de la consommation et de la répression des fraudes (DGCCRF) ww.finances.gouv.fr/DGCCRF	Unité d'alerte : Email address : Unite-d-alerte-dgccrf@dgccrf.finances.gouv.fr
GERMANY	Bundesministerium für Wirtschaft und Arbeit (BMWA) www.bmwi.de	
GREECE	Ministry of Development www.ypan.gr/structure/index_uk.htm	
HUNGARY	• www.fvf.hu • Nemzeti Fogyasztóvédelmi Hatóság www.nfh.hu	
ISLAND	Consumer Agency www.neytendastofa.is	
IRELAND	Office of the Director of Consumer Affairs (ODCA) www.odca.ie	
ITALY	Ministero delle Attività Produttive www.minindustria.it	

LATVIA	Consumer Rights Protection Centre www.ptac.gov.lv	
LITHUANIA	The State Non Food Products Inspectorate under the Ministry of Economy of the Republic of Lithuania (Valstybinė ne maisto produktų inspekcija prie Lietuvos Respublikos Ūkio ministerijos) www.vnmpi.lt	Email address : rastine@vnmpi.lt
LUXEMBOURG	Direction de la Concurrence et de la Protection des consommateurs (DCP) www.eco.public.lu/activites/direction_concurrence/index.html	
MALTA	Ministry of Finance and Economic Affairs -Market Surveillance Directorate www.gov.mt	
NETHERLANDS	Niuewe Voedsel en Waren Autoriteit www.vwa.nl	
NORWAY	Directorate for Civil Protection and Emergency Planning (DSB) www.dsb.no/en/	
POLAND	Urzad Ochrony Konkurencji I Konsumentów www.uokik.gov.pl	
PORTUGAL	• Inspecção-Geral das Actividades Económicas (IGAE) www.igae.pt • Instituto do Consumidor www.ic.pt	
SLOVAKIA	www.economy.gov.sk	
SLOVENIA	Tržni inšpektorat Republike Slovenije www.tirs.si	
SPAIN	Instituto Nacional del Consumo (INC) seguridad@consumo-inc.es	
SWEDEN	• Konsumentverket KO www.konsumentverket.se • Elsäkerhetsverket www.elsak.se	
TURKEY		
SWITZERLAND	Federal Department of economic affairs (FDEA) www.evd.admin.ch	
UNITED KINGDOM	Local Authorities Coordinators of Regulatory Services (LACORS) www.lacors.gov.uk	

Annex D – Contributors

This Guide was produced as a result of a project funded by the financial contributions and contributions in kind from some Members States and a grant from the European Commission through the EMARS project (Enhancing Market Surveillance through Best Practices). The project was carried out by a specific group called *Task D – Revision of CAG set up under the frame of the EMARS II project*.

Its main scope was to review and update the first Edition of the Corrective Action Guide that was published in 2004.

The following authorities and organisations took active part in the development of the Guide:

National Market Surveillance Authorities

- **Netherlands -** Ministry for Health, Welfare and Sport – New Food and Consumer Product Safety Authority (Niuewe Voedsel en Waren Autoriteit nVWA) www.vwa.nl
- **UK** - Department of Trade & Industry, Consumer and Competition Policy Directorate www.dti.gov.uk/ccp
- **Czech Republic -** National Institute of Public Health (NIPH) http://www.szu.cz
- **PROSAFE** - Product Safety Enforcement Forum of Europe (The network of European authorities responsible for market surveillance of consumer products)www.prosafe.org .

Organisations contributing to the project

- **ANEC -** The European consumer voice in standardisation www.anec.org
- **EuroCommerce** – The Retail, Wholesale and International Trade Representation to the EU www.eurocommerce.be
- **IFIA -** International Federation of Inspection Agencies
- **ORGALIME -** The European Engineering Industries Association representing the interests of the Mechanical, Electrical, Electronic, Metalworking & Metal Articles Industries. www.orgalime.org

Representatives of the following companies have also participated in the development of the Guide

- **Hogan Lovells -** Law firm www.hoganlovells.com
- **Laffineur** - Law firm www.laffineur.com
- **Product IP -** Internet based platform for the creation, management and sharing of technical compliance files www.productip.com

Annex E - Risk Estimation and Evaluation

E.1 Assessing the risk

An abstract of the contents of the Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive), Art 5 Part IV, is given as follows.

This is only a summary and reference should be made to the methodology set out in the Commission Decision 2010/15/EU.

Although the Decision is directed at Member States in assessing product risks on their markets, it will be prudent for producers to take it into account when conducting their own risk assessment.

It is recommended that a small team who have knowledge and experience of the product and its hazards carries out the Risk Assessment. Assessors may have to make subjective judgements if objective data is not available and it is hoped this procedure will help them to make consistent and reasoned judgements about actual or potential risks.

The assessment team should take the following approach:

a) **Describe the product unambiguously**. Does the hazard concern the entire product or only a (detachable) part of the product? Is there only one hazard concerning the product? Are there several hazards?

When performing this verification, the standards or the legislation applicable to the product should be taken into consideration.

See Table 1 for guidance on identification of the hazard

b) **Identify the type of consumer** you want to include in your injury scenario with the hazardous product. Start with the intended user and the intended use of the product. Afterwards, for further scenarios, select other consumers (See Table 2 for guidance) and different uses of the product.

It should be considered that much higher risks are acceptable in some circumstances, such as driving cars, than with others, such as children's toys. The main factors that affect the acceptability are:

- The vulnerability of the type of person affected, and
- For normal adults, whether the product has adequate warnings and guards, and whether the hazard and the ways to mitigate it are sufficiently obvious, with due consideration to the consumer's local and cultural environment.

For products such as knives, DIY and garden tools not intended or not likely to be used by children and elderly people, consumers could be lead to manage a certain level of risk provided that:

- The hazard is obvious and necessary for the product's use;
- The product has adequate warnings and/or instructions for a safe use;
- The product has adequate guards and/or personal protective equipment is provided.

c) **Describe an injury scenario,** in which the product hazard you have selected causes injuries or adverse health effects to the consumer you have chosen.

Describe the steps to the injury 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.

Consider the frequency and duration of use, the 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 injury to happen.

d) **Determine the severity of the possible injury.**

Determine the level of severity (1 to 4) of the possible injury to the consumer. (See Table 3 for guidance.)

If the consumer suffers from several injuries in your injury scenario, estimate the severity of all those injuries together.

For many scenarios, it is possible to envisage unlikely injuries that could result from a hazard e.g. tripping over a cable, which causes a fall and a bang on the head, leading to death. However, it is more likely that a less serious outcome will occur. For this reason, the severity of the injury resulting from a given hazard should be based on reasonable evidence that the injury attributable to the product could eventually appear. This could be the worst case for injuries that have occurred with similar products.

It is important to realise that the severity should be assessed as much as possible objectively. The aim is to determine the severity of different scenarios, not to judge the acceptability of an injury. Any injury that could easily have been avoided will be difficult to accept for a consumer.

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

e) **Determine the probability of the injury scenario.**

Assign a probability to each step of your injury scenario. (See Table 4 for guidance.) Multiply the probabilities to calculate the overall probability of your injury scenario.

When assessing the probability, the assessment team should take account of the following information:

- Statistics (where available) for the:
  - Failures of this or similar products;
  - Typical use of the product type;
  - Accidents that have occurred for this or similar products.
- Predictions based on the understanding of
  - Product failure modes;
  - Typical exposure of users of the type of product;
  - Behaviour of users which can lead to accidents.

Most risk assessments are likely to be based on a combination of the above sources of information and it is recognised that the accuracy of the assessment will depend on the quality of statistical information and the judgement of the assessors.

f) **Overall assessment: determine the risk level.**

Combine the severity of the injury and the overall probability of the injury scenario by reading the risk level from a table (See Table 5 for guidance). The following four basic levels of risk can be detected:

- Serious Risk – normally requiring immediate action

- High risk – normally requiring rapid action
- Medium risk – normally requiring some action
- Low risk - not generally requiring action for products on the market, but it may require changes to the design of the product, or to manufacturing or quality control processes.

This procedure evaluates the individual risk level for the individual user of the product and it is this risk that should be the main factor in deciding whether to take Corrective Action. However, a producer may also wish to take other factors (such as the total number of consumers affected) into account when deciding what action to take. Taking action is however not part of the risk assessment, but of the risk management.

g) **Check whether the risk level is plausible**.

If the risk level does not seem plausible, or if you are uncertain about the severity of injuries or about the probabilities, move the probability level and the severity level one level up and down and recalculate the risk. This 'sensitivity analysis' described further below 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, as well as comparing it with the actual experience with the product on the ground, if sufficient and reliable data is available.

h) **Develop several injury scenarios to identify the highest risk of the product**.

If your first injury scenario identifies a risk level below the highest risk level set out in these guidelines, or 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.

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

- the injuries considered are at least at levels 3 or 4 (see Table 3);
- the overall probability of an injury scenario is at least > 1/100.

See Table 5 for guidance.

i) **Document and pass on your risk assessment**.

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

The following chart shows a schematic flow on the risk assessment process as described above.

An example for a risk assessment is given in F.2.

Schematic flow of risk assessment

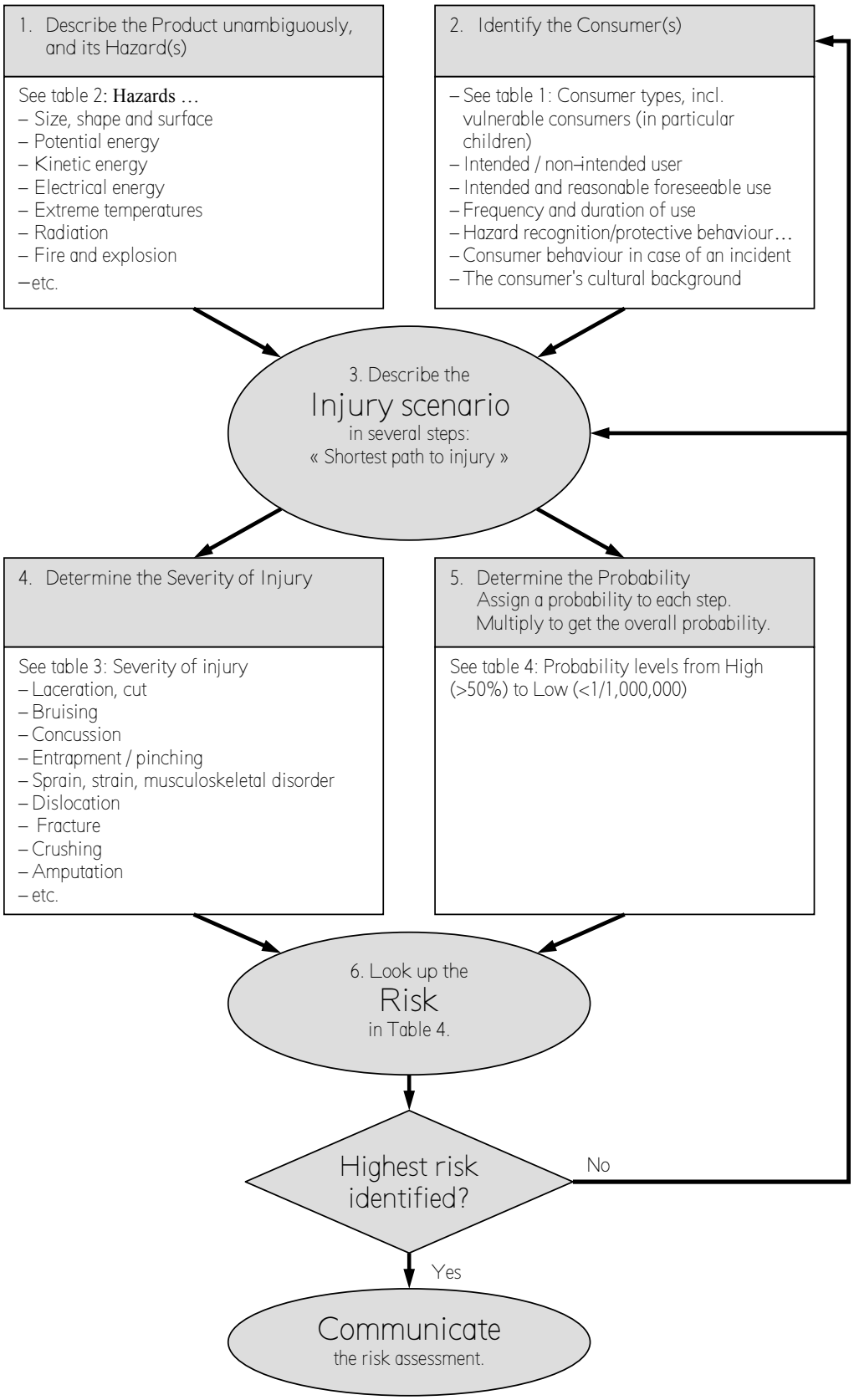


Table 1 - Hazards, typical injury scenarios and typical injuries

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
	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; person in the line of movement is hit by the product	Bruising; dislocation; fracture, concussion; crushing
	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)

Hazard group	*Hazard (product property)*	*Typical injury scenario*	*Typical injury*
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 support to hold on to and falls with some speed	Dislocation; fracture, concussion; crushing
	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, osteo-articular disorder, trauma of the spine, vascular disorder	Bruising; dislocation; fracture; crushing
	Noise	Person is exposed to noise from the product. Tinnitus and hearing loss may occur depending on sound level and distance	Hearing injury
Electrical energy	High/low voltage	Person 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
Extreme temperatures	Open flames	Person near the flames may sustain burns, possibly after his/her 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

Hazard group	*Hazard (product property)*	*Typical injury scenario*	*Typical injury*
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 substances	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; an ignition source causes an explosion; the person is hit by the shock wave, burning material and/or flames	Burn, scald; eye injury, foreign body 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, e.g. by putting it in mouth, and/or substance gets on skin or in eyes	Irritation, dermatitis; skin burn; eye injury, foreign body in eye
	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

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

Table 2 – Consumers

Consumers	*Description*
Very vulnerable consumers	Very young children: 0 to 36 months 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 3 – Severity of injury

Level of injury	Consequence
1	Injury 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	Injury 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	Injury or consequence that normally requires hospitalisation and will affect functioning for more than 6 months or lead to a permanent loss of function.
4	Injury or consequence that is or could be fatal, including brain death; consequences that affect reproduction or offspring; severe loss of limbs and/or function, leading to more than approximately 10 % of disability.

See RAPEX Guidelines for more details.

Table 4 - Probability

Probability of damage during the foreseeable lifetime of the product	
High	> 50 %
	> 1/10
	> 1/100
	> 1/1 000
	> 1/10 000
	> 1/100 000
	> 1/1 000 000
Low	< 1/1 000 000

Table 5 - Risk level

Probability of damage during the 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

Sensitivity analysis

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 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 some time: 30 % (0.3). Furniture or curtains catch fire: 50 % (0.5) (depends on surface on which candle is placed) Persons inhale toxic fumes: 5 % (0.05).	0.00675 >1/1 000	Serious

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.

A support tool for carrying out a risk assessment has been developed by a Group of experts under DG SANCO and is available under:

http://europa.eu/sanco/rag/public/index.cfm?event=home&CFID=2326069&CFTOKEN=1aaf08c156deb9a1-AB6984BC-00D5-CC39-1B1D7850D7A28FEB&jsessionid=3602556e768c3d1cb4fdTR

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

E.2 Example

Folding chair

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

Injury scenario	Injury type and location	Severity of injury	Probability of injury		Overall probability	Risk
Person unfolds the chair, chair is clamped, person tries to push down the seat and grips seat close to the corner by mistake (Person inattentive/distracted), finger gets caught between seat and backrest	Fracture of finger	2	Unfolding the chair Chair clamps Gripping the seat at corners while unfolding Finger gets caught Fracture of finger	1 1/1 000 1/50 1/10 1	1/500 000 >1/1 000 000	Low risk
Person unfolds the chair, chair is clamped, person tries to push down the seat and grips seat at the side by mistake (Person inattentive/distracted), finger gets caught between seat and link	Fracture of finger	2	Unfolding the chair Chair clamps Gripping the seat at the side while unfolding Finger gets caught Fracture of finger	1 1/1 000 1/50 1/10 1	1/500 000 >1/1 000 000	Low risk
Person is sitting on chair, wants to move the chair and tries to lift it by gripping the chair at the rear part of the seat, finger gets caught between seat and backrest	Loss of digit	3	Sitting on chair Moves the chair while sitting Grips chair at rear part while moving Chair partially folds, creating a gap between the backrest and seat Finger is between backrest and seat Finger gets caught Loss of (part of) finger	1 1/2 ½ 1/3 1/5 1/10 1/10	1/6 000 > 1/10 000	High risk
Person is sitting on chair, wants to move the chair and tries to lift it by gripping the chair at the rear part of the seat, finger gets caught between seat and link	Loss of digit	3	Sitting on chair Moves the chair while sitting Grips chair at rear part while moving Chair partially folds, creating a gap between the backrest and seat Finger is between backrest and seat Finger gets caught Loss of (part of) finger	1 1/2 1/2 1/3 1/5 1/10 1/10	1/6 000 >1/10 000	High risk

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