Consumer Product Safety in Europe

CORRECTIVE ACTION GUIDE

EMARS II

Guidelines for Businesses to manage Product Recalls & Other Corrective Actions

PROSAFE Joint Actions Best Practice

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Czeck Republic - National Institute of Public Health

www.szu.cz

Netherlands – New Food and Consumer Product Safety Authority (Nieuwe Voedsel en Waren Autoriteit) www.vwa.nl

UK –Department of Business Innovation and Skills (former DTI) www.bis.gov.uk/

PROSAFE – Product Safety Enforcement Forum of Europe www.prosafe.org

EuroCommerce – The Retail, Wholesale and International Trade Representation to the EU www.eurocommerce.be

ORGALIME - The European Engineering Industries Association representing the interests of the Mechanical, Electrical, Electronic, Metalworking & Metal Articles Industries. www.orgalime.org

ANEC - the European consumer voice in standardisation

www.anec.org

Disclaimer

This guide is not legally-binding. It represents a synthesis of the information and experience available to the Commission. It is intended as a summary of business practices on product recall and other corrective actions. The guide is not intended to be a rigid set of rules to be followed in all circumstances.

The mere fact that there is so much diversity between companies across the EU means that no one solution is applicable or appropriate for all situations.

The guide should be seen more as a description of the process and a reminder of the key elements that could be considered when considering a product recall or any other corrective action for product placed on the market in application of Directive 2001/95/EC (the General Product Safety Directive) at local levels.

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Foreword

This revision of the voluntary Guide for carrying out Corrective Actions for product safety, which was originally published in April 2004, was undertaken by PROSAFE through the EMARS (Enhancing Market Surveillance through Best Practices) project.

This project, which has been financially supported by the European Commission, has shown that cooperation between the representatives of Market Surveillance Authorities and representatives of organisations representing the main interested parties (see Annex D) can be beneficial and can also boost the overall performance of Market Surveillance activities with advantages for all the stakeholders involved.

PROSAFE

As the professional organisation of the product safety enforcement authorities in Europe, PROSAFE strongly recommends this Guide. It provides the best practice for Corrective Actions to protect consumers and it is a common guideline for businesses in Europe. The Guide underpins the benefits of mutual cooperation in the field of product safety in Europe and enhances harmonised market surveillance.

ANEC

ANEC is the European consumer voice in standardisation, representing and defending consumer interests in standardisation and conformity assessment as well as in the development or revision of legislation related to standards and their use.

ANEC was set up in 1995 as an international non-profit association under Belgian law and represents consumer organisations from the 27 EU Member States and 3 EFTA countries. ANEC is funded by the European Commission and the EFTA Secretariat, while national consumer organisations contribute in kind. Its Secretariat is based in Brussels.

EuroCommerce

EuroCommerce represents the retail, wholesale and international trade sectors in Europe. Its membership includes commerce federations and companies in 31 European countries.

Commerce plays a unique role in the European economy, acting as the link between manufacturers and the nearly 500 million consumers across Europe over a billion times a day. It is a dynamic and labour-intensive sector, generating 11% of the EU's GDP. Over 95% of the 6 million companies in commerce are small and medium-sized enterprises.

IFIA

IFIA is a trade association that represents over 37 of the world's leading international testing, inspection and certification companies. These have a combined turnover of almost €10 billion and over 160,000 employees.

IFIA members' activities encompass every aspect of inspection, certification and related testing.

ORGALIME

ORGALIME, the European Engineering Industries Association, speaks for 33 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries.

The industry employs some 9.7 million people in the EU and in 2010 accounted for some €1,510 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.

Contents

Outline

This outline of the Guide is intended for readers who are familiar with the content of the Guide and want to have a short list of main items covered for quick reference

It consists in a series of hyperlinks to the relevant parts of the Guide, in which detailed information is given.

- *Carry out the Corrective Action*
    - *Collect products*
    - *Correct the products*
    - *Dispose of products*
- *Monitor progress*
- *Learning from experience*
    - *How can we stop it happening again?*
    - *How can we improve our Corrective Action procedure?*

1 Aim of the Guide

If you are a producer or distributor of consumer products on sale in the European Union (EU), this Guide aims to provide general advice about what you should do if you have evidence that one of your products is unsafe.

This is a voluntary guide intended only as guidance for producers and distributors, to carrying out Corrective Actions for product safety. This Guide is supported by the market surveillance authorities in the Member States and the consumer and trade organisations within the EU. It is recommended that producers and distributors cooperate (and sometimes they are required to do so according to the GPSD) with the authorities in the Member States, when carrying out Corrective Actions, if appropriate, following any codes of practice where they exist. There may be differences between Member States concerning the conditions, procedures and requirements for such actions.

The Guide is aimed particularly at management with responsibility regarding product safety compliance, quality control, legal affairs and public and corporate relations within businesses and organisations. Organisations should have their own documented Corrective Action procedure applicable to their own circumstances.

2 Scope

The Guide covers all types of Corrective Actions (not just product recalls) adopted by producers or distributors, aimed at removing a safety risk posed by a consumer product[1], which they have placed on the market.

For products covered by Sector specific Directives or Regulations, the requirements of such Directives or Regulations have to be primarily considered in assessing risks posed by the product.

Corrective Actions can include:

- Changing the design of products;
- Changing the manufacturing process;
- Changes to Quality Control Procedures;
- Withdrawing products from the distribution chain;
- Sending information and warnings about correct use of consumers products;
- Modifying or repairing products at the consumer's premises or elsewhere;
- Recalling products from consumers for repair, replacement or refund.

The contents of the Guide have been summarised in a checklist on pages 12-13, and the flow chart on page 14 describes the process for carrying out the Corrective Action.

[1] This guide is primarily intended to cover corrective actions for consumer products other than food, pharmaceuticals and medical devices

Legal obligations

- Many of the procedures described in this Guide are covered by national and European legislation, which are subject to change. The Guide is not intended to describe all these legal obligations and it should not be used as a substitute for expert legal advice in any case involving a potentially unsafe product. More information about some of the sector-specific EC Directives can be found in the *EC Guide to the implementation of directives based on the New Approach or the Global Approach 1999*. Other information can be found in the sources listed in Annex B.

- For information relevant to specific Member States you will need to refer to specific sources of information (e.g. Market Surveillance Authority, a legal expert, a trade association for the manufacturer or distributor, the internet)

Obligations of producers and distributors

According to the General Products Safety Directive (GPSD), in addition to the basic requirement to place only safe products on the market, producers of consumer products must as much as possible inform consumers of the risks associated with the products they supply. They must take appropriate measures to prevent such risks and be able to trace dangerous products.

It is important that in his/her assessment of the risk posed by a consumer product, the involved economic operator duly takes into consideration the obligation set up by GPSD[2] concerning sales and distribution of safe consumer products and all necessary measures to be taken to prevent risks for consumers.

By "consumer product" it is meant "any product...which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them (...)".

In particular, the GPSD, under Article 5(3)[3], requires the economic operators to notify the competent authorities appointed by the Member States when a product they have made available on the market is found to be dangerous, as well as taking Corrective Action to deal with the identified risk.

Depending on the nature of the risk, the authorities might require further action from the economic operator, such as tracing the concerned product and taking it off the market, informing the public and, as a last resort, organising a product recall.

Obligations of the Member States

Under the GPSD, the Member States are obliged to enforce the requirements on producers and distributors. They must appoint the authorities in charge of market surveillance and enforcement. In addition to the power to impose penalties, the GPSD gives to the surveillance authorities a wide range of monitoring and intervention powers.

Commission Decision 2010/15/EU of 16 December 2009[4] gives details on the procedures to be followed by the Member States to notify dangerous products and on how to carry out the risk assessment.

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[2] Directive 2001/95/EC of 3 December 2001on general product safety

3 Commission Decision of 14 December 2004 laying down guidelines for the notification of dangerous consumer products to the competent authorities of the Member States by producers and distributors, in accordance with Article 5(3) of Directive 2001/95/EC of the European Parliament and of the Council

Note: The risk assessment methodology contained in these Guidelines has effectively been superseded by the methodology contained in Commission Decision 2010/15/EU of 16 December 2009 (see footnote 4).

[4] Commission Decision 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)

Who's responsible for Corrective Action?

Producers' and distributors' responsibilities for Corrective Action will, in practice, vary depending on the circumstances. Companies need to have agreements with their suppliers, which define their respective responsibilities for Corrective Action. The legal responsibility will, however, always depend on the company's role in the supply chain and, therefore, its position as a "producer" or a "distributor". The summary below is intended to help companies to decide which parts of the procedure apply to them, and what their role might be in practice.

Producers

The "producer" is defined in the General Product Safety Directive[5] as:

- The manufacturer of the product, when he is established in the Community;
- Any other person presenting himself as the manufacturer (including another manufacturer) by affixing to the product his name, trademark or other distinctive mark, or the person who reconditions the product;
- The manufacturer's representative, when the manufacturer is not established in the Community, or
- If there is no representative established in the Community, the importer of the product;
- Other professionals in the supply chain, if their activities affect the safety of the product. This may include modification of the product or, in some case, re-packaging.

The producer of a product must place only safe products on the market. He shall provide consumers with the relevant information to enable them to assess the risks inherent to a product, where such risks are not immediately obvious, unless there are adequate warnings. He shall take adequate measures against those risks.

It is suggested that, in practice, the organisation that takes the main responsibility for a Corrective Action will be determined as follows:

- **For products made in the EU and branded by the manufacturer**, the legal responsibilities of the producer lie with the manufacturer of the product.
- **For products made in the EU and branded by a Company**, the legal responsibilities of the producer lie with that Company.
- **For products made outside the EU and branded by the manufacturer**, the legal responsibilities of the producer belong to the company that imports the product into the EU (which may be the manufacturer's agent in the EU), but in practice the brand-name manufacturer will usually also wish to be involved in any Corrective Action.
- **For products made outside the EU and branded by an EU Company,** the legal responsibilities for the product should be accepted by that Company that may wish to involve also the manufacturer or his agent in any Corrective Action.

Distributors

The "distributor" is defined in the General Product Safety Directive[6] as "any professional in the supply chain whose activity does not affect the safety properties of the product".

Where a distributor (wholesaler or retailer) of a product does not also take on the role of producer (e.g. by importing or own-branding the product), he has to accept the following

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5 Note that definitions for the persons responsible for taking corrective action under particular product-sector Directives may be different under those Directives.

6 See footnote 5.

responsibilities for Corrective Action. According to contractual relationships, the distributor can shift some of the actions to be taken to its suppliers.

- He shall act with due care to help to ensure compliance with the GPSD;
- He shall not supply products to consumers, which he knows or has presumed that they are unsafe;
- He shall participate in the monitoring of the safety of products on the market according to the information made available to him;
- He shall pass on information on product risks, and he shall keep and provide documentation necessary for tracking the origin of products;
- He shall provide information to help trace the origin of products;
- He shall provide information about the consumers of products as far as possible (if the provisions of the Data Protection legislative requirements allow so);
- Cooperating with producers and the competent authorities in the Corrective Actions by, for example:
  - Assisting the producer in the implementation of recalls and other Corrective Action programmes;
  - Isolating and withdrawing products and returning them to the producer;
  - Cooperating in publicising the Corrective Action notice;
  - Contacting consumers of products at the request of the producer;
  - Cooperating in collecting products and returning them to the producer.

Corrective Action Procedure Checklist

Key considerations for a successful Corrective Action are **acting quickly** and **communicating effectively**. Consumer safety and your company's reputation may depend on these.

1. Plan ahead – before you have a problem

- Establish a policy and procedure for Corrective Action;
- Discuss your policy with your trade partners;
- Set up a Corrective Action team;
- Monitor information about the safety of your products;
- Keep good sales and distribution records to help trace products and identify consumers and end users as much as reasonably possible;
- Assemble documents about your product's design and safety;
- Update contact information for key people and organisations.

2. Decide whether to take action - assess the risk

- Identify the hazard and understand its root cause, whenever possible;
- Estimate how many products are affected ;
- Identify who might be affected;
- Consider the severity of injury that may result;
- Assess the likelihood of such an injury over the life time of the product;

- Identify additional factors applicable across the various countries where the product is sold and that would affect the risk level i.e. electrical installation etc.;
- Determine if the risk varies with time;
- Evaluate acceptability of the overall risk.

3. If Corrective Action is needed – what to do?

- Decide whether the Corrective Action needs to involve:
  - New products (design and manufacturing changes);
  - Products in the supply chain and potentially;
  - Products in the hands of consumers.
- Decide what Corrective Actions need to be carried out;
- Agree responsibilities and actions with distributors;
- Inform market surveillance authorities (see 5.2).

If the action involves products in the hands of consumers you need to:

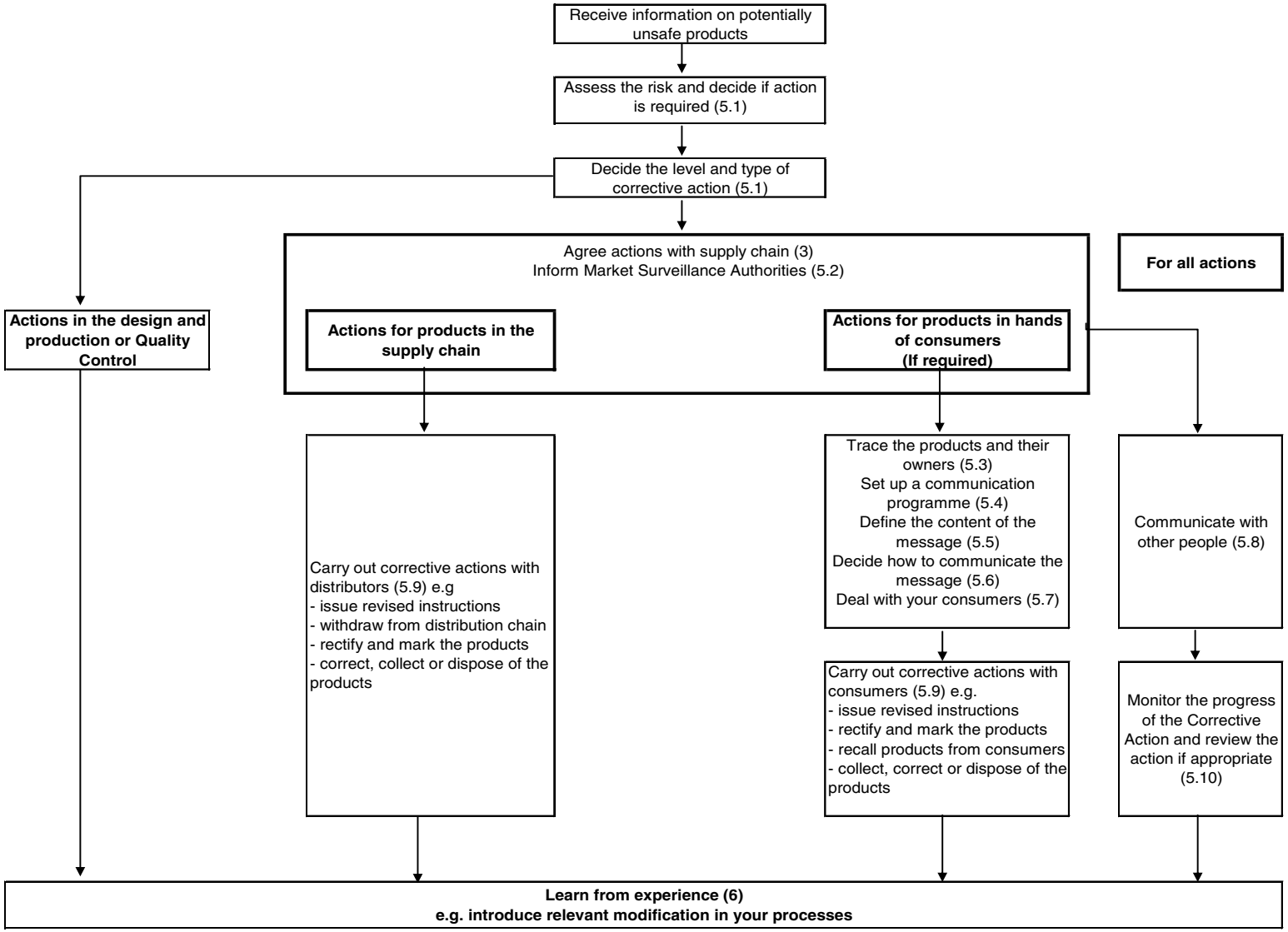
- Determine how to trace the products and their owners;
- Set up a communication programme;
- Draft any Corrective Action message clearly and simply;
- Decide how to communicate the message;
- Deal with your consumers;
- Communicate with others who need to know;
- Carry out Corrective Actions or recall the products concerned;
- Deal with products that have been returned;
- Monitor the response to the Corrective Action and decide if further action is needed.

4. After Corrective Action – learn from experience

- Review design requirements and improve quality system to try to avoid future problems (if not already fully covered as part of the Corrective Action programme);
- Assess the success of your Corrective Action procedure and make any improvements;
- Send comments and thanks to key participants.

Corrective Action Procedure Flowchart

(The numbers in the brackets refer to the relevant section in this Guide)



3 Preparing Corrective Action Strategy

Planning ahead is vital so that producers and distributors can act quickly if they need to. This section describes the policies, organisation and plans that have to be in place to make effective Corrective Action possible.

3.1 Establish your policy

Both the producers and distributors need Corrective Action policies.

Details of such policy may vary, but should include a statement by the company management of its aims and commitment to the following:

- To speed the Corrective Action to restore product safety;
- To provide all the necessary resources to undertake Corrective Action;
- If necessary, to inform consumers clearly and promptly of the Corrective Action being taken.

Such a policy should be designed to enable your company:

- To comply with European and national legislation concerning the safety of products, the notification of unsafe products, and the taking of Corrective Action;
- To take all reasonable steps to eliminate or minimise unexpected risks;
- To minimise the inconvenience to the consumer;
- To enhance the company's reputation for dealing responsibly with its consumers;
- To minimise the damage to your products' and to your brand reputation;
- Anyone who may be involved in the process should be familiar with the policy.

3.2 Agree your Action Plan

The details of your Corrective Action plans and procedures will depend on the size and structure of your business. As far as possible, a Corrective Action plan should include the following components:

3.2.1 A Corrective Action Team

The producer should assemble a team with knowledge of the following functions:

- Design;
- Production;
- Product safety/risk management/risk assessment;
- Quality assurance;
- Purchasing;
- Distribution;
- Marketing and consumer service;
- Public and corporate relations, external communication;
- Web communication and website management;

- Legal compliance, in particular as it relates to product safety;
- Accounts.

In small organisations some functions may be the responsibility of one person.

Some of these functions may be carried out or supported by external organisations. One person should have overall responsibility for external communication. A senior manager who reports to the company Board or the Chief Executive (or the equivalent person in a small organisation) should lead the team. The Chief Executive or his delegated representative should make the main decisions about Corrective Action.

Team members should be trained in their roles and the team needs to test the procedures they plan to use with simulation exercises. This could also involve external organisations.

In addition to the team set up by the producer, the distributor may also need to set up a team with some of those functions.

3.2.2 Monitoring procedures

Producers and distributors must have procedures for monitoring real and potential problems with their products.

If the distributors have indications from consumers that the product involves a risk they should share these with the producers.

Systems should be put in place to collect and analyse the following information:

- Reports of accidents involving products;
- Complaints from consumers, which were filed directly or via retailers;
- Warranty claims;
- Insurance claims or legal actions;
- Non-compliances reported by the company's quality control procedures or by other organisations;
- Results of product testing;
- Information from service engineers or from after sales/repair centres;
- Reports on returned components and products;
- Any evidence of hazards arising from sales to unexpected user groups;
- Any evidence of consumer abuse or un-appropriate use of the product;
- Any evidence of malicious tampering with products;
- Developments in legislation or standards concerning the products involved;
- Notifications and requests made by Market Surveillance Authorities.

This information needs to be reviewed regularly to verify if there may be a safety risk to consumers from any of the company's products. This is especially important when the design of the products changes, or new suppliers are employed.

3.2.3 A Product Traceability Plan

Consumers need to be able to identify those of your products which you have assessed as unsafe and you need to be able to trace back your consumers who have bought these products. This means that you should have the following three systems:

3.2.3.1 A Way of Identifying Affected Products

Although attaching identifying numbers or marks to some products is difficult or even impossible, producers need to recognise that not having such marks may make it more difficult to trace products later. In any event, in addition to the general product marking requirement contained in Article 5(1) of the General Product Safety Directive, many product sector-specific Directives contain particular marking requirements that need to be observed. As far as traceability is concerned, Commission Decision 768/2008/EC[7] will require serial numbers or other means of specific identification on the product or packaging to be included in the future in all New Approach Directives. Most New Approach Directives require already that the manufacturer/importer affixes its name and address on the product and/or on the packaging.

- Ideally producers need to mark products with a serial number so that the individual products affected can be identified. Otherwise you may have to carry out Corrective Action on more products than you would need to;
- For some types of products it may be enough to be able to identify a batch number;
- Bar codes are widely used for identifying and tracing different types of products.

3.2.3.2 A Consumer Database

Where appropriate and in accordance with Data Protection legislation, for effective corrective action, producers and distributors should keep records of customers (including consumers) and their purchases. This information may include:

- Name, address, postcode, telephone number and email address of the consumer;
- Brand, model number, and date of the purchase of the products.

The following records may provide sources for this information:

- Sales records should identify which products have been supplied to whom;
- Records kept by retailers of products;
- Guarantee or registration cards or on-line registrations;
- Servicing records may be a source of consumer information;

Companies selling products via the Internet or by mail order should also be able to identify consumers.

If you sell products outside your own country, you need to become familiar with the selling systems used elsewhere.

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[7] See Articles R2.5 and R2.6 of DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

3.2.3.3 A supplier database

If a component from a supplier has caused a safety problem into your product, you may need to be able to identify the relevant details by involving the supplier.

3.2.4 Technical documentation

Many European Directives require manufacturers to draw up a technical file which demonstrate how their products conform to the relevant legal requirements, and they need to keep this for ten years.

To deal with problems concerning the safety of a product, producers need to have easy access to all documentation relating to:

- The design of their products (including material specifications), especially those items concerning the product safety;
- Any changes that have been made and the corresponding dates and/or the serial numbers or batch numbers of products they apply to.

If the manufacturer is outside the EU, the importer or the manufacturer's representative needs to have access to the file, or ensure that the manufacturer will provide the documentation upon request of the market surveillance authorities.

3.2.5 Communication and Contact Lists

You need to maintain a list of all the people and organisations that may need to be contacted. It is important to ensure that you identify the right contact person in each of these organisations and keep the information up to date. Most people will need to be contacted by telephone or by email as soon as the problem arises and, for some contacts, it is useful to have a number at which they can be called outside the normal office hours and the name and number of their deputy. The contact list should include:

3.2.5.1 Contacts in your company

- Responsible senior management;
- Members of the Corrective Action team;
- Other key personnel;
- Manufacturers representatives and other selling agents;
- Repair centres;
- Warehouse;
- Carriers.

3.2.5.2 Contacts in other organisations

- Professional users;
- Suppliers;
- National trade associations;
- Market surveillance authorities;
- Police;
- Press, TV and other relevant media.

3.2.5.3 Service providers

- Servicing companies;
- Testing laboratories;
- Other experts or consultants such as:
    - Legal advisors;
    - Risk assessment consultants;
    - Public relations consultants;
- Insurers;
- Call centre agencies;
- Waste disposal agencies.

You need to be familiar with the information, requirements and procedures of some of these contacts, (particularly market surveillance authorities). The authorities in Member States listed in Annex C may also be able to provide information about local situations.

It may be useful that you establish good relations with the Market Surveillance Authority in your own Country, when such approach is agreed by the relevant Authority. You should make it your business to meet the officer responsible for your area. Familiarise him/her with your product and your manufacturing process; explain your procedures for dealing with reports of unsafe product, safety testing and risk assessment; make sure you understand how he/she operates, especially when dealing with reports of unsafe products; exchange phone numbers to use in case of emergency – and keep regular contact with him/her.

Preventive actions

Although this Guide is mainly concerned with how to carry out Corrective Action, companies may take measures to prevent the need for such action in the first place. Quality management procedures are established for anticipating and preventing problems that can arise from a production process. References to sources of information about safety requirements and quality management systems are given in Annex C.

3.2.6 Risk Assessment and Corrective Action procedures

Companies should have a written procedure for how they would carry out a risk assessment and take Corrective Action for a potentially unsafe product. (See Sections 0and 5)

Insurance

It may be possible to get insured against the cost of a Corrective Action and against the cost of your liability for product defects. Check whether your existing insurance policy covers these liabilities. Your insurance provider will probably require you to implement certain quality management measures.

4 Assessing the Risk

If monitoring procedures adopted by a producer/distributor indicate that one of the products, which they have placed on the market, poses risks to the consumer that are incompatible with the general safety requirement according to GPSD, than they need to assess the risk to determine whether Corrective Action is needed. This is mainly the producer's, responsibility but distributors may be able to supply information that will help.

Risk assessment needs to be carried out by a person or a small team with experience relative to the product and the hazards involved. This risk assessment can also be delegated to laboratories or other organisations that have specific competence, business and accident expertise, and additional human resources. The manufacturer's risk assessment should take into account the new and recently published RAPEX guidelines for authorities[8], especially for products not covered by harmonised legislation that contains more appropriate risk assessment procedures. However, one should be acknowledge that the risk assessment methodology in the RAPEX Guidelines is not mandatory and will not necessarily be applicable in all circumstances. Compliance with applicable harmonised standards is likely to be relevant in assessing the risk.

Risk assessment has usually several phases incorporating the following principles:

4.1 Identify the hazard

Analyse the information you have collected and try to answer the following questions:

- What is the nature of the hazard (e.g. is it obvious to the user, e.g. a sharp edge? Or is it hidden to the user?)
- Who is affected by the hazard? (user, bystander)
- What factors could affect the severity and the probability of the injury? (reasonably foreseeable use, behaviour of the user, competence of the user, age of product, method of use etc)

Distributors who have doubts about whether, in an isolated case, a risk is due to the safety of a product or the un-appropriate usage of a product by the consumer, they should transmit this information to the producer who can properly assess the risk. In this context, an isolated case is a situation, where a problem with only one sample of a product has been detected.

[8] 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)

4.2 Estimate the Level of Risk

When the producer/distributor has collected the requisite information they should estimate the level of risk, in order to assist them in deciding whether action is required. Estimating the risk depends on two main factors (see Annex E for further guidance):

- The ***severity*** of a possible injury to a person using or coming into contact with the product;
- The ***probability*** of a possible injury. This is affected by the following variables:
    - The probability that a product is or becomes unsafe and the time to failure;
    - The frequency with which a user is exposed to the hazard;
    - The probability of being injured when exposed to the hazard;
    - The risk level may change with time due a number of important factors (i.e., time from the factory to the date the product was sold) and some defects will depend on the level of usage;
    - Hazard avoidance behaviour of the user.

The ***severity*** and the ***probability*** estimates are combined to give the overall risk, which may be expressed as one of the following levels:

- Serious Risk – normally requiring immediate action;
- High risk – normally requiring rapid action;
- Medium risk – normally requiring some action;
- Low risk - normally not requiring action for products on the market.

Annex B gives sources of information on risk assessment and Annex E gives details of an example of a risk assessment that is based on the RAPEX guidelines. Other methods may be suitable and your choice of method may depend on your resources.

5 Managing Corrective Action

Producers have the main responsibility for carrying out Corrective Actions, but distributors may also have a role to play – see 'Who's responsible for Corrective Action' on page 11. Producers should ask distributors to cooperate and keep them informed throughout the Corrective Action. Different steps in the process below apply to different levels of Corrective Action. Sections 5.1, 5.2, 5.8, 5.9, 5.10 apply to all actions. Sections 5.3 to 5.7 apply only if the problem affects products in the hands of consumers.

5.1 Decide What Action Is Needed

The decision about the type of action to be taken will be mainly dependent on the overall level of the risk, but it can also take into account:

- The total number of unsafe products on the market;
- The total number of the products sold which are likely to be still in use;
- The range of products (models) affected;
- The total number of products/consumers affected;
- The cause of the hazard (occasional product defect, product deterioration, unusual operating conditions, misuse of the product, random failure etc);
- The practicalities of taking action (e.g. the traceability of the products.);
- The expected effectiveness of the action;
- The advice of the market surveillance authorities;
- Media sensitivity to the hazard.

In order to decide whether you need to take action, you also have to assess whether or not the level of risk is acceptable in the framework of the applicable legislation. Certain types of products have inherent hazards (such as tools or machines with sharp blades) that are acceptable if the manufacturer has taken appropriate safety measures. Nevertheless, for products likely to be used by more vulnerable people (such as child care products), consumers would not normally accept anything more than a very low level of risk.

It is suggested that:

If the overall level of risk is judged to be serious, Corrective Action is likely to involve products in the hands of consumers and the producer should normally take immediate action to:

- Inform the market surveillance authorities;
- Isolate producer's own stocks;
- Ask distributors to isolate affected products;
- Inform suppliers of any affected components;
- Set up a communication programme to contact consumers.

If the overall level of risk is judged to be less than serious, then less extensive Corrective Actions will be required.

The following guidelines may be applicable:

If the overall level of risk is judged to be high, the actions mentioned for serious risk may still be appropriate to be performed. In any case, the final decision, on which actions have to be taken, falls under the responsibility of the Corrective Action team.

If the overall level of risk is judged to be medium, it may be appropriate to limit the Corrective Action to products in the distribution chain and/or to issue revised warnings or instructions to consumers and, if relevant, to give details to the authorities regarding what has been/is being done.

If the overall level of risk is judged to be low, it may be sufficient to limit Corrective Action to changes affecting products in design and production.

In all cases, the Corrective Action that should be taken must be assessed by the Corrective Action team, taking all the circumstances into account.

In the case of isolated circumstances or products, which do not require any verification, and when it is clear that the risk is related to a limited number of well identified products (or batches), the producer or distributor may conclude that the risk has been fully controlled. This may imply that a notification is unnecessary, as the information would not be useful to the competent authorities for the purposes of risk assessment or consumer protection.

Type of action

Possible Corrective Actions may include:

- Changing the design of products;
- Changing the production method;
- Introducing additional Quality Control Measures;
- Media or web communication to alert consumers on the proper use of the product;
- Isolating and withdrawing products from distribution;
- Modifying products in the distribution chain;
- Improving the instructions supplied with a product;

- Disseminating additional information to consumers about the correct use of products;
- Modifying products at consumers' premises;
- Return of products by consumers for modification;
- Instruction to consumers to dispose of products;
- Offering consumers a replacement or refund for recalled or discarded products (this is likely to make the action more successful).

5.2 Inform the Market Surveillance Authorities

If applicable, producers and distributors should give the authorities some preliminary information about unsafe products as soon as they are aware of it noting the obligations as in Art. 5.3 from the GPSD.

If the overall risk is judged to be serious, you should notify the market surveillance authorities[9] and give them the details listed as follows:

- Information enabling a precise identification of the product or the batch of products affected;
- A full description of the risk presented by the product;
- All available information relevant to the tracing of the product;
- A description of the actions taken (and proposed) to protect consumers;

With this information the authorities may be able to help you carry out the Corrective Action more effectively. There can be advantages for producers and distributors in building good working relationships with their local authorities, even before a safety issue arises.

The contact details of the main national authorities needing to be informed of unsafe products are given in Annex C. Producers and distributors should inform the authorities in each of the Member States in which the products are sold, unless they have verified that the authority has already been informed by another company or authority. In some countries the information may be placed on a national database in which details of all Corrective Actions are recorded.

Producers/distributors need to ensure that they are familiar with the EC guidelines for notification (see Annex B) and the details of the procedures in the countries of notification.

5.3 Trace Products and Their Owners

The work needed to trace products and their owners can start as soon as the producer/distributor has decided to take action. The Corrective Action team needs to coordinate these activities, but if Corrective Actions have to be carried out in different countries, one may need to delegate them to a local agent.

5.3.1 Products

Having identified which model(s) are potentially unsafe, the producer/distributor needs to:

- Estimate the number of products affected;
- Identify the products using one of the methods described in 3.2.3.1.

Products can also be identified by describing them as having a particular feature or as fitted with a particular type of component.

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[9] One of the possible options to notify the Member State Authorities is by using the online Business Application notification form: https://webgate.ec.europa.eu/gpsd-ba/pdf/GPSD_EN.pdf

5.3.2 Owners

Producers/distributors may also need to identify the people, who have purchased the affected products using their consumer database (see 3.2.3.3). For products in the hands of consumers you could also use the records of other companies in the supply chain.

5.4 Set up a Communication Programme

Whether or not a producer/distributor has the contact details of the consumers affected, he will need to set up a communication programme to try to make contact with affected consumers. Effective communication is the key element in a successful Corrective Action programme. Swift and efficient action, and clear consistent communication, may even enhance the producers/distributors reputation in front of the businesses and also the consumers with whom they collaborate. The communication programme should include the following elements:

- A central communication centre with free telephone number (hotline) and a specific web site concerning the Corrective Action with all the information suitable to explain the situation and the actions taken and an email address/hot line number to be contacted by consumers;
- Whenever feasible, a list of the businesses and consumers to be contacted;
- A list of media to be used;
- Draft a communication plan for different media and audiences.

5.5 The Communication Message and Who to Contact?

The communication message

The message needs to be clear, concise and easily understandable. Base the message on confirmed facts and do not include statements that could be seen as biased or might not be completely true, or that might be confusing or misleading. Check the status of promotions and advertising activities as these may conflict with the Corrective Action message.

A Corrective Action announcement should contain:

- A clear heading that draws attention to the announcement containing words such as 'Important Safety Warning';
- Product identification details (brand, model, batch number, serial number, bar code, colour, size and a picture or a drawing of the unsafe product);
- A clear description of what is wrong with the product;
- Details of the safety risk or the potential safety risk;
- Information on the type of Corrective Action proposed and any proposed refund or replacement;
- Clear instructions on how to deal with the product (e.g. whether and where to bring or send back the product or how to arrange for a repair);
- A web site address or hot line for further information;
- If appropriate, apologies for any inconvenience.

The Corrective Action announcement usually reaches the public in the following forms:

- A personal letter, phone call or e-mail to consumers (direct contact asking the consumer to act – factual and informative);
- Media release (a core statement for media usage – short and factual);
- Corrective Action announcement in the media (advertisement asking the consumer to act – factual and informative);

- Point-of-sale material (if appropriate).

Producers/distributors are not required to use all of the media listed; often the method to be chosen will be dependent on the risk, on the product type and on the targeted consumers.

An example of a Corrective Action announcement is given in Annex A. If the geographical spread of the product affects few consumers or the risk is not serious, the Corrective Action team may decide not to issue a media release, but it's a good idea to have a release ready in case the scale of the problem suddenly becomes worse.

A Q&A document needs to be ready to support the team answering questions from consumers and distributors and will help them to give consistent answers to difficult questions. The Q&A document shall also be on the website of the Corrective Action. This document should be updated regularly during the Corrective Action period.

Who to contact?

The following audiences need to be contacted:

- Consumers;
- Internal staff members;
- Key business consumers, distributors and suppliers,
- The market surveillance authorities.

Although there is a need of some priority in informing different audiences, they all need to receive the same message within a short time frame, especially if the risk is serious.

5.6 How to Communicate the Message

It is important for the brand image of the producer/distributor that they control the way that information about the Corrective Action reaches consumers. Ideally they need to try to contact consumers directly. If that's not possible, you should choose the most appropriate communication channel depending on the following:

- Which types of media best serve the geographical spread of affected consumers?
- What is the most effective and timely way to inform consumers?

Possible communication channels

Communication consultants can help you to choose from the following media:

- Advertisements in newspapers or specialist publications;
- Consumer telephone services (hot line, info line, free lines);
- Point-of-sale information (leaflets, mini-posters);
- Radio/TV news and consumer programmes;
- Radio/TV advertising;
- Press service (web site, media room and dedicated media telephone lines), directed at the news editors of daily national and regional newspapers;
- Web sites (sometimes called 'Dark Sites' that have been prepared in advance and can be activated when you need them);
- Web groups and/or social network sites: e.g. Facebook, Linkedin, Twitter.

Producers/distributors should evaluate which amongst those communication channels are the most appropriate to reach the targeted consumer group and to get the maximum effectiveness out of the proposed action.

Recall advertisements in the press should be placed in the most suitable publications in each country to reach your target audience. Publishing the notice in specialist publications can sometimes be more effective than publishing it in newspapers.

Producers/distributors need a trained spokesperson that can make the Corrective Action a priority and deal with any media enquiries. Responding quickly and competently to other (sometimes disturbing) information in the media is essential. This helps to avoid speculation and keeps control of information reaching the public.

5.7 Deal with Consumers

Personal contact with the consumers is generally the best way to ensure that a Corrective Action is effective. If a producer/distributor has access to consumers' contact details they should send a personal letter or email or make a phone call giving the information of the Corrective Action announcement. However they need to recognise that some consumers will have changed the address or passed the product on to someone else.

The staff at the information desk need to be well briefed and to able to handle calls 24/7. If the calls are limited to business customers, then these calls may be able to be handled by the existing staff. There may be a need to consider employing the services of a call centre if a much larger number of calls are expected. If there is a need to deal with customers in different countries, they may need to share the task between a representative and local distributors in each country.

Producers/distributors can help the staff responsible for contacting consumers by supplying them with:

- A letter, email or fax, explaining what is expected from them and informing them that a dedicated Corrective Action team is available to answer questions and deal with problems;
- A Corrective Action package containing all technical details (this should be issued at the same time as the Corrective Action announcement or soon after);
- An extensive Question & Answer Document;
- Training on how to deliver messages and deal with problems.

It is advisable to keep records regarding customer contacts or responses in accordance with data protection legislation.

5.8 Communicate with other People

Producers/distributors should pass the same information to all their appropriate staff, and consider informing the general public, as quickly as possible.

5.9 Carry out the Corrective Action

Producers/distributors need to carry out the Corrective Actions decided in 5.1 by taking into account of the applicable data legislation, for products in the hands of consumers and for products still in the supply chain, in each of the countries involved. Any refunds, repairs or replacements need to be carried out as quickly and as efficiently as possible. Furthermore, they may need to make use of the agents in different countries.

Products need to be dealt with in the following ways:

5.9.1 Collect Products

If the products are to be returned to the producer, he will need to:

- Arrange to collect them from distributors;
- Ask consumers to take them, if they are portable, to an appropriate collecting point, for example their nearest distributor or retailer;
- Arrange for them to be collected from the consumer if they are not portable.

Recalled products should be clearly identified and the stock movements properly recorded. The distributor should check the identity of the product and compensate the consumer with a replacement or a refund.

The practicalities of doing this will depend on the country in which it is being done. Producers/distributors may need to make use of local transport companies, agents or distributors. Market Surveillance Authorities in individual Member States may be able to give more information.

5.9.2 Correct the products

If a producer/distributor has offered to repair or rectify the product he may:

- Have this carried out by an agent or dealer at their premises, or
- Send an engineer to the consumer's home to carry out the modification;
- Where appropriate, send replacement parts to the consumer.

Modified products should be clearly identified.

Producers/distributors need to decide what to do with products that have been recalled. It may be acceptable to:

- Carry out work that will bring the product up to an acceptable standard for resale. Products that have been rectified need to be clearly identified and the documents accompanying them may need to be updated;
- Re-work some of the materials or components to enable them to be reused in other products.

It is obviously prohibited to sell or pass on unsafe products to consumers.

There are restrictions on the re-exporting of unsafe products (e.g. for modification) and producers/distributors will need to check the legal requirements in the countries concerned if they wish to do so.

5.9.3 Disposal of products

Products for disposal need to be clearly identified and stored securely. The aim is to dispose them safely, taking into account any environmental risks that might arise and there may be a need to make use of specialist waste disposal contractors. The local Market Surveillance Authorities may be able to give further information about acceptable ways of disposing unsafe products.

5.10 Monitor progress

Before the Corrective Action starts the producer/distributor will find it helpful to set a target for the level of response in each country. Authorities in individual countries may be able to provide information about the potential level of response. There may be different targets set for the response from distributors and the one from consumers. This is a complex issue and it is difficult to lay down firm rules; the target should reflect the seriousness of the risk, but should also be realistic. If data is available about the effectiveness of past recalls carried out by a particular

business or in an industry, than this can be considered a useful indication. Expert advisors, with experience in dealing with recalls in a range of industries can also help with this.

The target may also depend on the quality of the sales and distribution records held by the producer/distributor.

The level of response to the Corrective Action will depend on factors such as:

- The type of product;
- How long the product has been on the market;
- The expected life of the product. This may enable you to estimate what percentage of the total product is still in use and what percentage shall not be subjected to the recall;
- The type of Corrective Action offered;
- The media used to communicate the message;
- Local conditions in the country concerned.

When the Corrective Actions have started, the producer/distributor needs to monitor the level of response. They should have systems to record how many consumers have been contacted and the number of products that have been returned, collected, corrected or disposed. This information should be analysed and monitored for a period of weeks and further action may be needed if the target is not reached. In some cases, the target might have to be revised - either upwards or downwards - in response to the information and insights obtained as the Corrective Action proceeds. If one continues to receive further information about new accidents or injuries to consumers, producers/distributors may need to review their risk assessments and re-evaluate the effectiveness of the Corrective Action. If the target is reached, then they should consider formally ending the Corrective Action, and being prepared to deal with products that may be returned at a later date.

6 Learning from Experience

After the Corrective Action, producers/distributors need to investigate what caused the problem in the first place, and to try to stop it from happening again. Finally they should assess the success of the Corrective Action procedure to try to evaluate if it need improvement for the future.

6.1 How to Stop It Happening again?

This part of the review is likely to focus on a review of:

- The procedures and design principles that were utilised for the product, and
- The effectiveness of the quality management system related to the manufacturing process and the product safety/risk management systems.

The parts of the system that failed to prevent the problem have to be studied and improvements need to be considered.

If the producer/distributor is not the manufacturer, then he/she must make sure that the manufacturer has gone through this process and put the results on the technical file of the product.

6.2 How Can We Improve our Corrective Action Procedure?

The operation of each part of the Corrective Action procedure should be reviewed to determine whether it could be improved. For example the producer/distributor should:

- Monitor the effectiveness of the communication methods employed (possibly by carrying out opinion research) and adapt the policy where necessary;

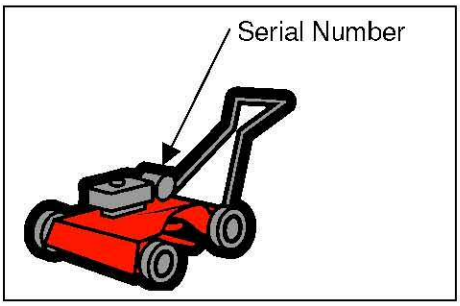
- Evaluate the internal procedures for Corrective Action and assess the need for changes in policy or training;
- Evaluate each technique used, especially for external and internal communication;
- Compile a full report of all actions taken and issues solved during the period of the action;
- Report to the retailers and the suppliers of the product on the success of the Corrective Action and any improvements that have been put in place – particularly any that affect them.

"Thank you" Notes

When the Corrective Action has been completed all key participants and important audiences should receive thank you notes, information relevant to the success of the action and proposals for improvement.

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

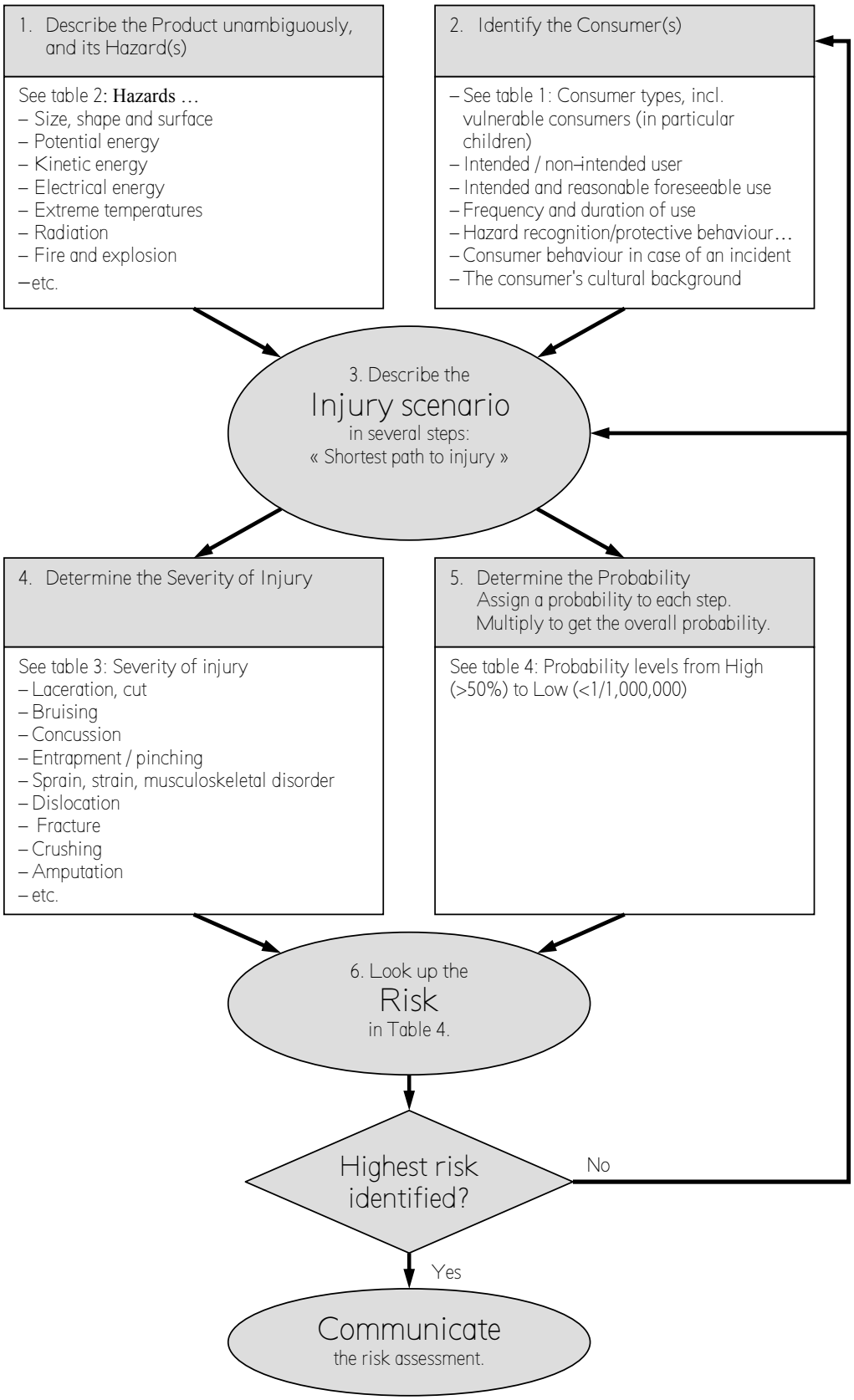


Table 1 - Hazards, typical injury scenarios and typical injuries

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’.