

PRODUCT SAFETY IN EUROPE:

A Guide to corrective action including recalls

- helping businesses to protect consumers from unsafe products



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Health and Consumer Protection Directorate General.



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UK - Department of Trade & Industry, Consumer and Competition Policy Directorate www.dti.gov.uk/ccp

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UNICE – Union of Industrial and Employers Confederations of Europe www.unice.org

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

Intertek RTC – www.intertek-rtc.com

Foreword

This voluntary guide to carrying out corrective actions for product safety was produced by Intertek Research and Testing Centre on behalf of the UK Consumers Association, in collaboration with representatives of organisations representing the main interested parties, (see [Appendix IV](#)). The project was supported by a 50% grant from the European Commission (DG Health and Consumer Protection). The guide is endorsed by the following organisations:



Product Safety Enforcement Forum of Europe

As the professional organisation of product safety enforcement authorities in Europe, PROSAFE strongly recommends this guide. It provides the best practice for corrective actions to protect consumers and 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

Dirk Meijer, Chairman of PROSAFE



Union of Industrial and Employers Confederations of Europe

This guide embodies the best practice of European businesses in the field of product safety. It also incorporates the expertise and knowledge of enforcers and consumers. UNICE is confident it will prove a valuable aid to companies, in particular to small and medium enterprises, undertaking voluntary corrective actions to protect consumers.

Dr. Jürgen Strube, President of UNICE



The Retail, Wholesale and International Trade Representation to the EU

We are very pleased with the publication of these comprehensive, compact and practical Guidelines for Corrective actions. The step by step guide for taking such actions will be of invaluable help to the commerce sector, especially for small businesses that account for 95% of the sector. It will further enable them to best serve the interests of their customers and ensure their increased safety.

Dr Peter Bernert, President of EuroCommerce



European Consumers' Organisation

BEUC welcomes the production of this Guide, which will help to improve consumer safety. This guide provides specific and relevant information that all businesses can make use of. We need to ensure that any unsafe product will be removed or rectified on the EU market as soon as possible. The key consideration to bear in mind is that the producers and distributors have to act quickly if necessary and inform the consumers fully and immediately.

Jim Murray, Director of BEUC

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INTRODUCTION

Aim of this guide

If you are a producer or distributor of consumer products on sale in the European Union (EU), this guide gives you general advice about what you should do if you have evidence that one of your products may be unsafe.

It is a voluntary guide to carrying out corrective actions for product safety, supported by the market surveillance authorities in Member States and consumer and trade organisations within the EU. Producers and distributors are encouraged to consult and cooperate with the authorities in Member States when carrying out corrective actions, following any codes of practice where they exist. There may be differences between Member States in the conditions, procedures and requirements for such actions.

The guide is aimed particularly at managers with responsibility for quality control, legal affairs and public and corporate relations. Organisations should have their own documented corrective action procedure applicable to their own circumstances.

Scope

The guide covers all types of corrective action (not just product recall) by producers or distributors, aimed at removing a safety risk arising from a non-food product they have placed on the market.

Corrective actions can include:

- Changing the design of products
- Withdrawing products from the distribution chain
- Sending information and warnings about correct use of products to consumers
- Modifying products at the customer's premises or elsewhere
- Recalling products from consumers for replacement or refund.

The contents of the guide have been summarised in a checklist on page 9, and the flow chart on page 10 describes the process for carrying out the corrective action. [Appendix I](#) describes a case study that illustrates many of the principles incorporated into the Guide.

[ANNEX I](#) is an abridged version of the guide that is intended for readers who are familiar with the content of the guide and want to have a shorter document for quick reference. The sections of both the full guide and the abridged guide are numbered in the same way for ease of reference.

Legal obligations

Many of the procedures described in this Guide are covered by national and European legislation. The Guide is not intended to describe all these legal obligations and it should not be used as a substitute for legal advice in any case involving a potentially unsafe product. More information about EC Directives can be found in the *EC Guide to the implementation of directives based on the New Approach or the Global Approach 1999*; and from the sources of information in [Appendix III](#). For information relevant to specific Member States you will need to contact the market surveillance authorities.

Who's responsible for corrective action?

Producers' and distributors' responsibilities for corrective action vary depending on the circumstances. Companies need to have agreements with their suppliers, which define their respective responsibilities for corrective action. These responsibilities are summarised below to help companies decide which parts of the procedure apply to them.

Producers

The producer of a product must take appropriate corrective action to avoid risks presented by the product.

For the purposes of corrective action the producer is defined 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, trade mark 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.

It is suggested that the organisation that takes the main responsibility for a corrective action should be determined as follows:

- **For products made in the EU and branded by the manufacturer**, the responsibilities of the producer should be accepted by the manufacturer of the product.

- **For products made in the EU and branded by the distributor**, the responsibilities of producer should be shared between the manufacturer and the distributor.
- **For products made outside the EU and branded by the manufacturer**, the responsibilities of the producer should be accepted by the company that imports the product into the EU (which may be the manufacturer's agent in the EU). In practice the importer will generally need to involve the manufacturer in any corrective action.
- **For products made outside the EU and branded by the EU distributor**, the responsibilities of the producer should be accepted by the distributor. The distributor may wish to involve the manufacturer or his agent in any corrective action.

Distributors

Where the distributor (wholesaler or retailer) of a product does not take on the role of producer, he should still accept the following responsibilities for corrective action:

- Collecting information about unsafe products and passing it on to the producer and competent authorities.
- Providing information to help trace the origin of products.
- Providing information about the purchasers of products (if data protection requirements allow).
- Cooperating with producers and the competent authorities in corrective actions by, for example:
 - Carrying out corrective actions on behalf of the producer
 - Isolating and withdrawing products and returning them to the producer
 - Cooperating in publicising the corrective action notice
 - Contacting purchasers 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 records to help trace products and identify customers and end users
- 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 its cause
- Estimate how many products are affected
- Identify who might be affected
- Consider what severity of injury could result
- Assess the likelihood of such an injury
- Evaluate acceptability of overall risk.

3. If corrective action is needed – what to do?

Decide whether the corrective action needs to involve:

- o products in the supply chain and possibly
- o 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.

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

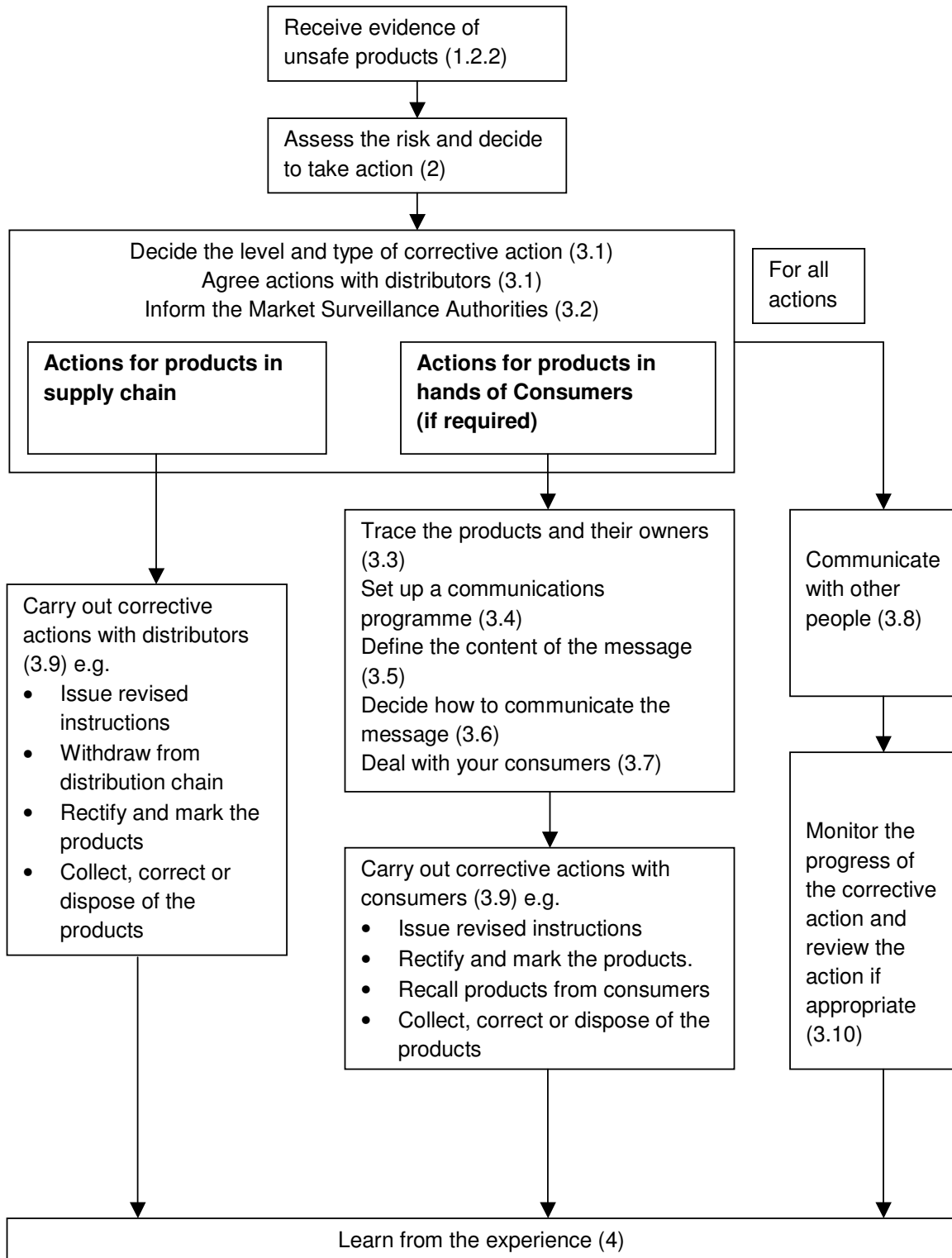
- Trace the products and their owners
- Set up a communications programme
- Draft any corrective action message clearly and simply
- Decide how to communicate the message
- Deal with your consumers
- Communicate with others who need to know
- Carry out corrective action on the products
- Deal with products 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 standards and improve quality systems to try to avoid future problems
- 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 brackets refer to the relevant sections of the guide.



1 Preparing your 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.

1.1 Establish your policy

Producers and distributors both need corrective action policies.

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

- To speedy corrective action to restore product safety
- To provide all the necessary resources to undertake corrective action
- If necessary, to inform consumers fully and immediately 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 minimise the inconvenience to the consumer
- To enhance the company's reputation for dealing responsibly with its customers
- To minimise the damage to its products' reputation.

Anyone who may be involved in the process should be familiar with the policy.

1.2 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:

1.2.1 A corrective action team

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

- Design
- Production
- Product safety/risk management
- Quality assurance
- Purchasing
- Distribution
- Marketing and customer service
- Public and corporate relations
- Legal
- Accounts.

In small organisations some functions may be the responsibility of one person or they may be carried out by outside organisations. One person should have overall responsibility for external communications. A senior manager who reports to the company board or 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 outside organisations.

A distributor may also need to set up a team with some of these functions.

1.2.2 Monitoring procedures

Producers and distributors must have procedures for monitoring problems with their products. This means you need to have systems to collect and analyse the following information:

- Reports of accidents involving your products
- Complaints from customers, 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
- Reports on returned components and products
- Any evidence of hazards arising from sales to unexpected user groups.
- Any evidence of consumer abuse or misuse of the product.
- Any evidence of malicious tampering with products.

This information needs to be reviewed regularly for signs that there may be a risk to consumers from any of the company's products. This is especially important when the design of products changes or new component suppliers are used. If distributors have this information, they should share it with producers.

1.2.3 A product traceability plan

Customers need to be able to identify products which may be unsafe and you need to be able to trace the customers who have bought them. This means that you should have the following three systems:

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 this may make it more difficult to trace products later.

- 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 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 product.

A customer database

For effective corrective action, producers and distributors should keep records of customers and their purchases.

This information should include:

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

Producers should recognise that data protection requirements may limit the amount of customer information that distributors or credit card companies can supply.

The following records may provide sources for this information:

- Sales records for business customers should identify which products have been supplied
- Records kept by retailers of products customers have bought
- Guarantee or registration cards can also help
- Servicing records may be a source of customer information
- Companies selling products via the Internet or by mail order should also be able to identify purchasers.

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

A supplier database

If a safety problem has been caused by a component from a supplier, you need to be able to identify the supplier's reference number on the components fitted to your products.

You should keep these records for the expected life of the products.

1.2.4 Technical documentation

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 concerned with product safety
- Any changes that have been made and the dates and/or the serial numbers or batch numbers of products they apply to.

Many European Directives require manufacturers to draw up technical files which demonstrate how their products conform with the relevant requirements. If the manufacturer is outside the EU, the importer or the manufacturer's representative needs to keep a copy of the file.

You should keep these records for a period of 10 years from the date of manufacture of the product.

1.2.5 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 in each of these organisations and keep the information up to date. Most people will need to be contacted by telephone initially and, for some contacts, it is useful to have a number at which they can be called out of normal office hours, and the name and number of their deputy. The contact list should include:

Contacts in your company

- Responsible senior management
- Members of the corrective action team
- Other key personnel
- Manufacturers representatives and other selling agents
- Warehouse
- Carriers.

Contacts in other organisations

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

Service providers

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

With some of these contacts, (particularly market surveillance authorities), you need to be familiar with their information requirements and procedures. The authorities in Member States listed in [Appendix III](#) may also be able to supply information about local services.

1.2.6 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 2 and 3](#))

Insurance

It may be possible to insure against the cost of a corrective action and against the cost of your liability for product defects. Check whether your existing insurance covers these liabilities. Your insurer will probably require you to implement certain quality management measures.

Preventive action

Although this guide is principally concerned with how to carry out corrective action, companies will want to take other measures to prevent the need for such action in the first place. There are established quality management procedures for anticipating and preventing hazards that can arise from a production process. References to sources of information about safety requirements and quality management systems are given in Appendix III.

2 Assessing the risk

If your monitoring procedures suggest one of your products may pose a risk to consumers, you 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 small team with experience of the product and the hazards involved. [Appendix III](#) gives sources of information on risk assessment and [Appendix V](#) gives details of an example of a risk assessment method that is based on the guidelines to the EC General Product Safety Directive. Other methods may be suitable and your choice of method may depend on your resources. Risk assessment usually has several phases incorporating the following principles:

2.1 Identify the hazard

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

- What is the nature of the hazard?
- What is the cause of the hazard?
(occasional product defect, product deterioration, unusual operating conditions, misuse of product, random failure etc)
- What range of products (models) is affected?
- Who is affected by the hazard? (user, bystander)
- What factors could affect the severity and probability of injury? (competence of user, age of product, method of use etc)

2.2 Estimate the level of risk

When you have collected this information you should estimate the level of risk to help you to decide whether action is needed.

Estimating the risk depends on two main factors:

- The **severity** of the possible injury to a person using or otherwise coming into contact with the product
- The **probability** of the possible injury. This is affected by the following factors:
 - o The probability of a product being or becoming defective and the time to failure.
 - o The frequency with which a user is exposed to the hazard.
 - o The probability of being injured when exposed to the hazard.

The severity and probability estimates are combined to give an overall risk estimation. To help you to evaluate the scale of the problem you also need to collect and evaluate the following information:

- How many defective products are on the market?
- How many of the products sold are likely to be still in use?

2.3 Assess the acceptability of risk

To decide whether you need to take action you also need to assess whether or not the level of risk is acceptable to consumers. Certain types of products (such as tools or machines with sharp blades) have obvious hazards that are accepted by consumers if they consider that the manufacturer has taken appropriate safety measures. For products likely to be used by more vulnerable people (such as child care products) consumers would not accept anything more than a very low level of risk.

2.4 Overall risk

Having evaluated all these factors you should make an overall risk assessment which may be expressed as one of the following levels:

- Serious risk – requiring rapid action
- Moderate risk – requiring some action
- Low risk – not generally requiring action for products on the market

3 Taking 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 8. 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 3.1, 3.2, 3.8, 3.9, 3.10 apply to all actions.

Sections 3.3 to 3.7 apply only if the problem affects products in the hands of consumers.

3.1 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 account of:

- The total number of products/consumers affected
- The practicalities of taking action
- The anticipated success of taking action
- The advice of the market surveillance authorities
- Media sensitivity to the hazard.

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 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 communications programme to contact consumers.

If the overall level of risk is judged to be moderate, the corrective action may be limited to products in the distribution chain, and it may be enough to withdraw these and give the authorities details of what is being done - see Section 3.2.

If the overall level of risk is judged to be low, corrective action may generally be limited to consideration of changes affecting products in design and production.

Type of action

Possible corrective actions may include:

- Changing the design of products.
- Changing the production method.
- Isolating and withdrawing products from distribution
- Modifying products in the distribution chain (such products need to be marked)
- Improving the instructions supplied with a product
- Sending additional information to consumers about the correct use of products
- Modifying products at consumers’ premises (such products need to be marked)
- Return of products by consumers for modification
- Recalling products from consumers for replacement or refund
- 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).

3.2 Inform the market surveillance authorities

Producers and distributors should give the authorities some preliminary information about a product risk as soon as they are aware of it. If the overall risk is judged to be serious enough, you should notify the market surveillance authorities giving them the details listed below. With this information the authorities may be able to help you carry out your corrective action more effectively.

- Information enabling a precise identification of the product or 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 planned) to protect consumers.

The contact details of the main national authorities needing to be informed of unsafe products are given in [Appendix III](#). Producers and distributors should inform the authorities in each of the Member States in which the products are sold, unless they have ensured 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.

You need to ensure that you are familiar with the EC guidelines for notification (ref [Appendix III](#)) and the details of the procedures in the countries of notification.

3.3 Trace products and their owners

The work needed to trace products and their owners can start as soon as you have decided to take action. These activities need to be coordinated by your corrective action team, but if you are carrying out corrective actions in different countries you may need to delegate many of them to a local agent.

Products

Having identified which model or models are unsafe, the producer needs to:

- Estimate the number of products affected
- Identify the products using one of the methods described in [Section 1.2.3](#).

You can also identify products by describing them as having a particular feature or as fitted with a particular type of component.

Owners

Producers also need to identify people who have purchased the affected products using their customer database (see [Section 1.2.3](#)). For products in the hands of consumers you may depend on the records of other companies in the supply chain.

3.4 Set up a communications programme

Whether or not you have the contact details of your customers, you need to set up a communications programme to make contact with them. Effective communication is the key element in a successful corrective action programme. Fast and efficient action may even enhance your reputation with your customers. The communications programme should include the following elements:

- A central communication centre with free telephone number (hotline)
- A list of audiences to be contacted
- A list of media to be used
- Draft communications for different media and audiences

3.5 The message and who to contact?

The message

The message needs to be clear, concise and easily understood. Base the message on confirmed facts and do not include statements that could be seen as biased or might not be completely true. 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 (name of product, batch number, serial number, bar code, colour, size and a picture or line drawing of the unsafe product)

- A clear description of what is wrong with the product
- Details of the safety risk or potential safety risk
- Information on the type of corrective action proposed and any 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 email 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)

An example of a corrective action announcement is given in [Appendix II](#). 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 problem suddenly gets worse.

A Question and Answer document needs to be ready to support the team answering questions from consumers and distributors and will help them give consistent answers to difficult questions. This document should be updated regularly during the corrective action period.

Who to contact?

The following audiences need to be contacted:

- Consumers (see [Section 3.7](#))
- Internal staff members
- Key business customers, distributors and suppliers
- The market surveillance authorities (see [Section 3.2](#)).

Although there needs to be 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.

3.6 How to communicate the message

It is important for your brand image that you control the way that information about the corrective action reaches consumers.

Ideally you need to try to contact consumers directly. If that's not possible, 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 choose from the following media:

- Newspaper advertisements
- 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).

Recall advertisements in the press should be placed in the most suitable newspapers in each country to reach your target audience.

You need a trained spokesperson who 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.

3.7 Deal with your consumers

Personal contact with consumers is generally the best way to ensure your corrective action is effective. If you have customers' contact details you should send a personal letter or email or make a phone call giving the information in the corrective action announcement. However you need to recognise that some consumers will have changed address or passed the product on to someone else.

Staff on your information desk need to be well briefed and able to handle calls at any time of the day. If calls are limited to just business customers you may be able to handle them with your normal staff. But you may need to consider using a call centre if a much larger number of calls are expected. If you need to deal with customers in different countries, you may need to share the task between your representative and local distributors in each country.

You can help staff responsible for contacting consumers by giving them:

- A letter, email or fax, explaining what is expected of 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 and Answer Document
- Training on how to deliver messages and deal with problems.

3.8 Communicate with other people

You should pass the same information to all your staff, and consider informing the general public, as quickly as possible.

3.9 Carry out the corrective action

You need to carry out the corrective actions decided in [Section 3.1](#), for products in the hands of consumers and for products in the supply chain, in each of the countries involved. Any refunds, repairs or replacements need to be carried out as quickly and efficiently as possible. Again you may need to make use of agents in different countries. Products need to be dealt with in the following ways:

Collect products

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

- Arrange to collect them from distributors.
- Ask consumers to take the product to their nearest distributor or retailer if they are portable
- Arrange for them to be collected from the consumer if they are not portable.

Unsafe 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. You may need to make use of local transport companies, agents or distributors.

Authorities in individual Member States may be able to give more information.

Correct the products

If you have offered to repair or rectify the consumer's product you 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.

Modified products should be clearly marked.

You 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 marked and the documents accompanying them may need to be updated
- Rework some of the materials or components to enable them to be reused in other products.

It is not acceptable to sell or pass on uncorrected products to consumers.

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

Dispose of products

Products for disposal need to be clearly identified and stored securely. Your aim is to dispose of them safely taking into account any environmental risks that might arise. You may 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 of unsafe products.

3.10 Monitor progress

Before your corrective action starts you will find it helpful to set a target for the level of response in each country. Authorities in individual countries may be able to give you information about the likely level of response. You may set different targets for

the response from distributors and the response from consumers. This is a complex issue and it is difficult to lay down firm rules, but the target should reflect the seriousness of the risk. Your target may also depend on the quality of your customer records.

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
- The type of corrective action offered
- The media used to communicate the message
- Local conditions in the country concerned

When your corrective action has started, you need to monitor the level of response. You should have systems to record how many customers contact you and the number of products that have been returned, collected, corrected or disposed of. This information should be analysed and monitored for a period of weeks and further action may be needed if the target is not reached. If you receive information about further accidents or injuries to consumers, you may need to review your risk assessment and reassess the effectiveness of your corrective action. If you reach the target, the corrective action can be formally ended, but you still need to be able to deal with products that are returned to you at a later date.

4 Learning from experience

After the corrective action you need to look at what caused the problem initially, to try to stop it happening again. Finally you should assess the success of your corrective action procedure to try to improve it for the future.

4.1 How can we stop it happening again?

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

- the standards and design principles that you use and
- the effectiveness of your quality assurance and product safety/risk management systems.

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

4.2 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 you should:

- Monitor the effectiveness of the communication methods used (possibly by carrying out opinion research) and adapt your policy where necessary
- Evaluate your internal procedures for corrective action and assess the need for changes in policy or training
- Compile a full report of all actions taken and issues solved during the period of the action.

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.

Appendix I - Case Study

Corrective action case study

Boots



The Company

Boots is a large UK high street pharmacy and retailer of health and beauty products. It has 1400 shops in the UK and Irish Republic and sales in 2002/3 were £4.2bn. The company sells a large number of products and it has a reputation for providing high-quality, safe goods. It has a central customer service department in Nottingham that deals with the contacts or complaints that are received from customers at the company's head office. Specialist teams are employed in the task of monitoring and *analysing* these contacts and complaints, and inspecting products that have been returned by customers. The company has documented procedures for monitoring this information, carrying out risk assessments and taking corrective action if appropriate.

The Product

Crook handle walking stick



The product that was the subject of corrective actions was a lightweight collapsible walking stick. The product was made in Taiwan and sold in most Boots shops, priced £21. The stick was classed as a medical device and subject to the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA). Since first going on sale in October 2001, around 5,000 walking sticks had been sold when the problem was discovered.

The problem

In some cases it was reported that the wooden handle became detached from the aluminium tube, which had the potential to cause the user to fall and possibly sustain injury.

Discovery

An analysis of product returns for December 2002 showed that customers had returned 19 walking sticks and two stores had considered the fault to be serious enough to send a report to the customer service department. The products were batch coded enabling faults to be narrowed down to specific batches.

Following a risk assessment meeting, the company agreed to withdraw the product from sale and monitor returns. During January and February a further four complaints were received, including some that were regarded as “near incidents” – possibility of injury to the user.

Risk assessment

As soon as the initial batch of faults was reported, the Boots Issue Management process came into effect. This began with a meeting of a Risk Assessment Group, comprised of representatives from Product Quality Development (PQD), Buying, Legal Services, Customer Service, Public Relations and Medical Services. This team received a report from PQD of the initial evaluation of the seriousness of the risk, based on an assessment of the probability and severity of injury and taking account of the vulnerability of the users. The PQD team also checked that the products met the specification, which included a test for the strength of the joint between handle and tube. These tests did not reveal a quality problem and the testers were not able reproduce the failure in simulated use of the product at this stage. The product was also found to meet all the requirements of the relevant British Standard.

When further reports of customer complaints were received the Customer Service team asked the customers detailed questions to help evaluate the problem. PQD then assessed the information gathered and carried out further tests in February to try to replicate the fault. Through a combination of the effects of extreme temperature changes, twisting forces and use of the product as a hook to lift shopping bags, the team managed to replicate the fault. Once the findings from these new tests were available, the Risk Assessment Group was reconvened.

Corrective action decision

As a result of their first assessment, the Risk Assessment Group made a decision to withdraw the products from shops and to continue to monitor returns. Withdrawal is carried out by sending an electronic communication to all shops and a *recalled item till bar* is sent to the tills in all stores, preventing the sale of the withdrawn items. All withdrawn stock is returned to the central warehouse.

At their February meeting the risk assessment group decided to carry out a public recall i.e. a full recall from consumers. Customers were offered a replacement with a different model of walking stick or a refund.

Communication

Boots operates a loyalty card scheme that is used by a high proportion of its customers. By this means it was possible to identify 43% of the purchasers of these products. Within days of the decision to issue a public recall, a letter (see illustration) was sent to the customers in an envelope that carried a red message emphasising the importance of the contents. At the same time, notices (see illustration) were sent to all Boots stores, to be displayed in prominent positions, in view of the large number of regular customers. Additionally, some Boots store managers gained agreement from local doctors' surgeries to display the notices there. The notice was also placed on the Boots website.

Communication with customers



Boots Customer Service
PO Box 5300
NOTTINGHAM
NG90 1AA

Tel: 0845 070 8090
Minicom: 0845 070 8091
Fax: 0115 959 5525
E-mail: btc.eshelpdesk@boots.co.uk

Mrs A Customer
101 Trent Road
Anytown
AB1 1CD

Dear Mrs Customer

**IMPORTANT PRODUCT
Adjustable Crook Walking
Item Code: 20 82 551**

I am writing to tell you that you have had a problem with the above walking stick during use.

Because our customers' safety is our priority, we have removed this product from sale.

If you have one of the walking sticks, please visit your nearest Boots store for a full refund. If you have purchased this product online, please contact us to know about this as soon as possible.

If you have any queries, please contact your nearest Boots store team or call Boots Customer Service.

United Kingdom 0800 915 0004
Republic of Ireland 1800 509 115

I am very sorry for any inconvenience caused.

Yours sincerely

Anne Williamson

**Anne Williamson
Customer Service**



Important Product recall



Crook Handled Walking Stick – Item Code 20-82-551

We have discovered a potential quality problem with the above walking stick, which could cause it to break during use.

We have therefore stopped selling this product and are asking customers not to use it. If you have one, would you please return it to your nearest Boots store for a full refund, or alternative walking stick. If you know someone else who has one would you please ask them to return it to us.

If you have any questions, please ask a member of the Boots store team, or contact Boots Customer Service:

United Kingdom **0800 915 0004**
Republic of Ireland **1800 509 115**

We apologise for any inconvenience caused.

Recall Number: 99995503 Recall notice issued: March 2

Carrying out corrective actions

Customers returned 2,165 products to the shops, where they were offered either an alternative product as a replacement, or a refund.

Boots has agreements with its suppliers that define the extent of their liability for defective products, and their respective responsibilities in the event of a need for corrective action.

The PQD team worked with the supplier to redesign the product following the public recall. The new design had a tighter joint between the handle and the tube and could withstand being cycled through extremes of temperature and extremely high twisting forces. The test specification now includes a requirement to withstand pull and twisting forces such as would be experienced if the handle is used for lifting.

Notification of the authorities

The MHRA were notified as soon as the fault had been identified and then notified again when the decision to carry out a public recall was made. They did not ask the company to carry out any additional actions.

As part of the “home authority” arrangement the company has with the Local Authorities Coordinators of Regulatory Services in the UK (LACORS), who are the national market surveillance authority, the local Trading Standards Office was also informed. They arranged for the recall notice to be placed in the safety warnings section of the national Trading Standards website www.tradingstandards.gov.uk

Monitoring the recall

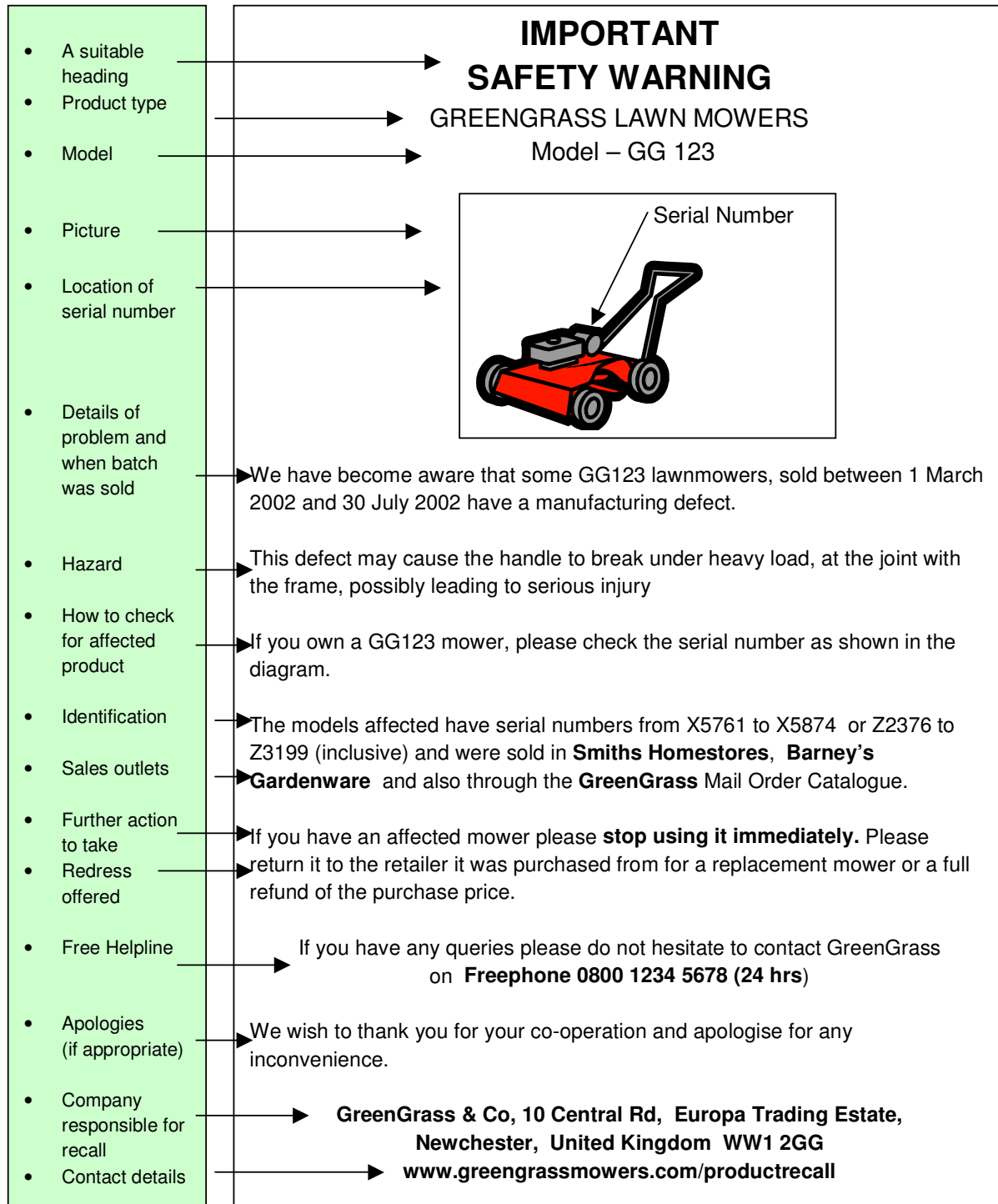
When customers returned the products to the stores, the transactions were registered at the tills. The tills were programmed to allow the reason for the return to be recorded, including the means by which the customer was informed of the recall. Using this information, the success of the recall could be monitored by the customer service department. The number of products returned was 2165, which represents over 40% of the total sold and is better than the typical response to newspaper recall notices. Taking account of the fact that some products will have been lost or thrown away, and that many of the customers are likely to be elderly and infirm, this was considered to be a successful response.

Lessons learnt

- Having a mechanism, to enable the business to monitor customers’ comments and complaints, was a key enabler of quickly identifying problems with the product.
- Letters to loyalty card customers were the most effective method of contacting purchasers.
- Large type was effective in helping elderly customers to read the contents of the letter and the in-store notice.
- Returns volume could be improved for products of this nature in future, if additional methods of contacting this type of customer, such as via doctors’ surgeries, are included in the company-wide approach.
- In designing this type of product it is important to not solely rely on the requirements of an accepted standard to determine the specification. Seek to anticipate foreseeable use of the product, such as use of the walking stick to lift shopping bags from the floor, and design the product accordingly.

Appendix II - 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.**



Appendix III - European Information Sources

SAFETY DIRECTIVES

General Product Safety

- 2001/95/EC - General Product Safety Directive (GPSD)
- 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
- 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://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/revisedGPSD_en.htm

SAFETY STANDARDS

Reference should be made to national standards organisations for information about standards that are applicable to your products. Contact details are given on the following website: -

www.iso.ch/iso/en/aboutiso/isomembers/MemberCountryList.MemberCountryList

PRODUCT SAFETY GUIDELINES

- Guide to the implementation of directives based on the New Approach or the Global Approach. European Commission 2000
<http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm>

RISK ASSESSMENT

- EN 1050:1996 – Safety of Machinery. Principles of Risk Assessment
- IEC 300-3-9:1995 – Risk analysis of technological systems

QUALITY MANAGEMENT

- EN ISO 9001:2000 - Quality Management Systems- Requirements
- BS 8600:1999 – Complaints Management Systems. Guide to design and implementation

INFORMATION SOURCES at the European Commission

- European Union legislation www.europa.eu.int/eur-lex/en/index.html
- DG Enterprise – Activities <http://europa.eu.int/comm/enterprise>
- DG Enterprise – Euro Info Centre Network <http://eic.cec.eu.int> AND <http://europa.eu.int/comm/enterprise/networks/eic/eic.htm>
- DG Health and Consumer Protection <http://europa.eu.int/comm/consumers>
- DG Trade <http://europa.eu.int/comm/trade>
- New Approach Standardisation in the Internal Market www.newapproach.org

NATIONAL MARKET SURVEILLANCE AUTHORITIES

The organisations below are the main contacts for market surveillance in each of the countries concerned. In some countries responsibility for some aspects of market surveillance is delegated to regional organisations. An up to date list of contacts can be found at the EC website www.europa.eu.int/comm/consumers

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
CZECH REPUBLIC	Česká obchodní Inspekce www.coi.cz
DENMARK	Sikkerhedsstyrelsen www.sikkerhedsstyrelsen.dk
ESTONIA	www.consumer.ee
FINLAND	<ul style="list-style-type: none"> ○ Kuluttajavirasto - www.kuluttajavirasto.fi ○ TUKES – Turvatekniikan keskus www.tukes.fi
FRANCE	<ul style="list-style-type: none"> ○ 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) www.finances.gouv.fr/DGCCRF
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
IRELAND	Office of the Director of Consumer Affairs (ODCA) www.odca.ie
ITALY	Ministero del Attività Produttive www.minindustria.it
LATVIA	www.ptac.gov.lv
LITHUANIA	www.inspekcija.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	Voedsel en Waren Autoriteit www.vwa.nl
POLAND	www.uokik.gov.pl
PORTUGAL	<ul style="list-style-type: none"> ○ Inspeção-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	<ul style="list-style-type: none"> ○ Konsumentverket KO www.konsumentverket.se ○ Elsäkerhetsverket www.elsak.se
UNITED KINGDOM	Local Authorities Coordinators of Regulatory Services (LACORS) www.lacors.gov.uk

Appendix IV - Contributors

This guide was produced as a result of a project funded by financial contributions and contributions in kind from the organisations represented on the Steering Committee and a grant from the European Commission (DG Health and Consumer Protection) for 50% of the project costs. The project was carried out by Intertek Research and Testing Centre, on behalf of the Consumers Association, with additional material supplied by Burson Marsteller – communication consultants. The project was carried out under the control of a Steering Committee composed of representatives from the following organisations:

National Market Surveillance Authorities

Belgium - Office of the Belgian Federal Minister for the Environment, Consumer Protection and Sustainable Development – Federal Public Service Economy, SMEs, Self Employed and Energy www.mineco.fgov.be

Denmark - Danish Safety Technology Authority (Sikkerhedsstyrelsen) www.sikkerhedsstyrelsen.dk

Netherlands - Ministry for Health, Welfare and Sport - Food and Consumer Product Safety Authority (Voedsel en Waren Autoriteit VWA) www.vwa.nl

Sweden - Consumer Agency (Konsumentverket) www.konsumentverket.se

UK - Department of Trade & Industry, Consumer and Competition Policy Directorate www.dti.gov.uk/ccp

PROSAFE – Product Safety Enforcement Forum of Europe (The network of European authorities responsible for market surveillance of consumer products). www.prosafe.org

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

UNICE – Union of Industrial and Employers' Confederations of Europe. www.unice.org

BEUC – European Consumers' Organisation (Bureau Européen des Unions de Consommateurs) www.beuc.org

Consumers Association - The UK consumers' organisation and publishers of Which magazine www.which.co.uk

Intertek RTC – The Intertek Research and Testing Centre in the UK carries out testing and consultancy projects for the safety and performance of consumer products www.intertek-rtc.com

Appendix V - Risk Estimation and Evaluation

This procedure is an example of a risk assessment method that could be used by companies to assist them in deciding whether to take corrective action. It is based on the guidelines to the EC GPSD. It is recommended that it is carried out by a small team who have knowledge and experience of the product and its hazards. 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 assessor should analyse the information collected and use the **Risk Assessment Table** (Page 38) as follows:

- 1 Use Table A to estimate the level of risk, depending on the severity and probability of the possible injury to a person using or otherwise coming into contact with the product (see notes below).
- 2 Use Table B to determine the level of risk that is acceptable for that product. This depends on factors such as the type of user and, for normal adults, whether the product has adequate warnings and guards and whether the hazard is sufficiently obvious (see notes below).
- 3 Overall assessment - compare the estimated level of risk from Table A with the acceptable levels in Table B to decide on the overall seriousness of the risk, which will influence the level of corrective action required (see Section 3.1 of the Guide).

1 Table A - Risk estimation

In Table A the two main factors affecting the estimation of risk - the severity and probability of injury - are combined. The following definitions of severity and probability have been drawn up to help choose appropriate values.

1.1 Severity of injury

The following table gives definitions of the severity classifications, with examples of typical injuries.

Slight	Serious	Very Serious
Less than 2% incapacity Usually reversible and not usually requiring hospital treatment.	2 – 15% incapacity Usually irreversible requiring hospital treatment	More than 15% incapacity Irreversible requiring hospital treatment
		Death
Minor cuts	Serious cuts	Serious injury to internal organs
Very minor fractures	Major fractures, loss of finger or toe	Loss of limbs
	Damage to sight	Loss of sight
	Damage to hearing	Loss of hearing
Minor burns	Moderate burns	Serious burns (more than 25%)
Sprains	Moderate disability	Severe permanent disability
		Serious mental disorder or prolonged coma

For many hazards it is possible to envisage unlikely circumstances that could lead to very serious injury e.g. tripping over a cable, which causes a fall and a bang on the head, leading to death. But a less serious outcome is often much more likely. For this reason the severity of injury

selected for a given hazard should be based on reasonable evidence that the injury attributable to the product could occur in foreseeable use. This could be the worst case from injuries that have occurred with similar products.

If it is possible for several people to be injured by a single product (e.g. fire or gas poisoning), this would increase the severity of risk. If injuries can become evident over a long period of time the assessment should take account of the predicted delay.

1.2 Overall Probability

The overall probability of injury combines all the probabilities which contribute, such as:

- The probability of a sample of the product being or becoming defective as a result of unpredictable failures (if all products carry the defect then this probability would be 100%). For defects that develop during the life of the product the probability should take account of the predicted time to failure.
- The probability of injury per year to someone using a defective product (for the type(s) of user who are intended or likely to be exposed to the product). This should take account of:
 - o typical exposure of a regular user of the product to the hazardous situation.
 - o the probability of injury to the person(s) exposed to the hazardous situation.

These probabilities are combined in the following table to give an overall probability that is entered into [Table A](#).

Overall Probability of Injury		Probability of product being defective		
		1%	10%	100% (All)
Probability of injury per year from regular exposure to hazardous product	Hazard is always present and injury is likely to occur in regular normal use	Medium	High	Very High
	Hazard is present intermittently and injury is likely to occur	Low	Medium	High
	Hazard is present intermittently and injury is possible.	Very Low	Low	Medium
	Hazard is present occasionally and/or injury is unlikely.	Extremely low	Very Low	Low

These assessments should take account of the following information: -

- Statistics (where available) for the
 - o Failures of this or similar products.
 - o Typical use of the product type
 - o Accidents that have occurred for this or similar products.
- Predictions based on understanding of
 - o Product failure modes
 - o Typical exposure of users of the type of product.
 - o 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 assessor(s). These assessments of the severity and overall probability of injury are combined in [Table A](#) to give an estimate of the level of the risk.

2 Table B - Risk evaluation

Much higher risks are acceptable in some circumstances, such as driving cars, than with others, such as children's toys. Table B shows the levels of risk that are acceptable in different circumstances. 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 is sufficiently obvious.

2.1 Vulnerable people

If the product is intended or very likely to be used by vulnerable people, the level of risk that is acceptable should be set at a lower level. Two categories of vulnerable people are shown below, with examples:

Very vulnerable	Vulnerable
Blind	Partially sighted
Severely disabled	Partially disabled
Very old or frail	Elderly, having some reduction in their physical and mental capabilities.
Very young (under 5yrs)	Young (5 – 11yrs)

2.2 Normal adults

For products such as knives, DIY and garden tools not intended or likely to be used by vulnerable people, consumers may accept a certain level of risk depending on:

- Whether the hazard is obvious and necessary for the product's use
- Whether the product has adequate warnings
- Whether the product has adequate guards and/or personal protective equipment provided.

3 Overall assessment

The overall seriousness of the risk is determined by comparing the estimated level of the risk with the acceptable levels of risk.

Table B shows 3 levels of overall risk:

- Serious Risk – requiring rapid action
- Moderate risk – requiring some action
- Low risk – not generally requiring action for products on the market

This procedure evaluates the seriousness of risk to an 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 in deciding what action to take, as described in Section 3.1 of the guide.

Risk Assessment Table

Risk Assessment of consumer products for the GPSD

This procedure is intended to help producers and distributors to decide if a risk from a consumer product is serious enough to require corrective action. The table is used to determine whether the overall risk is moderate, requiring some action, or serious, requiring rapid action.

Table A - Risk Estimation

		Severity of injury			Level of risk
		Slight	Serious	Very Serious	
Probability of injury	Very High		Very High	High	Very High
	High		High	Medium	High
	Medium		Medium	Low	Moderate
	Low		Low	Very Low	Low
	Very low		Very Low		Very low
					Extremely low

Table B - Risk Evaluation

Vulnerable people		Normal adults				Adequate warnings and guards? Obvious hazard?
		Very vulnerable	Vulnerable	No	Yes	
		No	Yes	No	Yes	
		No	No	Yes	Yes	

Very High	High	Moderate	Low	Very low	Extremely low	Very vulnerable	Vulnerable	No	Yes	No	Yes	Adequate warnings and guards? Obvious hazard?	SERIOUS RISK - RAPID ACTION REQUIRED
													MODERATE RISK - SOME ACTION REQUIRED
													LOW RISK - ACTION UNLIKELY

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Example (with reference to the arrows)

Table A, If the severity of the possible injury is **Very Serious** and the probability is **Very Low**, the level of risk is **Low**.

Table B The acceptability of the risk depends on the type of user (e.g. normal adult) and, for normal adults, whether the product has adequate warnings and guards (**No**) and whether the hazard is obvious and necessary for the product to work (**No**).

Overall assessment From the above, the overall level of risk is **moderate**, and some action is required.

4 Examples

The following examples are included to illustrate the method:

1) Gas barbecue

A gas barbecue has inadequate warnings against using the product indoors and it does not have a flame failure device to prevent gas escaping and causing a hazard if used indoors.

- **Table A** - The injury could be **very serious** (death) but the probability of injury is considered to be **very low** giving a **low** level of risk..
- **Table B** - The barbecue is for use by normal adults, has an inadequate warning (**No**) and a hazard that is not obvious (**No**), so the overall level of this risk would be **moderate**.

Table A - Risk Estimation				Table B - Risk Evaluation					
Severity of injury				Level of risk	Vulnerable people		Normal adults		Adequate warnings and guards? Obvious hazard?
Slight	Serious	Very Serious	Very vulnerable		Vulnerable	No No	Yes No	No Yes	
Probability of injury	Very High	High	Medium	Very High	SERIOUS RISK - RAPID ACTION REQUIRED	MODERATE RISK - SOME ACTION REQUIRED	LOW RISK - ACTION UNLIKELY	LOW RISK - ACTION UNLIKELY	
	High	Medium	Low	Moderate					
	Medium	Low	Very Low	Low					
	Low	Very Low		Very low					
	Very low			Extremely low					
				low					

2) Chain saw

A chain saw user suffers a badly cut hand. It is found that the chain saw has an inadequately-designed guard allowing the user's hand to slip forward and touch the chain.

- **Table A** The assessment of probability is **high** because the hazard is present on all products and may occur under certain conditions. The assessment of severity is **serious** so the overall level of risk is **high**.
- **Table B** The chain saw is for use by normal adults, has an obvious hazard (**Yes**) but inadequate guards (**No**), so the overall level of this risk would be **serious**.

Table A - Risk Estimation				Table B - Risk Evaluation					
Severity of injury				Level of risk	Vulnerable people		Normal adults		Adequate warnings and guards? Obvious hazard?
Slight	Serious	Very Serious	Very vulnerable		Vulnerable	No No	Yes No	No Yes	
Probability of injury	Very High	High	Medium	Very High	SERIOUS RISK - RAPID ACTION REQUIRED	MODERATE RISK - SOME ACTION REQUIRED	LOW RISK - ACTION UNLIKELY	LOW RISK - ACTION UNLIKELY	
	High	Medium	Low	Moderate					
	Medium	Low	Very Low	Low					
	Low	Very Low		Very low					
	Very low			Extremely low					
				low					

3) Christmas tree lights

The wires supplying some Christmas tree lights can be pulled out of the lamp socket, exposing live wires and causing a risk of electrocution.

- Table A** There is a risk of **very serious** injury (electrocution). The probability of that risk depends on the percentage of products that can be expected to develop the fault, and the probability of the combination of circumstances required to lead to serious injury. If only 1% of products are expected to come loose, and death only occurs if several conditions are met then the overall probability might be **very low**. This would give a **low** level of risk.
- Table B** The overall level of this risk for normal adults would be **moderate** because the hazard is not obvious (**No**) and a warning would be inappropriate. If the lights are accessible to very young children (**Very vulnerable**) the overall level of risk would be **serious**.

Table A - Risk Estimation				Table B - Risk Evaluation							
Probability of injury	Severity of injury			Level of risk	Vulnerable people		Normal adults				
	Slight	Serious	Very Serious		Very vulnerable	Vulnerable	No	Yes	No	Yes	Adequate warnings and guards? Obvious hazard?
Very High	Very High	High	Medium	Very High	↓	↓	↓	↓	↓	↓	↓
High	Medium	Low	Moderate	↓							
Medium	Low	Very Low	Low		↓	↓	↓	↓	↓	↓	↓
Low	Very Low		Very low	↓							
Very low			Extremely low								

4) Children's toy

A toy bear has eyes and buttons that are easily removable and could be a choking or inhalation hazard.

- Table A** There is a possibility of choking, which could lead to a **very serious** injury. All products are affected but the probability of choking depends on the size of the button and the ease of removal, so a few conditions have to be met. If the probability was considered to be **low** this would result in a **moderate** level of risk.
- Table B** Since the product is for use by very young children (**Very vulnerable**) the overall level of risk would be **serious**.

Table A - Risk Estimation				Table B - Risk Evaluation							
Probability of injury	Severity of injury			Level of risk	Vulnerable people		Normal adults				
	Slight	Serious	Very Serious		Very vulnerable	Vulnerable	No	Yes	No	Yes	Adequate warnings and guards? Obvious hazard?
Very High	Very High	High	Medium	Very High	↓	↓	↓	↓	↓	↓	↓
High	Medium	Low	Moderate	↓							
Medium	Low	Very Low	Low		↓	↓	↓	↓	↓	↓	↓
Low	Very Low		Very low	↓							
Very low			Extremely low								

Product Safety in Europe – A guide to corrective actions including recalls

Annex I - Abridged Guide

This is an abridged version of the Introduction and Sections 1 to 4 of the full guide, which should be referred to for more detailed information. Section numbers in this version are the same as in the full guide.

INTRODUCTION

Aim of this guide

If you are a producer or distributor of consumer products on sale in the European Union, this voluntary guide gives you general advice about what you should do if you have evidence that one of your products may be unsafe.

Scope

The guide covers all types of corrective action (not just product recall) by producers or distributors aimed at removing a safety risk arising from a non-food product they have placed on the market.

Corrective actions can include:

- Changing the design of products
- Withdrawing products from the distribution chain
- Sending information and warnings about correct use of products to consumers
- Modifying products at the customer's premises or elsewhere
- Recalling products from consumers for replacement or refund.

Who's responsible for corrective action?

Producers' and distributors' responsibilities for corrective action vary depending on the circumstances. Companies need to have agreements with their suppliers, which define their responsibilities for corrective action.

These responsibilities are summarised below to help companies decide which parts of the procedure apply to them.

Producers

The producer of a product must take the main responsibility for corrective action. For the purposes of corrective action the producer is defined as:

- **The manufacturer of the product**, when he is established in the Community,
- **Any other person presenting himself as the manufacturer** by affixing to the product his name, trade mark 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.

Distributors

Even if the distributor (wholesaler or retailer) of a product does not take on the responsibility of producer, he should still cooperate with the producer in taking corrective action.

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 records to help trace products and identify customers and end users
- 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

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- Identify the hazard and its cause
- Estimate how many products are affected
- Identify who might be affected
- Consider what severity of injury could result
- Assess the likelihood of such an injury
- Evaluate acceptability of overall risk.

3. If corrective action is needed – what to do?

- Decide whether the corrective action needs to involve:
 - o products in the supply chain and possibly
 - o 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.

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

- Trace the products and their owners
- Set up a communications 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 action on the products
- 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 standards and improve quality systems to try to avoid future problems
- Assess the success of your corrective action procedure and make any improvements
- Send comments and thanks to key participants.

1 Preparing your corrective action strategy

Planning ahead is vital so that producers and distributors can act quickly if they need to.

1.1 Establish your policy

Producers and distributors both need corrective action policies.

- Any evidence of consumer abuse or misuse of the product
- Any evidence of malicious tampering with products.

1.2 Agree your action plan

The main components of a corrective action plan are described below:

1.2.1 A corrective action team

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

- Design
- Production
- Product safety/risk management
- Quality assurance
- Purchasing
- Distribution
- Marketing and customer service
- Public and corporate relations
- Legal
- Accounts.

1.2.2 Monitoring procedures

Producers and distributors must have procedures for monitoring problems with their products. This means you need to have systems to collect and analyse the following information:

- Reports of accidents involving your products
- Complaints from customers, 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
- Reports on returned components and products
- Any evidence of hazards arising from sales to unexpected user groups.

1.2.3 A product traceability plan

Customers need to be able to identify products which may be unsafe and you need to be able to trace the customers who have bought them. This means that you should have:

A way of identifying affected products

- 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 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 product.

A customer database

For effective corrective action, producers and distributors should keep records of customers and their purchases. This information should include:

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

The following records may provide sources for this information:

- Sales records for business customers should identify which products have been supplied
- Records kept by retailers of products customers have bought
- Guarantee or registration cards can also help

- Servicing records may be a source of customer information
- Companies selling products via the Internet or by mail order should also be able to identify purchasers.

A supplier database

If a safety problem has been caused by a component from a supplier, you need to be able to identify the supplier's reference number on the components fitted to your products.

1.2.4 Technical documentation

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 concerned with product safety.
- Any changes that have been made and the dates and/or the serial numbers or batch numbers of products they apply to.

1.2.5 Communication and contact lists

You need to maintain a list of all the people and organisations that may need to be contacted. The contact list should include: -

Contacts in your company

- Responsible senior management
- Members of the corrective action team
- Other key personnel
- Manufacturers representatives and other selling agents
- Warehouse
- Carriers.

Contacts in other organisations

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

Service providers

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

1.2.6 Risk assessment and corrective action procedures

Companies need a written procedure for how they would carry out a risk assessment and take corrective action on a potentially unsafe product. (See Sections 2 and 3)

2 Assessing the risk

If your monitoring procedures suggest one of your products may pose a risk to consumers, you 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 small team with experience of the product and the hazards involved. [Appendix III](#) gives sources of information on risk assessment and [Appendix V](#) gives details of a risk assessment method that has been incorporated into the guidelines to the EC General Product Safety Directive. Other methods may be suitable and your choice of method may depend on your resources. Risk assessment usually has several phases incorporating the following principles:

2.1 Identify the hazard

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

- What is the nature of the hazard?
- What is the cause of the hazard? (occasional product defect, product deterioration, unusual operating conditions, misuse of product, random failure etc)
- What range of products (models) is affected?
- Who is affected by the hazard? (user, bystander)
- What factors could affect the severity and probability of injury? (competence of user, age of product, method of use etc)

2.2 Estimate the level of risk

When you have collected this information you should estimate the level of risk to help you to decide whether action is needed.

Estimating the risk depends on two main factors:

- The severity of the possible injury to a person using or otherwise coming into contact with the product.
- The probability of the possible injury. This is affected by the following factors:
 - o The probability of a product being or becoming defective and the time to failure
 - o The frequency with which a user is exposed to the hazard
 - o The probability of being injured when exposed to the hazard.

The severity and probability estimates are combined to give an overall risk estimation. To help you to evaluate the scale of the problem you also need to collect the following information:

- How many products are on the market?
- How many of the products sold are likely to be still in use?

2.3 Assess the acceptability of risk

To decide whether you need to take action you also need to assess whether or not the level of risk is acceptable to consumers. Certain types of products (such as tools or machines with sharp blades) have obvious hazards that are accepted by consumers if they consider that the manufacturer has taken appropriate safety measures. For products likely to be used by more vulnerable people (such as child care products) consumers would not accept anything more than a very low level of risk.

2.4 Overall risk

Having evaluated all these factors you should make an overall risk assessment which may be expressed as one of the following levels:

- Serious risk – requiring rapid action
- Moderate risk – requiring some action
- Low risk – not generally requiring action for products on the market

3 Taking 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’ in the Introduction. 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 3.1, 3.2, 3.8, 3.9 and 3.10 apply to all actions.

Sections 3.3 to 3.7 apply only if the action affects products in the hands of consumers.

3.1 Decide what action is needed

The decision about the type of action to be taken will be mainly dependent on the level of acceptability of the risk but it may also take account of:

- The total number of consumers affected
- The practicalities of taking action
- The anticipated success of taking action
- The advice of the market surveillance authorities
- Media sensitivity to the hazard.

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 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 communications programme to contact consumers.

If the level of risk is judged to be moderate the corrective action may be limited to products in the distribution chain, and it may be enough to withdraw these and give the authorities details of what is being done - see Section 3.2.

If the level risk is judged to be low corrective action may generally be limited to consideration of changes affecting products in design and production.

Type of action

Possible corrective actions may include:

- Changing the design of products
- Changing the production method
- Isolating and withdrawing products from distribution
- Modifying products in the distribution chain (such products need to be marked)
- Improving the instructions supplied with the product
- Sending additional information to consumers about the correct use of products
- Modifying products at consumers’ premises (such products need to be marked)
- Return of products by consumers for modification
- Recalling products from consumers for replacement or refund.
- Instruction to consumers to dispose of products
- Offering consumers a replacement or refund for recalled or discarded products is likely to make the action more successful.

3.2 Inform the market surveillance authorities

Producers and distributors should give the authorities some preliminary information about a product risk as soon as they are aware of it. If the overall risk is judged to be serious enough you should notify the market surveillance authorities immediately unless you have ensured that the authority has already been informed by another company or authority.

3.3 Trace products and their owners

The activities described in [Section 1.2.3](#) need to be coordinated by your corrective action team, but if you are carrying out corrective actions in different countries you may need to delegate many of them to a local agent.

3.4 Set up a communications programme

Whether or not you have the contact details of your customers, you need to set up a communications programme to make contact with them. This should include the following elements:

- A central communication centre with free telephone number (hotline)
- A list of audiences to be contacted
- A list of media to be used
- Draft communications for different media and audiences

3.5 The message and who to contact?

The message

A corrective action announcement should contain:

- A clear heading containing words such as 'Important Safety Warning'
- Product identification details (name of product, batch number, serial number, bar code, colour, size and a picture or line drawing of the unsafe product)
- A clear description of what is wrong with the product
- Details of the safety risk or potential safety risk
- Clear instructions on what to do.
- A web site address or hot line for further information
- If appropriate, apologies for any inconvenience.

An example of a corrective action announcement is given in [Appendix II](#).

Who to contact?

The following audiences need to be contacted:

- Consumers (see [Section 3.7](#))
- Internal staff members
- Key business customers, distributors and suppliers
- The market surveillance authorities (see [Section 3.2](#))

Although there needs to be 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.

3.6 How to communicate the message

Ideally you need to try to contact consumers directly. If that's not possible, 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 choose from the following media:

- Newspaper advertisements
- Consumer telephone services (hot line, info line, free lines)
- Point-of-sale information (leaflets, mini-posters)
- TV/radio news and consumer programmes
- TV/Radio advertising.
- Press service (web site, media room and dedicated media telephone line(s) directed at the news editors of daily national and regional newspapers.
- Web sites (sometimes called 'Dark Sites' that have been prepared and can be activated when you need them)

Recall advertisements in the press should be placed in the most suitable newspapers in each country to reach your target audience.

3.7 Deal with your consumers

Personal contact with consumers is generally the best way to ensure your corrective action is effective. If you have customers' contact details you should send a personal letter or email or make a phone call giving the information in the corrective action announcement. However you need to recognise that some consumers will have changed address or passed the product on to someone else.

3.8 Communicate with other people

You should pass the same information to all your staff, and consider informing the general public as quickly as possible.

3.9 Carry out the corrective action

You need to carry out the corrective actions decided in [Section 3.1](#), in each of the countries involved and for all products affected, as quickly and efficiently as possible. Products need to be dealt with in the following ways:

Collect products

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

- Arrange to collect them from distributors
- Ask consumers to take the product to their nearest distributor or retailer if they are portable
- Arrange for them to be collected from the consumer if they are not portable.

Unsafe 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.

Correct the products

If you have offered to repair or rectify the consumer's product you 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.

Modified products should be clearly marked.

You 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 which have been rectified need to be clearly marked and the documents accompanying them may need to be updated.
- Rework some of the materials or components to enable them to be reused in other products.

It is not acceptable to sell or pass on uncorrected products to consumers. If they cannot be corrected or reworked you will need to ensure that the products are disposed of safely.

3.10 Monitor progress

Before your corrective action starts you will find it helpful to set a target for the level of response in each country. Authorities in individual countries may be able to give you information about the likely level of response. You may set different targets for the response from distributors and the response from consumers.

When your corrective action has started, you need to monitor the level of response for a period of weeks and further action may be needed if the target is not reached. If you reach the target, the corrective action can be formally ended, but you still need to be able to deal with products that are returned to you at a later date.

4 Learning from experience

After the corrective action is over you need to look at what caused the problem initially with a view to trying to stop it happening again. Finally, you should assess the success of your corrective action procedure and try to improve it for the future.

4.1 How can we stop it happening again?

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

- the standards and design principles that you use and
- the effectiveness of your quality assurance and product safety/risk assessment systems.

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

4.2 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 you should:

- Monitor the effectiveness of the communication methods used (possibly by carrying out opinion research) and adapt your policy where necessary
- Evaluate your internal procedures for corrective action and assess the need for changes in policy or training
- Compile a full report of all actions taken and issues solved during the period of the action.