PAS 7100: 2018

Consumer product safety related recalls and other corrective actions:

Part I Code of practice for business

Part II Guidance for regulators

This draft of PAS 7100 is released for peer review and public comment over the period 25th September 2017 to 23rd October 2017.

Reviewers should be aware that the review draft of a PAS should not be thought of as the version that will necessarily be published. Its purpose is to unambiguously set out the Steering Group's current intentions as to the nature, extent and approach of the new specification, with a view to encouraging further input from other experts in the subject. It is acknowledged that the comments submitted during the review could lead to substantial change to the content of the PAS before publication.

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Foreword

Development of this Publicly Available Specification (PAS) was sponsored by the Regulatory Delivery Directorate of the Department of Business Energy and Industrial Strategy (BEIS) following a recommendation of the Working Group on Product Recalls and Safety (WGPRS). Its development was facilitated by BSI Standards Limited and it was published under licence from The British Standards Institution. It came into effect on xx February 2018.

Acknowledgement is given to the following organizations that were involved in the development of this PAS as members of the WGPRS and as members of the PAS steering group:

- *Editorial Note:*

A list of organizations nominating members to the PAS 7100 Steering Group will be inserted here prior to publication. (By agreement with individual organizations). Consideration will also be given to the inclusion of organization logos, also by arrangement with nominating organizations..

This PAS is not to be regarded as a British Standard. It will be withdrawn upon publication of its content in, or as, a British Standard. The PAS process enables a code of practice to be rapidly developed in order to fulfil an immediate need in industry. A PAS can be considered for further development as a British Standard, or constitute part of the UK input into the development of a European or International Standard.

Use of this document

It has been assumed in the preparation of this PAS that the execution of its provisions will be entrusted to appropriately qualified and experienced people, for whose use it has been produced.

Presentational conventions

The provisions of this standard are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is “shall”. Commentary, explanation and general informative material is presented in italic type, and does not constitute a normative element. Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. “organization” rather than “organisation”).

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application. Compliance with a PAS cannot confer immunity from legal obligations.

Ministerial Statement

- *Editorial Note:*

It is the intention that a ministerial statement be included here at time of publication.

Introduction

The development of this PAS has been informed by the work of the WGPRS and associated behavioural insight research into the effectiveness of product recalls.

The law requires that products placed on the market in the United Kingdom must be safe, with the responsibility for ensuring that safety being borne by businesses across the supply chain.

The responsibilities imposed by the legislation include duties to:

- place on the market only safe products, supported by information on their correct use;
- warn consumers about potential product-related risks;
- monitor the safety of products;
- take corrective action if a product safety problem is identified.

Although the vast majority of products are safe and do not become the subject of corrective action, the availability of a planned course of action is critical to ensuring a timely and effective response should a safety issue or potential safety issue arise.

Businesses may experience potential recall situations rarely and this code is intended to make it easier for them to prepare to deal with such situations.

Part 1 sets out a code of good practice for monitoring, assessing, notifying and correcting unsafe products, including through a recall or other corrective action if required with emphasis on the preparation of a corrective action plan (**CAP**), in advance of actual need. The code also provides guidance on activities required should a need for corrective action arise.

Part 2 sets out guidance for regulators on the assistance that should be available to businesses to support them in meeting their responsibilities in respect of issues or potential issues that arise which involve consumer product safety.

The code provides practical guidance for businesses and does not replace or override any of the legal duties to which businesses are subject.

Part 1 – Code of practice for business

1 Scope

This PAS consists of two parts, Part 1 sets out the code of practice for business and provides practical guidance to help them:

- prepare to manage a possible safety related product recall or other corrective action;
- establish mechanisms to monitor the safety of products
- investigate any potential product safety issue;
- establish mechanisms to deal with any product safety issue identified;
- review corrective action programmes to ensure that product safety responsibilities continue to be met.

The PAS is focussed on consumer products and is intended for use by manufacturers, importers, distributors. The content could also be relevant for business to business supply.

The PAS assumes that businesses placing products on the market will have already addressed their responsibility to supply only safe products therefore guidance on this is not provided.

The PAS is not intended to conflict with existing sector specific schemes (e.g. automotive) which should be referred to in respect of the product categories covered.

2 Terms and definitions

For the purposes of this PAS, the following terms and definitions and abbreviations, apply:

NOTE: Definitions for which a legislative source is identified are not necessarily presented in the normally accepted format for standards

2.1 authorised representative

any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specific tasks with regard to the latter's obligations under the relevant Community legislation

(Source: Regulation (EC) No 765/2008)

2.2 consumer

individual member of the general public purchasing or using property, products or services for private purposes

(Source: ISO 2600:2010)

2.3 corrective action

action undertaken with the intention of removing potential for harm and to reduce risk

(derived from: ISO 10393:2013)

2.4 distributor

a) any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market

(Source: Regulation (EC) No 765/2008)

b) professional in the supply chain whose activity does not affect the safety properties of a product

(Source: GPSR, SI 2005 No 1803)

Note: throughout this PAS distributor is used in a manner that includes retailer.

2.5 harm

Physical injury or damage to the health of people, or damage to property

(SOURCE: ISO/IEC Guide 51:1999, 3.3, modified)

2.6 hazard

potential source of harm

Note: the term hazard can be qualified in order to define its origin or the nature of the expected harm (e.g. electric shock hazard, biological hazard, crushing hazard, cutting hazard, toxic hazard, fire hazard, drowning hazard).

(SOURCE: ISO/IEC Guide 51:1999, 3.5)

2.7 importer

any natural or legal person established within the Community who places a product from a third country on the Community market

(Source: Regulation (EC) No 765/2008)

2.8 making available on the market

any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge

NOTE: The concept of making available refers to each individual product.

(Source: Regulation (EC) No 765/2008)

2.9 manufacturer

any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark

(Source: Regulation (EC) No 765/2008)

2.10 market surveillance authority (MSA)

any regulator with enforcement responsibilities in relation to consumer product safety regulations, including local weights and measures authorities in England, Scotland and Wales (often referred to as trading standards) district councils in Northern Ireland and the Secretary of State (Department for Business, Energy and Industrial Strategy)

2.11 placing on the market

The first making available of a product on the Community market

(Source: Regulation (EC) No 765/2008)

2.12 primary authority

a statutory scheme in which a single local authority can partner with a business, or with a group of businesses, taking on responsibility for providing regulatory advice and guidance to them which they are, subject to legal safeguards, entitled to rely on wherever they trade across the UK

2.13 producer

(a) the manufacturer of a product, when he is established in a Member State and 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;

(b) when the manufacturer is not established in a Member State—

(i) if he has a representative established in a Member State, the representative,

(ii) in any other case, the importer of the product from a state that is not a Member State into a Member State;

(c) other professionals in the supply chain, insofar as their activities may affect the safety properties of a product

(Source: GPSR, SI 2005 No 1803)

2.14 product

a) means a product which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them and which is supplied or made available, whether for consideration or not, in the course of a commercial activity and whether it is new, used or reconditioned and includes a product that is supplied or made available to consumers for their own use in the context of providing a service. “product” does not include equipment used by service providers themselves to supply a service to consumers, in particular equipment on which consumers ride or travel which is operated by a service provider

(Source: GPSR, SI 2005 No 1803)

b) any product - including in the context of providing a service - which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers

even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.

This definition shall not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect

(Source: GPSD 2001/95/EC)

2.15 recall

any measure aimed at achieving the return of a product other than a safe product, that has already been supplied or made available to consumers

(Source: GPSR, SI 2005 No 1803)

2.16 risk

a) combination of the probability of occurrence of harm and the severity of that harm

(Source: ISO/IEC Guide 51:1999)

b) combination of the probability of occurrence of a hazard generating harm in a given scenario and the severity of that harm

(Source: EU general risk assessment methodology)

2.17 risk assessment

a) overall process comprising a risk analysis and a risk evaluation

(Derived from: ISO/IEC Guide 51:2014)

2.18 safe product

product which under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risk compatible with the products use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
ii) the effect on other products where it is reasonably foreseeable that it will be used with other products;
iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;
iv) the categories of consumers at risk when using the product, in particular children and the elderly

NOTE: The feasibility of obtaining high levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be "dangerous".

(Source: GPSR, SI 2005 No 1803)

2.19 safety

freedom from risk which is not tolerable

(Source: ISO/IEC Guide 51:2014, 3.14]

2.20 supporting regulator

A national regulator or government department that has a statutory role in Primary Authority of providing support to a primary authority in its provision of advice, or its development and management of an inspection plan. The following are specified as supporting regulators:

- the Health and Safety Executive;
- the Food Standards Agency;
- the Gambling Commission;
- the Competition and Markets Authority; and
- the Secretary of State, in relation to his regulatory functions concerning weights and measures and product safety regulation.

(derived from Primary Authority Statutory Guidance)

2.21 technical documentation

information on the design, manufacture and operation of the product

(Source: the 'Blue Guide' on the implementation of EU products rules, 2016/C 272/01)

2.22 tolerable risk

level of risk that is accepted in a given context based on the current values of society

(Source: ISO/IEC Guide 51:2014, 3.15]

2.23 withdrawal

any measure aimed at preventing a product in the supply chain from being made available on the market

(Source: Regulation (EC) No 765/2008)

Abbreviations, acronyms and initializations

The following representations are used in this document:

CAP	corrective action plan
BEIS	UK Government Department for Business, Energy and Industrial Strategy
GPSR	General Product Safety Regulations *(Implementing the General Product Safety Directive in the UK)*
ICSMS	**i**nformation and communication system for market surveillance (database)
MSA	market surveillance authority
RAPEX	rapid alert system for non-food consumer products
WGPRS	working group on product recall and safety

3 Regulatory context

Summaries of the regulatory requirements to supply only safe products complying with the general product safety requirement and also with product specific safety regulations are set out in **Annex A** together with details of product liability under civil law.

The Annex also sets out the specific responsibilities of manufacturers, importers, distributors with respect to product safety.

4. Advance planning for corrective actions

4.1 Context

Advance planning is essential to enable a business to act quickly if, as and when questions as to the safety of a product arises. This section of the PAS is intended to provide practical guidance on the preparation of a corrective action plan **CAP.**

A **CAP** should be in place and include the entirety of policies, organization and plans required to make delivery of an effective corrective action possible. Both producers and distributors should have **CAP**s in place.

4.2 Senior management commitment

It is essential that the senior management of the business commit to the development and operation of a **CAP.** This will be, at Board level where this exists or with the owner or most senior decision maker. There needs to be clarity as to who is responsible and accountable for development and operation of the **CAP**.

The **CAP** will ensure that the organization is prepared to deal with any incident potentially requiring corrective action should it arise and devote sufficient resources to deal with it. Where possible, the **CAP** should be referenced in the organization's management system e.g. implementing ISO 9001.

Key elements of this **CAP** commitment include:

- allocation of responsibility for leading and developing the **CAP,** and preparation of a business policy statement;
- securing support for the **CAP** internally
- engagement with relevant supply chain partners;
- internal publication and dissemination;
- arrangements for periodic review;
- formal senior management or business owner endorsement.

4.3 Developing a CAP

A **CAP** should be developed by persons having knowledge of the following functions:

- design;
- production;
- technical / quality assurance;
- risk management (including insurance liability considerations);
- purchasing;
- supply chain management /logistics/ distribution;
- sales;
- marketing
- customer services;
- product servicing;
- public and corporate relations;
- web communication and website management;
- product legal compliance;
- finance.

In smaller organisations, several functions may be the responsibility of one person.

Some of these functions may be carried out or supported by external organisations.

The **MSA** should be consulted in development of the **CAP**.

Where a business already has a primary authority, help will be available from that source. It is recommended that any business without a primary authority should consider entering into a partnership with a local authority which is an **MSA**.

4.4 Contents of the CAP

4.4.1 CAP elements

A CAP should include the elements described in **4.4.2** to **4.4.10**:

- traceability plan (**4.4.2**);
- product safety monitoring plan (**4.4.3**)
- legal notification plan (**4.4.4**);
- risk assessment plan (**4.4.5**);
- corrective action decision plan (**4.4.6**);
- communications plan (**4.4.7**);
- training plan (**4.4.8**);
- testing plan (**4.4.9**);
- review plan (**4.4.10**)

The CAP should set out responsibilities and actions (who, what, where, when, why and how) in respect of each of the above.

4.4.2 Traceability plan

4.4.2.1 Products

The General Product Safety Regulations and product sector-specific regulations contain traceability marking requirements that must be followed.

Being able to identify products and their key components is central to the ability to successfully withdraw or recall them from the market place.

This traceability information should identify: the producer or manufacturer of the item; the general product identifier (e.g. model reference); and a specific identifier for that product or series of products (e.g. serial number, batch reference, date of manufacture).

Providing this traceability information so that it is readily accessible by both consumers and market surveillance authorities is essential to a successful corrective action. Therefore, deciding what form the traceability information should take, where it should be positioned on the product to facilitate easy access, and the best way of including this information so that it remains legible after use all need to be considered within the design process.

While it is not always possible to include this information on the product itself, e.g. due to product size limitations, providing the information on the product itself is always the preferred approach, since packaging is often discarded, making it then far more difficult (if not impossible) to identify products should a corrective action be necessary.

Consideration should also be given to the durability of markings to enable them to withstand fire and /or water damage.

Another part of the design process should include deciding which parts, components, sub-assemblies etc. are likely to play an important part of the safety of the final product, since these too will need traceability information to be included on them. This information is likely to be vital to the manufacture, should a corrective action become necessary, as it not only allows cross-checking against complete products but also because it could affect spare parts held in stock or made available to third parties.

4.4.2.2 Customers

The **CAP** should allocate responsibility for ensuring that customer contact information is systematically captured.

The level of traceability that is possible will vary depending on the product type and method of sale.

Where appropriate in accordance with data protection rules, producers and distributors should aim to keep records of customers and their purchases. This information should include:

• name, address, postcode, telephone number and email addresses

• brand, model, serial number, and date of the purchase.

The following may provide sources for this information:

- sales records (including for internet transactions)
- records kept by distributors;
- guarantee or registration cards or on-line registrations;
- product delivery information;
- servicing records;

- post-purchase registration schemes enabling consumers to record the products they possess for product safety purposes;
- distributor loyalty card schemes;
- banks and credit card provider records

4.4.3 Product safety monitoring plan

Producers and distributors are required to establish mechanisms to carry out effective monitoring of the performance of their products to identify potential safety issues that might arise.

The **CAP** should set out the arrangements to collect and analyse the following information on an ongoing basis in respect of each product that a business supplies:

a) Information demonstrating compliance of the product type:

- internal quality control procedures;
- results of product testing;
- information from service engineers or from after sales/repair centres;
- reports on examination of returned components and products;

b) Incoming information from customers:

- direct reports of incidents or accidents involving products;
- complaints from consumers, direct or via distributors;
- guarantee / extended warranty claims;
- insurance claims or legal actions;
- media and social media reports

c) Other sources of information:

- information from supply chain partners
- retail and insurance sector notification of potential issues (arrangements for collation of incident information across sectors for example retail can enable early identification of potential issues)
- developments in legislation or standards concerning the products involved;
- notifications and requests made by regulators
- government product recall website
- trade associations
- EU RAPEX / OECD product recall databases

Businesses should also be mindful to gather any evidence of hazards arising from sales to unexpected user groups, consumer abuse or inappropriate use of the product, malicious tampering with products.

The **CAP** should provide for prompt investigation of any information suggesting a product may be unsafe.

4.4.4 Legal notification plan

Producers and Distributors within the limits of their respective activities are legally required to notify the relevant **MSA** forthwith if they know that a product they have placed on the market or supplied is unsafe.

This notification must include information taken to reduce risk to consumers and in the case of a serious risk must provide the following:

- information enabling a precise identification of the product or batch of products in question
- a full description of the risks the product presents
- all information relevant for tracing the product

Notification should not be delayed because the business is not yet in a position to provide all of the required information in this case the additional information should be provided as it becomes available.

UK Government guidance on the notification requirement under the general product safety requirement is available at gov.uk.

The **CAP** should emphasise the legal duty to notify the **MSA** and allocate responsibility for timely notification.

Best practice is for the **CAP** to make provision for early sharing of information (through Primary Authority) of any potential issue emerging from product safety monitoring activity which may assist the business in determining if and when notification is required.

4.4.5 Risk assessment plan

It is essential that decisions around the need for and content of corrective actions including recalls are evidence-based and take into account the severity of the hazard and the likelihood of its occurrence.

The **CAP** should include a plan for how incidents will be investigated and risk assessment carried out, including objective assessment of the severity of a potential hazard and the likelihood of its occurrence.

This CAP is recommends the use of risk assessment methodologies such as those provided at **Annex C**.

Risk assessment needs to be carried out by a person or a small team with relevant competence relating to the methodology of the risk assessment tool being used and relevant knowledge and expertise of the product and hazards involved.

In assessing the hazard and likelihood of its occurrence, specialist expertise is sometimes required and primary authorities, will be able to assist the business in identifying likely sources of such expertise. In matters involving fire risk, the expertise of a fire and rescue authority or other specialists in fire safety should be sought.

The **CAP** should include information as to the circumstances in which external knowledge and expertise may be sought and where this support is likely to come from.

An **MSA** may support a business during the risk assessment process and agree the outcome as reflecting the wider public interest.

The **CAP** should make provision for a full record of any risk assessment completed to be retained as a record setting out the objective evidence supporting the decisions made.

4.4.6 Corrective action decision plan

The **CAP** should set out clearly how decisions on corrective action will be made and by whom.

The **CAP** should identify nominated decision makers and set out the authorisation and consultation requirements that will be followed in the event that a programme of corrective action is instituted. The **CAP** should set out timescales involved and contingency plans if nominated decision makers are not available.

Decisions must be made objectively using all the available evidence in a timely manner to prevent potentially unsafe products reaching the market.

The **CAP** should require that corrective action be proportionate to the level of risk posed by the safety incident in question using accepted guidance.

The CAP should provide for the assessment of the overall level of risk as follows:

a) Serious risk:

Immediate action be taken to:

- 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;
- put arrangements in place to deal with affected product.
- Notify the **MSA**

(If the level of risk is assessed to be high the actions for serious risk may still be appropriate).

b) medium risk:

- Detail of circumstances in which corrective action may be limited to products in the distribution chain and/or to:
- issue revised warnings or instructions to consumers and,
- share details with the **MSA** regarding what has been/is being done.

c) Low risk:

circumstances in which it may be sufficient to limit corrective action to changes affecting products in design and production.

Consideration should be given in the **CAP** to arrangements for the safe and lawful disposal of affected products.

The **CAP** should provide for a nominated individual to keep a record and timeline of key decisions and actions during consideration and implementation of corrective actions.

4.4.7 Communications plan

4.4.7.1 Contacts
The **CAP** should provide for a list of the organisations and individuals that may need to be contacted (for each product) during a corrective action to be maintained.

It is important to ensure that the relevant contacts are identified in each of these organisations and that information is kept up to date.

Most individuals will need to be contacted by email and telephone as soon as a problem is identified.

The contact list should include:

a) Internal business contacts

- responsible senior management;
- nominated decision makers;
- members of the corrective action team;
- manufacturer's representatives and other selling agents;
- repair centres;
- logistics;
- communications;

b) Contacts in other organisations

- **MSAs**
- professional users;
- component suppliers;
- distributors
- trade associations;
- legal advisors;
- risk assessment experts;
- medical experts;
- technical product experts;
- TV and other relevant media.

c) Service providers

- servicing businesses;
- test laboratories;
- insurers;
- call centre agencies;
- waste disposal specialists;
- media advisors.

4.4.7.2 Communications
Effective communication with identified contacts is central to a successful corrective action.

The **CAP** should establish mechanisms to ensure a comprehensive communications and media plan is in place that identifies a nominated person with responsibility for it. The plan

should set out how timely and effective messages will be prepared and disseminated to the following audiences:

- consumers;
- internal staff members;
- business customers, distributors and suppliers;
- the relevant **MSA(s);**
- media – (proactively and reactively).

The communication plan should include how the following will be delivered:

- communication plans for different media and audiences.
- communications capability centre with Freephone telephone access;
- corrective action web site and email address;
- a list of the businesses and consumers to be contacted;
- a list of media including social media to be used;

4.4.7.3 Content of recall and other corrective action announcements
The **CAP** should include template corrective action announcements

Announcements need to be clear, concise, factual and easily understandable.

A corrective action announcement should contain:

- a clear heading that draws attention to the announcement containing words ‘Important Safety Warning or Product Recall
- 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 the safety risk or the potential safety risk;
- details of when and where the product was available for sale;
- a description of the action required by any consumer who believes they have a product covered by the announcement;
- details of any proposed refund or arrangements for replacement;
- the statement ‘Unplug and do not use’ or ‘Do not use pending repair’ must be included if appropriate;
- a web site address and Freephone number for further information;
- apologies for any inconvenience.

Announcements should not include the words ‘voluntary’ or ‘precautionary’, ‘possible’ or contain information that otherwise detracts from the seriousness of the risk being communicated.

Fire risk should be described as such and not as an ‘Overheating’ or ‘Quality defect’.

The reading age for announcements should be kept low and graphics should be used where possible as English may not be the first language of some of the target audience.

An example corrective action announcement is given in **Annex H**.

4.4.7.4 Communication channels

The **CAP** should be clear on which communication channels will be used in which circumstances and plans should be in place to enable communications to be developed and implemented rapidly if required.

Examples of communication channels include:

- personal contact affected with consumers (some consumers will have changed address or passed the product on to others so additional actions to trace product are also likely to be necessary);
- dedicated corrective action web site;
- web site links should appear on all relevant company websites and be clearly visible on and signposted from the home page;
- social media;
- point-of-sale information (leaflets, mini-posters);
- .Gov.UK and third party recall web sites;
- radio/TV news and consumer programmes;
- media news rooms;
- advertisements in newspapers;
- advertisements in specialist publications or specialist publications;
- telephone services (free-phone contact capability);
- mailshots / door to door leaflets;
- store loyalty schemes.

Examples of direct consumer communication informed by behavioural insights research is included at **Annex H**.

Use of the media mechanisms listed above is not necessary for all corrective actions. The methods selected for each programme should relate to the assessed level of risk, the affected product type and the consumers likely to be affected.

Personal contact with affected customers is known to be the most likely method of ensuring effective engagement with a corrective action programme.

It is unlikely a single approach will deliver a successful corrective action programme.

It is highly unlikely that an A4 notice at an in-store customer service desk or an advertisement in a single daily newspaper will deliver an effective response.

Itis best practice for the action proposed to be discussed with the **MSA** to agree adequacy of the communications plan.

If a pro-active media release is not considered necessary a set of messages should be prepared to respond reactively to media enquiries. The decision to issue a media release would be kept under review in case the scale or nature of the issue subsequently makes it necessary.

4.4.7.5 Managing Communication:

a) with consumers:

As part of development of the **CAP** a plan should be developed to deal effectively with peaks of demand and increased levels of consumer enquiries. This is likely to involve additional or contracted consumer contact capability that will have capacity and capability to handle the volume and nature of incoming consumer contacts having regard to the number of products, models impacted by any potential corrective action.

Telephone enquiry staff will need to be competent to deal with likely enquiries and have information on affected products, be able to provide clear advice to consumers on next steps and have facilities to record details of enquiries.

The **CAP** should set out how staff will be trained – this could be through:

- face to face briefing on what is required;
- written materials explaining what is expected from them and support from a dedicated member of the corrective action team;
- a corrective action package containing all technical details (this should be issued at the same time as the corrective action announcement or soon after);
- a Q&A document updated regularly during the corrective action period;
- training on how to deliver messages and deal with problems.

Records of customer contact should be maintained in accordance with rules on data protection,

b) .with the media

Businesses should consider the need to have need a trained spokesperson to respond to that can make the corrective action a priority to deal with any media enquiries concerning potential corrective actions. This could be an internal or external resource, but the CAP should consider this matter in advance rather than waiting for a corrective action to occur.

Responding quickly and competently to information appearing in the media is essential to help avoid speculation and retain control of information affected consumers and the public.

c) with MSAs

It is advisable to have a nominated point of contact between the relevant **MSA** and the business including provision for out of hours contact.

Through primary authority relationships, it is anticipated that **MSAs** will be familiar with the business and its **CAP**, ahead of any incident arising.

d) with supply chain partners and industry bodies

This is most appropriately carried out by individuals who normally have day to day business contact with these organisations. These individuals need to be fully briefed on the corrective action and recall programme.

4.4.8 Training plan

It is essential that all managers and employees are informed of the importance of the **CAP** and that those who will be required to act should an incident arise are familiar with the detail of what is required of them.

This training should be documented and updated as new managers and employees become involved.

4.4.9 Testing plan

It is recommended that the whole **CAP** should be tested periodically by a combination of audit and trial exercises to ensure that it operates effectively and any shortcomings are identified and corrected.

A checklist for the assessment of corrective actions is included at **Annex D**.

Review by the relevant **MSA** may provide an effective form of external scrutiny.

4.4.10 Review plan

The **CAP** should provide for periodic review and updating of the plan. All such review and its outcomes should be documented and **CAP** revisions subject to version control.

5. Managing a corrective action

5.1 Context

Businesses should follow a detailed **CAP** setting out how any potential safety incident will be approached, with that plan being developed as recommended in **clause 4** of this PAS.

This section of the PAS is intended to provide practical guidance even where advance planning has not taken place. However, it is strongly recommended that following the completion of the required corrective action that the learning derived from it is used to develop a **CAP** in case of future need.

A detailed record and timeline should be kept recording all decisions made and actions taken and personnel involved. This task should be specifically allocated to one individual.

An example of a well-controlled corrective action is provided at **Annex B**.

5.2 Incident management

Should information become available indicating that a product safety issue may have arisen an individual familiar with the **CAP** and nominated to lead coordination of response by the business should:

- ensure legal notification requirements are met
- ensure competent individuals investigate the relevant circumstances (normally technical, customer services, communications specialists)
- develop a clear understanding of the issue*
- assess what the hazard is and how likely it is to occur
- review previous history of incidents and actions taken
- identify the products affected
- determine the number of products made and distributed
- determine if any products are still likely to be in the supply chain
- estimate the number of products still likely to be in use by consumers
- check whether product monitoring has found other relevant information
- decide whether more checks and/or increased monitoring is needed

Product technical files can often provide a useful source of information.

Once a need for more detailed investigation has been identified in the belief that there is in fact a product safety issue requiring corrective action the following preparatory steps should be taken:

- make arrangements to detain product currently in the supply chain as a precaution;
- complete a formal risk assessment using an accepted methodology;
- commence tracing product;
- give advance warning to other members of the corrective action team.

The risk assessment should be properly informed with input from relevant expertise relating to hazards identified on such issues such as fire, strangulation, choking risk if it does not exist within the business.

The risk assessment and decisions based on it must be kept under regular review as further information emerges.

The risk assessment may be agreed as primary authority advice.

Effective records should be kept of the data used to conduct the risk assessment and it should contain details of any assumptions on which it is based.

5.3 Making the decision as to appropriate corrective action

Decisions on the need for and nature of corrective action should be based on the level of risk determined by a risk assessment process.

Only persons with the appropriate authority nominated in the **CAP** should make the corrective action decision.

Corrective action can take a number of forms guided by the nature of the hazard, the level of risk identified and the type of product involved, for example::

- instruction to customers to dispose of products;
- recall ;
- offering consumers a replacement or refund for recalled or discarded products;
- modifying products in consumers homes;
- isolation and withdrawal of products from sale and distribution;
- improving the instructions supplied with a product;
- communication to alert consumers on the proper use of the product;
- modifying products in the distribution chain;
- introducing additional quality control measures;
- changing the design of products;
- changing the production method.

If corrective action involves modifying product at customer’s homes, a service visit, return for repair or product replacement; a risk assessment should be completed in respect of any additional risk to which consumers could be exposed during the time taken to complete such actions.

Special consideration should be given to prioritization of any accessibility issues in relation to vulnerable consumers and to situations involving higher risk for example products presenting a fire risk in high rise buildings.

The totality of risk surrounding use or non-use of a product, for example the need for food refrigeration to avoid food safety risks should be taken into account in determining the nature of corrective action required.

Advice should be sought from the relevant **MSA** as to the appropriateness of the planned corrective action. **MSAs** may seek advice from the Secretary of State on the appropriate course of action.

5.4 Alignment of the CAP with actual incident,
5.4.1 Focussing the plan

It is important to ensure that the **CAP**, which will have been developed generically, is adjusted to fit the particular circumstances of the actual incident before implementing corrective action.

It is necessary to ensure that the detail of actions required of and information provided to the relevant supply chain partners, consumers, **MSAs** and the media, is correct and complete.

Internal staff members, contact centre staff, business customers, distributors and suppliers need to be notified and briefed with specific information to deal with media and consumer enquiries when details of the corrective action are released.

A checklist of actions prior to launching a corrective action is included at **Annex E**.

The most effective corrective actions are where the consumer can be identified and communicated with directly. The following are means by which owners and users can be identified:

- records generated at retail point of sale
- Internet retail records;
- records kept by distributors;
- guarantee or registration cards or on-line registrations;
- product delivery information;
- servicing records;
- post-purchase registration schemes such as ‘Register my Appliance’ enabling consumers to record the products they possess for product safety purposes;
- distributor loyalty card schemes;
- banks and credit card provider records (see example 1 below)

As a minimum, the processes referred to in **5.4.2** to **5.4.4** will need to be considered and implemented where relevant, to deal with the products subject to corrective action:

Example 1 The use of bank cards

Payment cards (76% of total sales in 2016) have long accounted for the majority of retail spending by value, but in 2016 for the first time, cards also accounted for more than 50 per cent of all retail transactions by volume.

This campaign was in respect of an oil-filled radiator.

The supplier didn't have the luxury of a high customer data capture rate and following adverts, notices and letters to those that the supplier did have details of, assistance was sought from WorldPay & Amex.

A high % of customers purchased this (and most electricals) using some form of payment card.

The supplier provided a copy of the letter, and partial card details to enable customers to be identified.

WorldPay and Amex kindly took up the challenge of working with the card providers to send letters on the supplier's behalf.

In this instance, the service was provided without charge, but wasn't requested or expected. Charging to cover costs of generating and sending letters would have been entirely reasonable

5.4.2 Collection

If products are to be returned to the producer, the business will need to do one or more of the following:

- 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 ;
- Arrange for them to be collected from the consumer if they are not portable.

In order to prevent product re-entry into the supply chain appropriate measures should be taken to prevent its re-entry into the supply chain. Once received, it should be segregated. clearly identified and any stock movements properly recorded. The distributor should check the identity of the product and compensate the consumer with a replacement or a refund.

5.4.3 Correction

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

- Have this carried out by an agent or dealer at their premises;
- Send an engineer to the consumer's home to carry out the modification
  (This involves a need for proper training, briefing and monitoring of the activities of the 3rd party contractors involved); or
- Where appropriate, send replacement parts to the consumer. (subject to assessment of the practicality and safety of the actions requested of the consumer having regard to the fact that there may be vulnerable consumers.)

Modified products should be clearly identified e.g. by permanently marking modified products, and by updating records accordingly.

5.4.4 Disposal

Products returned for disposal need to be clearly identified and stored securely. The aim is to dispose of them safely, taking into account any environmental risks and responsibilities that might arise Care should be taken to prevent the re-entry of stock into the supply chain or second hand market.

Where instructions are given to the consumer on disposal of products, these should take into account any legal or environmental implications related to the product involved.

5.5 Implementing corrective action

During the development of the **CAP** the most appropriate communication channels for any particular product will have been determined.

Decisions on the communication channels to be used for any particular incident will be based on a range of factors including:

- the seriousness of the risk;
- scale and geography of product distribution;
- reliability of distribution data held by the business and third parties;
- traceability of the product to the consumer.

Before the corrective action goes live a final check should be made of the following:

- the notice to be published is factually correct and in line with this PAS (Annex H);
- technical information as to the level of risk and products affected remains correct;
- web site, email and phone links are all operational and provide the correct information;
- media and customer service points are fully briefed and equipped with a copy of the communication and back up Q & A;
- The relevant UK market surveillance authorities has been advised and supports the approach adopted.

5.6 Ensuring the effectiveness of corrective action

The aim of a corrective action is to ensure, by all practicable means, that the risk is removed from as many consumers as possible.

The level of effort required should reflect the level of risk that the unsafe product presents.

The level of consumer response to the corrective action will depend on factors such as:

- the type and value of the product;
- how long the product has been on the market;
- the expected life of the product;
- traceability;
- effective communication;
- emotional attachment (e.g. a child’s attachment to a toy);
- consumer tolerance to the risk.

Whilst response rates will necessarily vary the aim must be to substantially reduce risk to consumers. The business should, taking account of the above factors, set an appropriate target response level and should not consider a significantly lower level of response to be

satisfactory. Target response levels, should be set with the objective of meeting sector good practice for comparable products (see example 2),

Example 2 A successful campaign providing a possible benchmark

Through a safety campaign launched in May 2017, checking serial numbers for affected heating elements and replacing those affected, in the first 4.5 months the supplier has successfully contacted over 84% of customers and actioned the replacement from potentially affected machines.

The success of the campaign is attributed to:

- *Over 99% customer data capture at point of sale*
- *Strongly worded letters sent informing customers to stop using machine & contact supplier immediately*
- *Different version of letters sent quickly if no response from the initial letter (format / salutation / envelope)*
- *SMS & emails sent*
- *Ability for customers to contact supplier by phone, email, SMS*
- *Contact centre manned appropriately and called back anyone who abandoned call*
- *Door knocking with bespoke 'Out Cards' being left where necessary*
- *Registered letters*

Further action will be required if the target response level has not been achieved and the risk to consumers has not been reduced to an acceptable level.

When the corrective action has started, the business should monitor the level of response closely.

Records should be kept of how many consumers have been contacted, by what means at what time, the number of products that have been returned, collected, corrected or disposed of. Information should also include web site visits, timing, opening and click through on email and social media communications.

Comparing incoming contact information with outward communications including media mentions and advertising, can provide useful insights to help improve response rates.

The type and extent of corrective action taken should be reviewed and could require revision as further information about accidents or injuries to consumers becomes available.

Monitoring information can be useful to shape the communications plan should corrective actions become necessary in future.

5.7 Concluding corrective action

Unless 100% of product distributed is accounted for, a recall can never be completely closed.

When the producer in consultation with the **MSA** has decided that all practical steps have been taken, arrangements should be put in place to continue to respond to further product safety incidents and identification of product requiring corrective action.

It is likely that such arrangements will need to remain in place well beyond the anticipated life of the product.

A checklist for conclusion of a corrective action is included at **Annex F**.

5.8 Review

Businesses should assess the success of the corrective action to see if there is learning that can be used to improve the **CAP**.

The review should include checks to ensure that:

- products are no longer being sold;
- the intended final outcome for unsafe product has been achieved (i.e. correction or disposal);
- all practicable actions, short and longer term, to prevent a repeat of any incident have in fact been taken;
- any wider industry issues have been raised with sector, standards and regulators;
- all communications with others (regulators, customers, consumers, supply chain, etc.) were both timely and effective;
- level of returns was monitored and cross related to communication channels, timing and nature of communications;
- feedback has been taken from all CAP participants.

The review should include benchmarking to establish the effectiveness of action taken (including recovery rates) with that of other businesses and sectors, that have dealt with comparable incidents.

A checklist for review of corrective actions is included at **Annex G**.

Following the review, the **CAP** should be updated as necessary in the light of lessons learned.

Part 2 – Guidance for Regulators

1 Scope

This part of the PAS is relevant for all those having regulatory responsibility for consumer product safety i.e. from policy through to enforcement. It covers how regulators can better:

- monitor incidents and analyse data;
- support businesses in the preparation of their Corrective Action Plans (**CAP**);
- support businesses in their monitoring of incidents and their selection and implementation of appropriate corrective action; and
- respond proportionately where businesses fail to take appropriate and effective corrective action.

2. Regulatory context

2.1 Roles and responsibilities

2.1.1 Secretary of State

The Secretary of State for Business, Energy and Industrial Strategy

- has responsibility for the regulatory framework for consumer product safety, including both domestic and EU regulation;
- is the central point for incident intelligence, including through the operation of RAPEX and the Government's Product Recall website;
- provides technical expertise to assist **MSAs** in their enforcement role;
- is a "Supporting Regulator", providing assistance to primary authorities; and
- is able to use enforcement powers where appropriate.

2.1.2 market surveillance authorities (MSAs)

Those local authorities which have market surveillance responsibilities have a duty to:

- enforce consumer product safety regulations within their area;
- receive and share intelligence securely about consumer product safety, e.g. via RAPEX and ICSMS;
- carry out proactive and reactive checks on consumer products to assess their compliance with safety requirements; and
- work with businesses, including through the mechanism of Primary Authority, to support them in their efforts to comply.

Whilst there is some variation in the enforcement powers available to enforcement authorities, depending on the regulations under which they are acting, their powers include:

a) investigate potential criminal offences and initiate criminal proceedings for alleged contravention
b) serve a suspension notice, to prevent further supply of a product while appropriate safety evaluations, checks and controls are organised;

c) serve a requirement to mark, requiring a person to mark the product in a specified way, or to market it subject to certain conditions, so as to ensure its safety;
d) serve a requirement to warn, requiring that certain persons are warned of the risks that the product could pose to them;
e) serve a withdrawal notice, prohibiting further supply of the product and, where appropriate, requiring action to be taken to alert consumers to the risks that the product presents;
f) serve a recall notice, requiring reasonable endeavours to organise the return of the product from consumers.

MSA's can, in certain circumstances, apply to the Courts for an order for the forfeiture of a product that is not a safe product.

MSAs are required to act in a manner proportionate to the seriousness of the risk and to take due account of the precautionary principle. In this context, in the overwhelming majority of cases they encourage and promote voluntary action by producers and distributors.

However, if a product poses a serious risk to public safety, the enforcement authorities may themselves take action urgently where a business is unable or unwilling to do so within the timescales required to protect public safety.

2.2 Notification Requirements

Producers and distributors are legally required to notify an **MSA** when they become aware they have placed on the market, or distributed, a product that is not a safe product. A market surveillance authority that receives such a notification, or that otherwise becomes aware of that a product is not a safe product, is required to immediately provide that notification to the Secretary of State.

MSAs are required to immediately notify the Secretary of State of any consumer product that:

- presents a serious risk in need of urgent intervention; or
- presents a non-serious risk requiring **MSA** intervention.

Guidance for market surveillance authorities on such notifications is available on .Gov.uk.

3. Effective regulatory arrangements

3.1 Context

MSAs have an ongoing responsibility to ensure that they have arrangements in place to fulfil their role in an effective manner, including in relation to incident management, competency, data, collaboration and review.

3.2 Incident management

MSAs should have an incident management plan in place for response to serious product safety incidents.

3.3 Competency

MSAs should ensure that their staff who work with businesses in relation to consumer product safety:

- have a good knowledge and understanding of consumer product safety regulations;
- have a good knowledge and understanding of the sectors and product areas that they regulate;
- have the skills and knowledge and expertise needed to understand and assess relevant technical and safety data, seeking expertise where required.

3.4 Data

MSAs have legal duties in respect of maintaining the confidentiality of business information provided to them.

MSAs should make well-informed decisions, recognising the importance of assessing up-to-date information and gathering relevant data that is available from different sources. This may, for example, include:

- data held by the business;
- data in relation to consumer complaints to Citizens Advice consumer service;
- Home Office fire incident statistics;
- information that is held by Trade Associations (a list of the trade associations covering the main consumer product areas is available at **Annex K**)**.**

MSAs should always consider the broader picture. For example, an incident involving faulty components should lead the **MSA** to ask whether the same components have also been used in other products sold under different brand names, and follow up on supply chain connections where components have been so used.

Europe-wide information systems are in place to facilitate sharing of information about enforcement activities and unsafe products including RAPEX and ICSMS data systems.

For market surveillance authorities, the PROSAFE, organisation of product safety enforcement authorities in Europe, website publishes helpful information: http://prosafe.org/index.php/library/knowledgebase

3.5 Collaboration

MSAs should have appropriate arrangements in place to co-operate and collaborate. These might include arrangements to share data or expertise, or to work in partnership to address an issue or incident.

The Secretary of State has capability to provide access to scientific and technical support to **MSAs** dealing with product safety issues and is also able to provide assistance to primary authorities in the role of "Supporting Regulator".

The UK has a co-ordination committee for market surveillance (currently the Market Surveillance Coordination Committee). In addition, the Product Safety Focus group, Ports and Borders subgroup and Chartered Trading Standards Institute Lead Officer system all provide additional sources of support and assistance for **MSA**s.

Those having regulatory responsibility for consumer product safety are also likely to benefit from collaboration with relevant trade associations, who can provide useful knowledge and technical support.

3.6 Review

MSAs should have appropriate mechanisms in place for review of their own activities and arrangements that will provide assurance to the regulator and others, in accordance with the Regulators' Code. These might include, for example, arrangements for peer review of risk assessments.

4. Support to business to develop a CAP

MSAs are able, by working with a business or a group of businesses, to support business efforts to comply with their obligations in respect of consumer product safety. An **MSA** is best able to do this through a primary authority partnership, which enables businesses to receive advice that is "assured" across the UK.

Where an **MSA** is the primary authority for a significant manufacturer or importer of consumer products, operating across the UK, it will usually be appropriate for the primary authority to invite the Secretary of State to provide support in his role as a Supporting Regulator.

MSAs can play a valuable role in encouraging businesses that they are working with, to work to the Code of Practice set out in Part 1 of this PAS .

Some businesses have highly experienced and professional teams with systems and processes in place to deal with any potential safety issue and are often willing to share that expertise with regulators.

Conversely, some businesses experience product safety issues infrequently and could have far less experience than **MSA**s in dealing with such situations.

Ensuring that a business is well prepared should an incident arise in respect of one of its products should help to ensure the protection of the public. It may also save cost and time for both the regulator and the business should a situation requiring corrective action arise.

Support that might be provided to a business in developing its **CAP** could include advice on the following:

- link of the **CAP** to business structure;
- membership, training and awareness of the corrective action team**;**
- adequacy of product safety monitoring plan;
- adequacy of product traceability plan;
- technical file content and availability;
- adequacy of contacts lists and communication strategy;
- risk assessment plan and training;
- **CAP** training and awareness plan;
- testing and review arrangements for the **CAP.**

A checklist to assist in reviewing/assessing the adequacy of the **CAP** is included at **Annex G**.

5. Support to business incident investigation and risk assessment

When a business encounters a problem with a product it has manufactured or distributed, both having a pre-existing plan for handling such situations and an open relationship based on information sharing and trust with its regulator, is of critical importance.

Whilst legal responsibility rests with the business, regulatory expertise can be of considerable reassurance that the business is approaching the situation appropriately.

To provide appropriate support, regulators should receive specific training in risk assessment techniques as they relate to product safety.

Advisory support might include:

- participation in the corrective action team to provide enforcement expertise;
- liaising with the Secretary of State where technical/scientific support is required;
- assistance to review risk assessment methods and input of all relevant data;
- ensuring that the intended course of action meets required levels of public protection.

Regulators should aim to ensure that risk assessment processes adopted are objective and make use of all available factual information. They should ensure that the team conducting the risk assessment have an appropriate level of expertise in the field concerned to enable them to assess the hazard and the likeliness of its occurrence and to signpost to external sources of expertise if necessary. For example, areas such as flammability, strangulation and choking hazards are likely to require specialist expertise.

MSAs must ensure that corrective actions proposed are in line with the need to provide a high level of protection of public safety. MSAs should request support and guidance from the Secretary of State with regard to risk assessments, if necessary.

Regulators should advise the business as to circumstances in which a review of the risk assessment is required in the light of new evidence.

6. Support to business to implement corrective action

There is a need to move quickly and efficiently to manage what can often be a complex management task of considerable scale testing all involved.

Particular areas where regulators may provide useful experience include:

- ensuring that the format and content of messaging is in line with the Code of Practice;
- assisting in getting messages out to enforcement colleagues and channels and dealing with incoming questions;
- liaising with the Secretary of State;

- assisting in monitoring progress;
- assisting in assessment of additional incoming information;
- advising business on deciding conclusion on corrective action.

7. Support businesses to review/ revise CAP

An objective assessment as to how the various elements of the **CAP** worked in practice is of critical importance in driving continuous improvement.

The business should be encouraged to complete a timely and systematic review that looks in detail at all aspects of the processes followed and that these are followed through in improvements to the **CAP**. The review should include benchmarking to establish the effectiveness of action taken (including recovery rates).

MSAs should ensure businesses focus on addressing the underlying reason for the product safety failure from a design, standards and monitoring perspective both with regard to the product in question but more widely to consider whether business, standards or sector improvements are required.

A checklist for such a review of corrective actions is included at **Annex G.**

Annex A (Informative) Regulatory context for corrective action required of businesses

NOTE Although informative in the context of this PAS, the information provided in A1 to A4 refers to legal requirements that will be applicable to users of this PAS.

A.1 General product safety requirement

The General Product Safety Regulations[1] place a duty on producers (including importers) and distributors to supply only products that are safe in normal or reasonably foreseeable use.

The principal responsibility for day-to-day enforcement of the Regulations lies with local authorities.

A.2 Product specific safety regulations

Most consumer products are also covered by specific product safety regulations, often accompanied by a CE marking requirement evidencing that essential safety requirements have been met.

A full list of product specific safety regulations is accessible at the .GOV.UK website.

A.3 Product Liability

Strict liability under civil law applies to death, injury, loss or damage caused wholly or partly by defective (unsafe) products for the following:[1].

- the producer of the product;
- any person who, by putting his name on the product or using a trade mark or other distinguishing mark in relation to the product, has held himself out to be the producer of the product;
- any person who has imported the product into an EU member State from a place outside the member States in order, in the course of any business of his, to supply it to another.

There is a defect in a product if the safety of the product is not such as persons generally are entitled to expect.

In determining what persons generally are entitled to expect in relation to a product all the circumstances are required to be taken into account, including—

- the manner in which, and purposes for which, the product has been marketed, its get-up, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product;

[1] https://www.businesscompanion.info/en/quick-guides/product-safety/general-product-safety-distributors
[1] Consumer Protection Act 1987 Part 1

- what might reasonably be expected to be done with or in relation to the product; and

A defect cannot be inferred from the fact alone that the safety of a product which is supplied after that time is greater than the safety of the product in question.

A defence is provided that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control.

A.4 Supply chain obligations

In addition to ensuring the safety of products placed on the market producers, importers and distributors are responsible for monitoring the safety performance of their products.

A.4.1 Obligations of producers and importers

Within the limits of its activities, producers are required to adopt measures commensurate with the characteristics of the products which they supply to enable them to:

(a) be informed of the risks which the products might pose, and

(b) take appropriate action including, where necessary to avoid such risks, withdrawal, adequately and effectively warning consumers as to the risks or, as a last resort, recall.

Monitoring should include:

(I) sample testing of marketed products,

(ii) investigating and if necessary keeping a register of complaints concerning the safety of the product, and

(iii) keeping distributors informed of the results of such monitoring where a product presents a risk or may present a risk.

A.4.2 Obligations of Distributors

Distributors are required to act with due care in order to help ensure compliance with the applicable safety requirements and in particular are required:

(a) not to expose or possess for supply or offer or agree to supply, or supply, a product to any person which he knows or should have presumed, on the basis of the information in his possession and as a professional, is a dangerous product; and

(b) within the limits of his activities to participate in monitoring the safety of products placed on the market, in particular by—

(i) passing on information on the risks posed by the product,

(ii) keeping the documentation necessary for tracing the origin of the product,

(iii) producing the documentation necessary for tracing the origin of the product, and cooperating in action taken by a producer or an enforcement authority to avoid the risks.

Distributors are required to take measures enabling them to cooperate efficiently with other supply chain partners.

A.4.3 Notification requirement

Where a producer or a distributor subsequently discovers that a product he has placed on the market or supplied poses risks to the consumer that are incompatible with the general safety requirement, he shall forthwith notify an enforcement authority in writing of that information and—

(a) the action taken to prevent risk to the consumer; and

(b) where the product is being or has been marketed or otherwise supplied to consumers outside the United Kingdom, of the identity of each Member State in which, to the best of his knowledge, it is being or has been so marketed or supplied.

In the event of a serious risk the notification shall include the following—

(a) information enabling a precise identification of the product or batch of products in question,

(b) a full description of the risks that the product presents,

(c) all available information relevant for tracing the product, and

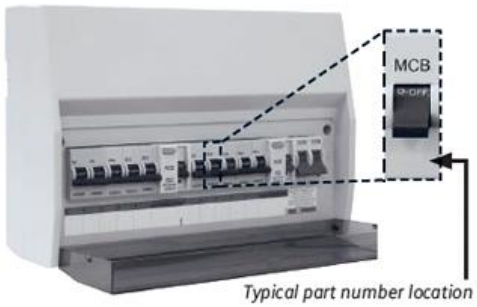
(d) a description of the action undertaken to prevent risks to the consumer.

Within the limits of his activities, a person who is a producer or a distributor is required to co-operate with an enforcement authority in action taken to avoid the risks posed by a product which he supplies or has supplied.

Enforcement authorities are required to maintain procedures for such co-operation, including procedures for dialogue with the producers and distributors on issues related to product safety.

Annex B (Informative) Case study - Example of a well-controlled corrective action

Recall of Mini-Circuit Breakers by Electrium



B1 Background:

- Electrium announced the recall of a range of miniature circuit breakers (MCB's) in March 2010
- The devices being recalled were produced between April 09 & February 10 and had been fitted in a large number of homes and other premises by a large number of electrical contractors
- All devices were date coded however the date code was on the back of the product and not visible when installed
- To check if the product is within the recall range the installation needed to be isolated and the MCB removed to check the date code
- It was not acceptable for a DIY check to be undertaken
- A competent person (qualified electrician) was required to check installation

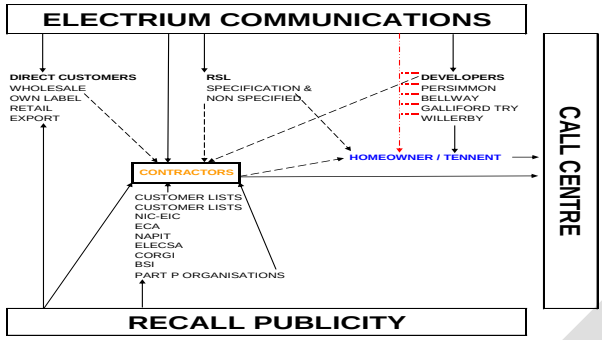
B2 Withdrawal and Recall Process

- Initial action was to set up a Crisis Force Team to manage the recall which included Quality, Supply Chain, Communications, Customer Care, Finance & Legal
- The Crisis Force team met regularly throughout the process
- The business knew the exact quantity of products sold in the recall period and to whom they had sold them. Due to the fact that its customers are electrical distributors and retailers the business had limited knowledge of the customer base they sold the products on to
- Communication programme was developed to notify customers and end users of the recall programme
- External call centre (Go Response) set up to handle property registrations generated from
    - Mailing activity to direct & indirect customers
    - Web site notifications
    - Wholesaler branch notifications
    - Direct mailing to wholesalers customer base
    - Trade press advertising campaign in all major journals

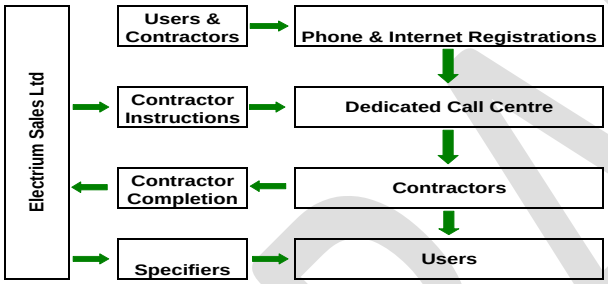
- Direct contact made with known Registered Social Landlords/Specifiers
- Recall notification/advertising through DIY outlets
- National press advertising

The Recall process was independently audited by external expert on 2 occasions with recommendations adopted

B3 Communicating the Recall



B4 Corrective action method for Product Recall Programme



B5 Management of Returns

Returns from remedial work by contractors

- To avoid contamination of stock the business set up a Recall Centre at a different location to the Electrium warehouse.
- All returns from remedial work by contractors were booked in and
    - MCB's sorted and logged by rating
    - MCB's checked for signs of heat damage
    - After booking in and sorting at Ionix the MCB's were sent to Electrium warehouse for storage in secure locked shipping containers

B6 A comprehensive instruction pack was issued to Contractors:

One exchange instruction pack was sent out for each installation including:

- MCB Exchange Procedure Check List (instructions)
- Completion label to be applied to customer electrical unit (Serial Numbered)

- New Supplier Authorisation Form (with site data fields included) Pre addressed returns label (for documents and devices)

- Bulk contracts were handled individually by Residential social landlords, the appointed contractor, and Electrium staff.

B7 Recall Communications - Publicity of Recall Notice in Trade Press

- Twelve specialist publications aimed at electrical contractors with a circulation of 272,449

Important Notice

ELECTRIUM - PRODUCT RECALL

It has come to our attention that a very small number of Electrium Miniature Circuit Breakers, sold under the brand names Wylex, Crabtree (Loadstar only) and Volex, are not performing to the required characteristics. This can lead to a potential risk of burning, in a small number of installations.

The affected MCBs were supplied from April 2009 to February 2010 and are listed in the following table. All other devices are unaffected. Devices supplied outside of these dates are unaffected.

MCB Rating	Wylex	Crabtree (Loadstar only)	Volex
6 Amp	NSB06	6M1B06	VB06
10 Amp	NSB10	6M1B10	VB10
16 Amp	NSB16	6M1B16	VB16

The immediate risk in any individual property is low, however Electrium is undertaking a free retrofit of replacement parts in all affected premises.

This work must be carried out by a qualified competent electrician, under no circumstances should the general public attempt any aspect of this work.

If you have purchased or installed any of the product listed above, between the dates shown please visit our dedicated web page for assistance:

http://www.mcbexchange.co.uk/electrium

Or call: **0844 5564787**

B8 General Press Notice

- The recall notice was placed in six national newspapers with a combined circulation approaching 10 million.
- We received 497 calls from the national press campaign

B9 Recall Communications - Publicity of Recall Notice in Trade Press

Important 2nd Notice

ELECTRIUM - PRODUCT RECALL

It has come to our attention that a very small number of Electrium Miniature Circuit Breakers, sold under the brand names Wylex, Crabtree (Loadstar only) and Volex, are not performing to the required characteristics. This can lead to a potential risk of burning, in a small number of installations.

The affected MCBs were supplied from April 2009 to February 2010 and are listed in the following table. All other devices are unaffected. Devices supplied outside of these dates are unaffected.

MCB Rating	Wylex	Crabtree (Loadstar only)	Volex
6 Amp	NSB06	6M1B06	VB06
10 Amp	NSB10	6M1B10	VB10
16 Amp	NSB16	6M1B16	VB16

Electrium have put in place a free retrofit of replacement parts in affected premises.

The retrofit programme is ongoing. Electrium continue to monitor and assess the risk and the number of problems experienced remains very small. However as the problem involves in a very few cases a risk of burning, this is being taken seriously. Please therefore ensure you fully cooperate with our efforts.

This work must be carried out by a qualified competent electrician, under no circumstances should the general public attempt any aspect of this work.

If you have purchased or installed any of the product listed above, between the dates shown please visit our dedicated web page for assistance:

http://www.mcbexchange.co.uk/electrium

Or call: **0844 5564787**

B10 Registered Social Landlord Letter & Notification in major DIY outlet

- A letter was sent to all UK Registered Social landlords – to over 450 independent bodies with follow up reminders and calls where no response.

Electrium

Electrium Sales Limited
Commercial Centre
Lakeside Place,Willenhall Lane
Bridgtown, Cannock
Staffordshire WS11 0XE
Tel: +44 (0)1543 455500
Fax: +44 (0)1543 455501

AL605

18th January 2011

Dear Customer

You may be aware that Electrium announced a product recall on certain ratings of miniature circuit breakers (MCBs) please see enclosed notice, and that Electrium has offered a free of charge exchange service where this proves to be necessary.

However, you may not be aware that your own properties may be involved. Therefore Electrium is writing to RSLs such as yourselves to ask that records are checked to see if there are any affected properties within your housing stock.

Affected properties would be those that have had electrical work that included the installation of affected MCBs between April 1st 2009 and February 28th 2010.

All affected properties require a visual inspection and may require the circuit breakers to be replaced. This work can only be carried out by a competent qualified registered Part P Domestic Installer. Under no circumstances should members of the public attempt to do this work.

If you believe that you have properties that have recalled MCBs installed to them please contact the following telephone number to speak to an operator tel 0844 556 4725.

The operator will need to ask you a series of questions to register your company and check that the properties are within the scope of this recall. After which one of our field based representatives will make contact with you to arrange and authorise the necessary remedial works.

However, if you are already in contact with us and this work is in hand, please disregard this letter.

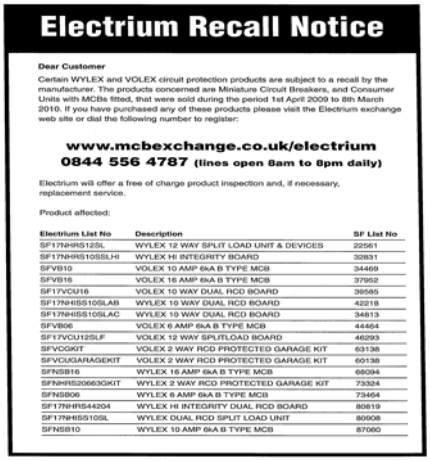
We would like to thank you for your co-operation with this very important safety work.

Yours Sincerely

Electrium Recall Team

Crabtree WYLEX VOLEX ACCESSORIES

Electrium Sales Limited - A Siemens Company



Electrium Recall Notice

Dear Customer

Certain WYLEX and VOLEX circuit protection products are subject to a recall by the manufacturer. The products concerned are Miniature Circuit Breakers, and Consumer Units with MCBs fitted, that were sold during the period 1st April 2009 to 8th March 2010. If you have purchased any of these products please visit the Electrium exchange web site or dial the following number to register:

www.mcbexchange.co.uk/electrium
0844 556 4787 (lines open 8am to 8pm daily)

Electrium will offer a free of charge product inspection and, if necessary, replacement service.

Product affected:

Electrium List No	Description	SF List No
SF17NHRS12SL	WYLEX 12 WAY SPLIT LOAD UNIT & DEVICES	22561
SF17NHRS10SSLHI	WYLEX HI INTEGRITY BOARD	32831
SFVB10	VOLEX 10 AMP 6kA B TYPE MCB	34469
SFVB16	VOLEX 16 AMP 6kA B TYPE MCB	37952
SF17VCU16	VOLEX 10 WAY DUAL RCD BOARD	39585
SF17NHSS10SLAB	WYLEX 10 WAY DUAL RCD BOARD	42218
SF17NHSS10SLAC	WYLEX 10 WAY DUAL RCD BOARD	34813
SFVB06	VOLEX 6 AMP 6kA B TYPE MCB	44464
SF17VCU12SLF	VOLEX 12 WAY SPLITLOAD BOARD	46293
SFVCGKIT	VOLEX 2 WAY RCD PROTECTED GARAGE KIT	63138
SFVCUGARAGEKIT	VOLEX 2 WAY RCD PROTECTED GARAGE KIT	60138
SFNSB16	WYLEX 16 AMP 6kA B TYPE MCB	68094
SFNHRS20663GKIT	WYLEX 2 WAY RCD PROTECTED GARAGE KIT	73324
SFNSB06	WYLEX 6 AMP 6kA B TYPE MCB	73464
SF17NHRS44204	WYLEX HI INTEGRITY DUAL RCD BOARD	80819
SF17NHSS10SL	WYLEX DUAL RCD SPLIT LOAD UNIT	80908
SFNSB10	WYLEX 10 AMP 6kA B TYPE MCB	87080

B11 Small contractors

- Follow up letters were sent to contractors who had not registered where the business knew they had purchased MCB's from the customer record list of the Electrical Wholesalers

B12 Electrium Website

- Interactive information was included on the Electrium website to provide answers to any questions or information that contractors might require

B13 Third Party Customer Websites

- Recall notices were placed on 12 electrical wholesaler websites
- Recall notices were place on a further 12 sites routinely used by electrical contractors

B14. Electrical registration bodies & Electrical Safety Council

- Recall notices were placed on the Electrical Safety Council website and the web sites for Part P providers which contractors are required to be registered with.

B15 Lessons Learned from the Process

- Act quickly as the further you get from the recall dates it gets more difficult to engage stakeholders
- Key action to remove stock from the distribution chain as soon as recall is advised
- Visibility of date code information on products
- Access to Customer records proved very difficult
    - Data not available
    - Data not maintained or incorrect
    - Refusal to access data
- Trade & National Press advertising had limited impact
- Apathy from Electrical Contractors & Wholesalers to the recall notification

Annex C (Informative) - Risk assessment methodologies

C.1 Introduction

A number of methodologies are available for making an objective assessment of the level of risk based on analysis of the seriousness of the potential harm and the likelihood of its occurrence

The EU RAPEX methodology is the one used by **MSA's** and by most businesses in consumer product safety matters. Use of the EU Rapex methodology is sometimes supplemented by use of a Nomograph methodology applied in Australia and New Zealand.

Details of both methodologies and where further information on them can be found are given below.

C.2 EU RAPEX Risk assessment methodology

It is recommended that a small team who have knowledge and experience of the product and its hazards should carry out the Risk Assessment.

The assessment team should take the following approach:
a) **Describe the hazard**.

- 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.

b) **Identify the consumer at risk** Start with the intended user and the intended use of the product. Afterwards, for further scenarios, select other consumers 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 safeguards,
- whether the hazard and the ways to mitigate them are sufficiently obvious, with due consideration being given to the consumer's local and cultural environment.

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). If there are several concurrent injuries in your scenario, include them all in that same scenario.

The following should be taken into consideration:

- the frequency and duration of use,
- whether the consumer is likely to recognise the hazard
- 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
- any 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.

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 objectively as possible. The aim is to determine the severity of different scenarios, not to judge the acceptability of an injury.

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.

e) **Determine the probability of the injury scenario**.
Assign a probability to each step of your injury scenario. 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:

i. 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.
ii. 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 table below.

Risk can be classified into one of four basic levels of risk can be detected:

i. Serious Risk – normally requiring immediate action
ii. High risk – normally requiring rapid action
iii. Medium risk – normally requiring some action
iv. 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.

g) **Check whether the risk level is plausible**.
If the risk level does not seem realistic, 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' will show whether the risk changes when the input changes.

If the risk level remains the same, you can be quite confident of your risk assessment. If it changes easily, it may be wise to err on the side of caution and take the higher risk level.

The plausibility of the risk level should be discussed with the **MSA** or 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 the 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.

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.

Table C1 Hazards, typical injury scenarios and typical injuries

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

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
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
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

Table C2 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 C3 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.

Table C4 Probability and 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

C.3 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. 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.

EU RAPEX Risk Assessment Guidelines are available at:
http://ec.europa.eu/consumers/safety/rapex/docs/rapex_guid_26012010_en.pdf
An on-line tool for the RAPEX methodology is available at:
http://europa.eu/sanco/rag/public/index.cfm?event=home&CFID=1734987&CFTOKEN=2f22fb417085e209-859FBF87-D3B3-DB94-40F068D85D241C13&jsessionid=2202237f1edd3c302697TR.

C.4 Risk of multiple fatalities

It is possible to envisage a 5th level of injury that being of multiple fatalities resulting from a single unsafe consumer product for example an electrical product that may cause a fire that spreads.

For a level 5 scenario the acceptable probability of its occurrence would be substantially lower than that even for a level 4 injury scenario.

Table C5 A modified probability and risk matrix taking risk of multiple fatalities into account is included below.

Table C5 Modified probability and risk matrix

	Severity level				
Probability	**1**	**2**	**3**	**4**	**5**
>50%	H	S	S	S	S
>1/10	M	S	S	S	S
>1/100	M	S	S	S	S
>1/1000	L	H	S	S	S
>1/10,000	L	M	H	S	S
>1/100,000	L	L	M	H	S
>1/1,000,000	L	L	L	M	S
< 1/1,000,000	L	L	L	L	H

C.5 Austalian/NZ Nomograph methodology

1. Define scope of assessment

The first step is to clearly specify the hazard and the affected population. Depending on the nature of the assessment, the assessor may choose to complete multiple assessments for multiple hazards or population groups with different capacities to tolerate injury, to recognise and avoid hazards and with different access to the product in question. However, a single assessment is sufficient for many product safety problems in which the affected population is determined by the nature of the product and the hazard under assessment. Specify the product, hazard and affected population in the nomograph tool (Attachment 1).

2. Assess severity of injury

Select an EU RAPEX injury severity level between 1 and 4 based on the tables in Attachment 2. Enter the selected level in the nomograph tool (Attachment 1), including a short explanatory statement. For types of injury not explicitly addressed in the tables, use the general RAPEX injury criteria also defined in Attachment 2. The severity level should be based on the estimated maximum potential injury for the specified population, but neglecting extremely unlikely injury scenarios that are not supported by injury data.

3. Estimate probability of hazard occurring

Select one of the six defined probability levels between ‘Remote’ and ‘Almost inevitable’ for the hazard, injury and population specified for the assessment. Enter the selected level in the nomograph tool,

including a short explanatory statement. This estimate is based on the premise that the consumer is in possession of the product. In practice, the data necessary to support this estimate is sometimes weak and the result is at times subject to uncertainty. Factors to consider in the estimate include:

- Is every unit delivered inherently unsafe or does the hazard occur in only a subset of products?
- Does the hazard occur with almost every use or in only rare circumstances?
- Does the hazard occur with new product or only after use and/or ageing?
- Is the product used frequently (e.g. daily) or rarely (e.g. annually)?
- What is known about the rate of failure or injuries?

4. Estimate the potential for hazard recognition

Select one of the five defined recognition levels between 'Highly improbable' and 'Almost inevitable' for the hazard, injury and population specified for the assessment. Enter the selected level in the nomograph tool, including a short explanatory statement. The assessor should estimate the ability of an average consumer within the defined population to recognise and avoid the hazard. The assessor should consider whether warnings on the product increase the hazard recognition. For vulnerable groups such as children, the estimate should also consider the extent to which responsible carers such as parents can realistically act to recognise and avoid the hazard on behalf of the vulnerable group.

5. Hazard (initial risk assessment)

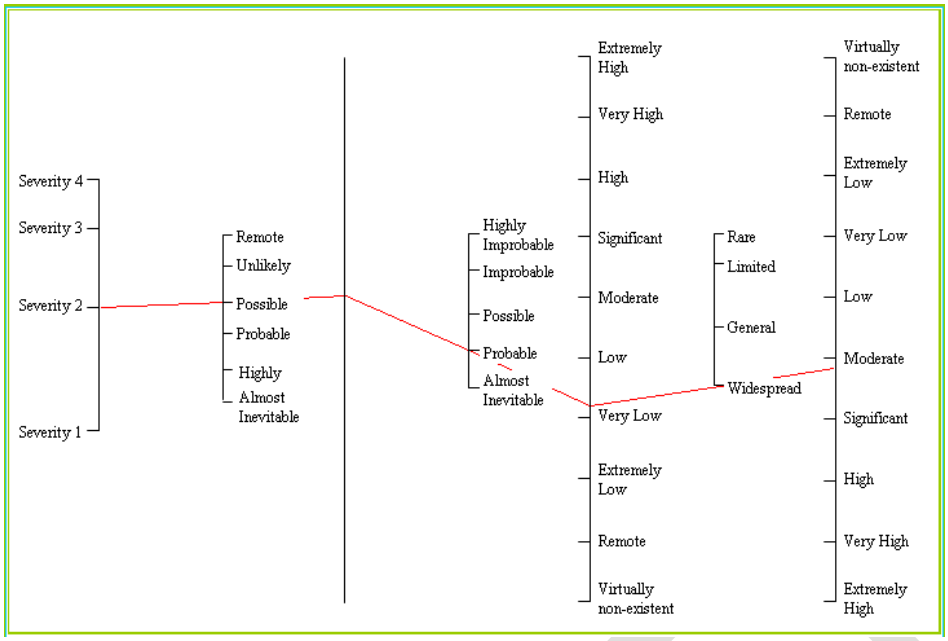
The nomograph multiplies the selected severity, probability and recognition estimates to generate an initial risk assessment of the hazard with one of ten values between 'Virtually non-existent' and 'Extremely High'.

6. Estimate availability

Select one of the four levels defined for the availability of the product and enter this in the nomograph tool, including a short explanatory statement:
'Rare' – scarcely available; not normally made or imported in this jurisdiction
'Limited' – distributed in small quantity or only in a small region
'General' – distributed and readily available across the jurisdiction
'Widespread' – distributed across the jurisdiction and in use in almost all households.

7. Risk (final risk assessment)

The nomograph modifies the initial risk assessment (hazard) with the selected availability estimate to generate a final risk assessment with one of ten values between 'Virtually non-existent' and 'Extremely High'. Based on experience, a final risk assessment below 'Moderate' may be considered for no further action. However, a final risk assessment of 'Moderate' or higher may be considered for more detailed assessment or intervention of some kind.



Annex D (Informative) Corrective action plan (CAP) assessment checklist

Requirement	Assessment method	Assessment Recommendations
Is policy for board / senior management/ business owner adoption of **CAP**, clear?	View supporting documentation	
Is the **CAP** available within the business, where required?	View document	
Are comprehensive product safety monitoring arrangements in place?	Check all arrangements in place to monitor retrospective and ongoing safety of products	
Is a traceability plan in place? Does it relate to all products, components and customers	Ask about arrangements for marking of products and components and linking them to customers	
Are contact lists available and up to date?	Validate the availability of relevant lists and sense check details. Ttest by making contact with individuals listed.	
Is a risk assessment plan in	View documentation and	

place?	validate understanding with key personnel	
Is a communications plan available? Has a model corrective action notice been prepared?	View plan and proposed actions in case of requirement for corrective action, including model notice	
Are relevant colleagues in the business aware and trained on the **CAP**?	Test understanding in key areas of the business as to what their role is in case of a product safety incident	
Has the **CAP** been reviewed and tested?	Date and report of last review and update. Has a test exercise taken place? Was the learning used to revise the **CAP**	

Annex E (Informative) Checklist of actions prior to launching a corrective action

Action	Validation	Completed yes/no
Risk assessment completed?	View completed risk assessments	
Board/ senior management/ business owner, informed?	Confirm relevant persons aware	
Relevant **MSA** notified and single point of contact in place?	View notification(s). Confirm with colleagues responsible.	
Internal stock isolated?	Seek evidence of isolation	
distributors informed to stop distribution and isolate product?	View notification and confirmation from distributors	
Target recovery rate set?	Check relevance of target set and method used to determine (e.g. benchmarking)	
Customers traced?	Review process employed and outcomes achieved	
Corrective action communications prepared?: Recall notice? Direct communications?	View and validate communication	
Q and A developed?	Test understanding	
Customer helpline set up and briefed?	Confirm by test activity (e.g. mystery calls)	
Media contact point briefed? Press release prepared?	Validate	
Arrangements made to deal with returned stock?	Seek evidence of relevant action.	

Annex F (Informative) Checklist for conclusion of corrective action

Review point	Validation	Assessment response
Number and percentage of products recovered?	View records Check whether target recovery rate was achieved	
Date of last reported incident?	View records	
Corrective actions completed in respect of all reported product?	View records	
Additional action likely to improve recovery rate	Review actions taken and communication methods used against industry/ sector norms	
Confirm call centre arrangements in place to deal with incoming contacts and for how long?	Check arrangements in place for identified life of product and test effectiveness (e.g. mystery caller)	
Has a review of the effectiveness of the corrective action been completed?	View records	

Annex G (Informative) Checklist for review of corrective action

Item for review	**Report of findings**
How effective was the corrective action? What % of product was corrected?	
Was the corrective action implemented in line with the corrective action plan (**CAP)**	
Did the corrective action team function effectively	
Were unnecessary delays or obstacles encountered during the process?	
Has the **CAP** been updated?	

Annex H (Informative) Example of model corrective action announcement

Important Safety Notice

PRODUCT RECALL

Horrible Histories Gladiator Fancy Dress Costume

Price: £14 / £15 Barcode: 5054620664246

On sale since: February 2016

What's happened?

Asda is recalling the George Horrible Histories Gladiator Fancy Dress Costume as a small number of products were found to contain a higher level of one chemical above the limits set by the Toy Safety Directive.

What you should do?

If you have purchased the Horrible Histories Gladiator Fancy Dress Costume, please take the product back to your local Asda store for a full refund. No receipt or packaging is necessary. We are very sorry for any inconvenience caused.

If you would like any further information please contact:

Asda Customer Relations – 0800 952 0101

Annex I (Informative) Example of model direct corrective action communication

RECALL NOTICE

We have identified a safety issue with Fisher Price Car seats.

As you have bought or reserved nursery products from us in the past we would like to draw your attention to a product recall on the car seats below items., which are sold under the Fisher Price brand name.

The safety restraints do not fully comply with our test requirements and could compromise your child's safety in the event of an accident.

If you have one of these car seats, please STOP USING IT IMMEDIATELY and return to an Argos store for a full refund, or replacement.

Images and details of the car seats affected, for visual reference:

Fisher Price Group 0-1 Car Seat
Catalogue number 414/9314

Fisher Price Group 1 Car Seat
Catalogue number 413/4082

If you have any questions please do not hesitate to contact the helpline on:

Freephone 0355 6005388 **ROI Landline : 18005355091; Mobile 012245387**

Our Contact centres are open between 8am-8pm Monday to Sat and 10-00-6.00 on Sunday.
We thank you for your cooperation and apologise for any inconvenience.

Annex J (Informative) Consumer Product Trade Associations

Trade Association Forum

Association of Manufacturers of Domestic Appliances

British Toy and Hobby Association

British Retail Consortium

British Hardware Federation

Cosmetics Toys and Perfumeries Association

Bibliography

HM Government Product Recall website
SI 2005 No. 1803 - *The General Product Safety Regulations 2005*
765/2008/EC - *Regulation on accreditation and market surveillance*
Directive 2001/95/EC of the European Parliament and of the Council on *general product safety*
Australian Competition and Consumer Commission (ACCC) - *Consumer Product Safety Recall Guidelines*
European Commission DG-SANCO - *PROSAFE Consumer product safety in Europe – Corrective action guide.*
International Standards Organization (ISO) *ISO 10393: 2013 – Consumer product recall – Guidelines for suppliers*
ISO 10377: 2013 – Consumer product safety – Guidelines for suppliers
Department for Business, Energy and Industrial Strategy (BEIS) *Guidance on Product Safety and Corrective actions for Manufacturers, Importers and their Oversight Bodies.*
BEIS - The General Product Safety Regulations 2005 – Notification guidance for producers and distributors
Chartered Trading Standards Institute (CTSI) - *The Consumer Codes Approval Scheme (CCAS)*
The Consumer Product Safety Commission - *Recall Handbook*
Council Regulation (EEC) 339/93 on checks for conformity with the rules on product safety in the case of products imported from third countries
Guidance Document on the Relationship between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety
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
The RAPEX Guidelines (2008) 'GUIDELINES for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC
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