INTERNATIONAL STANDARD

ISO 10393

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Consumer product recall — Guidelines for suppliers

Rappel de produits de consommation — Lignes directrices pour les fournisseurs

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

The committee responsible for this document is Project Committee ISO/PC 240, *Product recall*.

Introduction

There is a wide variety of products available to consumers in the global marketplace. Products routinely travel across borders in order to meet increasing consumer demand as suppliers seek to lower cost and expand markets. While many products are safe and fit for intended use, statistics show that, each year, millions of people suffer injuries or illness, or die from unsafe products.

While regulations and standards exist in many countries, and industries do all they can to make products safe and fit for intended use, problems related to design flaws, manufacturing defects, inadequate warnings or instructions still result in unsafe products entering the marketplace. In those instances, it is critical that corrective actions, which include recall, are carried out quickly and effectively. Although many countries have regulatory requirements and guidance for suppliers to conduct product recalls, many do not. Even in countries with well-developed requirements, recalls may be ineffective. As a result, there are inconsistencies in the approaches to product recall and other corrective actions, and products that pose health or safety risks to consumers remain in the marketplace.

This International Standard is designed to provide practical guidance in determining whether corrective actions, including recalls, need to be carried out by the supplier of consumer products. It also provides best practices for conducting a product recall if it is necessary. The guidance provides information and tools that suppliers of all sizes can use to develop a documented and validated product recall programme that will help them implement timely and cost-effective recalls, minimize legal and reputation risks, and reduce health or safety risks to consumers.

Although this International Standard is intended for suppliers, it might also help government agencies in developing or improving product recall policies and guidelines.

Broad application of this International Standard will lead to a more consistent approach to removing unsafe products from the global marketplace, to improving coordination between government and consumer products organizations in different countries, and to increasing consumer confidence in the safety of products available in the marketplace.

This International Standard has been developed in parallel with ISO 10377, which focuses on product safety. The relationship between this International Standard and ISO 10377 is illustrated in Figure 1.

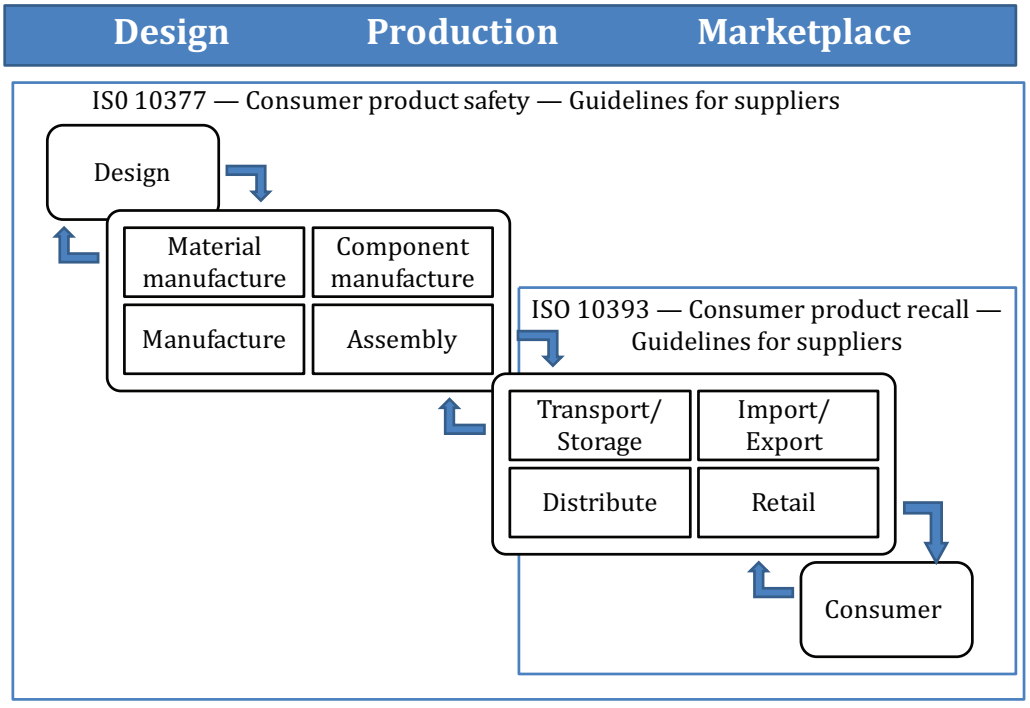


Figure 1 — Relationship between this International Standard and ISO 10377

Consumer product recall — Guidelines for suppliers

1 Scope

This International Standard provides practical guidance to suppliers on consumer product recalls and other corrective actions after the product has left the manufacturing facility. Other corrective actions include, but are not limited to, refunds, retrofit, repair, replacement, disposal and public notification.

This International Standard is intended to apply to consumer products, but might also be applicable to other sectors.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
consumer
individual member of the general public purchasing or using property, products or services for private purposes

[SOURCE: ISO 26000:2010, 2.2]

2.2
consumer product
product designed and produced primarily for, but not limited to, personal use, including its components, parts, accessories, instructions and packaging

[SOURCE: ISO 10377:2013, 2.2]

2.3
competent
suitably trained or qualified by knowledge and practical experience to enable the required task or tasks to be carried out

[SOURCE: ISO 22846-1:2003, 2.6]

2.4
corrective action
action intended to remove potential for harm and to reduce risk

Note 1 to entry: For the purposes of this International Standard, corrective actions are referred to as “recalls” because the public and media more readily recognize and respond to that description.

2.5
foreseeable misuse
improper or incorrect use of a product that is capable of being known or anticipated in advance, based on a supplier’s best knowledge about the product and human behaviour

EXAMPLE Improper use by children or the elderly.

[SOURCE: ISO 10377:2013, 2.5]

2.6
foreseeable use
use of a product that is capable of being known or anticipated in advance based on a supplier's best knowledge about the product

[SOURCE: ISO 10377:2013, 2.6]

2.7
harm
physical injury or damage to the health of people, or damage to property

[SOURCE: ISO/IEC Guide 51:1999, 3.3, modified]

2.8
hazard
potential source of harm

Note 1 to entry: 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]

2.9
incident
event or defect that caused or has the potential to cause death, injury or property damage, with respect to a consumer product

Note 1 to entry: "Incident" might be defined differently by law in some countries.

2.10
intended use
use of a product in accordance with information provided by the supplier

[SOURCE: ISO/IEC Guide 51:1999, 3.13, modified]

2.11
organization
entity or group of people and facilities with an arrangement of responsibilities, authorities and relationships and identifiable objectives

Note 1 to entry: For the purposes of this International Standard, organization does not include government acting in its sovereign role to create and enforce law, exercise judicial authority, carry out its duty to establish policy in the public interest or honour the international obligations of the state.

[SOURCE: ISO 26000:2010, 2.12, modified]

2.12
product recall
corrective action taken post production to address consumer health or safety issues associated with a product

2.13
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 51:1999, 3.2]

2.14
risk analysis
systematic use of available information to identify hazards and to estimate the risk

[SOURCE: ISO/IEC Guide 51:1999, 3.10]

2.15
risk assessment
overall process comprising a harm and a risk evaluation

[SOURCE: ISO/IEC Guide 51:1999, 3.12]

2.16
risk evaluation
procedure based on the risk analysis to determine whether the tolerable risk has been achieved

[SOURCE: ISO/IEC Guide 51:1999, 3.11]

2.17
risk management
coordinated activities to direct and control an organization with regard to risk

[SOURCE: ISO Guide 73:2009, 2.1]

2.18
safety
freedom from unacceptable risk

[SOURCE: ISO/IEC Guide 51:1999, 3.1]

2.19
supplier
organization or person that provides a product or service

EXAMPLE Designer, producer/manufacturer, importer, distributor, or retailer of a product.

[SOURCE: ISO 9000:2005, 3.3.6, modified]

2.20
supply chain
network that designs, manufacturers, imports, distributes and sells a product

[SOURCE: ISO 10377:2013, 2.25]

2.21
tolerable risk
risk which is acceptable for a specific user group based on the current values of society

Note 1 to entry: For the purposes of this International Standard, the terms "acceptable risk" and "tolerable risk" are considered to be synonymous.

[SOURCE: ISO/IEC Guide 51:1999, 3.7, modified]

2.22
traceability
ability to track a product or component forward through specified stages of the supply chain to the user, and trace back the history, application or location of that product or component

[SOURCE: ISO 9000:2005, 3.5.4, modified]

2.23
user
person who interacts with the product or service

2.24
vulnerable consumer
consumer who could be at greater risk of harm from products due to their age, level of literacy, physical condition or limitations, or inability to access product safety information

[SOURCE: ISO 10377:2013, 2.30]

3 Purpose and principles

The purpose of this International Standard is to help suppliers develop, implement and improve a product recall programme in order to reduce risk caused by unsafe products in the marketplace.

A product recall programme is a key element of the supplier's overall product safety programme. Suppliers should demonstrate their commitment to consumer product safety by adhering to the principles documented in this International Standard and in ISO 10377. These principles include the following:

— developing and maintaining appropriate processes and systems to prevent product-related incidents that could lead to a recall, including addressing product safety risks at the design stage and allocating appropriate resources for quality management, training, records management and product traceability;

— a commitment to the prompt and effective implementation of a product recall when it is assessed that a product is likely to pose a health or safety risk to consumers;

— promoting a product safety culture by building awareness of the importance of product safety, ensuring product safety programmes are supported and continually improving its product safety programme;

— promoting a product safety culture to others within its supply chain;

— establishing and maintaining compliance with all applicable laws, regulations and standards.

4 General requirements

4.1 General

All suppliers should be prepared to conduct a product recall. The supplier should have in place a product recall plan that includes the following:

— the recall policy (see 4.2);

— an outline of the documentation and records that will be created and maintained (see 4.3);

— an outline of the legal, industry and regulatory requirements (see 4.4);

— identification and explanation of the roles and responsibilities of the recall management team (see 4.5);

— a description of the training and exercise requirements for members of the recall management team (see 4.7);

— guidance on how product incidents will be investigated and a decision made on whether a recall is necessary (see Clause 5);

— identification of the resources required and processes used to implement a recall (see Clause 6);

— establishing the requirement for continual improvement of the supplier's processes (see Clause 7).

4.2 Policy

The supplier should develop and maintain a product recall policy and identify how decisions will be made to carry out a product recall. The policy should contain a simple, clear and precise commitment

by the supplier to ensure that products which present, or which have the potential to present, risks or hazards to consumers are effectively removed from the marketplace, or that safety or health issues or concerns are corrected.

4.3 Documentation and record keeping

Management should establish procedures to control and maintain all documents and record data relating to the recall programme for continual improvement, data analysis and facilitation of incident investigation, product identification and traceability, such as the following:

— a copy of the recall policy and procedures;

— records of training and assessment of employee competency;

— records of consumer complaints and product safety incidents;

— records of risk assessment, which may include test reports, and risk analysis;

— records of the recall decision;

— records of communication, including the communication plan, materials, methods used and dates;

— evidence of the effectiveness of the recall, including return rates, effectiveness per method of communication and evidence to show that the recall is working;

— financial records;

— records of repair, refurbishment or disposal.

4.4 Regulatory requirement

The supplier should identify, monitor, understand and comply with applicable legislative, regulatory and standard requirements for recalls, in all markets where a consumer product is produced or sold.

4.5 Expertise required to manage a recall

The supplier should ensure that it has the expertise to investigate the incident, to assess the risk, to make the recall decision and to carry out the recall. In larger suppliers, this may require the establishment of a recall management team made up of staff from a range of functional areas.

Regardless of size, suppliers may need outside assistance from advisors and consultants. Arrangements should be made with advisors and consultants so that they can develop an understanding of its recall programme before an incident occurs.

The objectives of the people responsible for managing the recall are as follows:

— assess all available information and determine the actions necessary to do the following:
  — protect the health or safety of consumers;
  — maintain relationships with consumers and stakeholders;
  — protect the reputation of the supplier;
  — fulfil all relevant legal obligations (e.g. mandatory reporting) in all countries of distribution;
— liaise with relevant government and industry authorities;
— ensure that key stakeholders are kept informed of the supplier's decisions and actions, including forthcoming media communications;

— ensure that decisions and recall actions are implemented effectively with least disruption to the normal operation of the supplier's day-to-day business.

Table 1 lists the typical expertise required for a product recall.

4.6 Authority for key decision

The supplier should identify the person or people who have the authority to make the decision to recall the product.

The key decisions that may need to be made are as follows:

— make a product recall decision and determine the scope of that recall, as discussed in 5.1;

— stop production and place product on hold during a product recall investigation, as discussed in 5.3;

— stop the sale of a product at any point in the supply chain, as discussed in 5.6;

— notify the regulator(s) about a product recall incident, comply with applicable regulatory requirements, and report the progress of the recall to regulator(s), as discussed in 6.3.3;

— notify the supply chain about a product recall incident, as discussed in 6.3.4;

— communicate to consumers about actions that should be taken during a product recall, as discussed in 6.3.5;

— execute the logistical requirements of the product recall, as discussed in 6.4;

— assess the effectiveness of the recall to make recommendations about its progress, as discussed in 6.6;

— bring an end to the monitoring phases of the product recall by the regulator and cease active recall operations, as discussed in 6.7.2.

4.7 Training and recall simulation

The staff responsible for the recall should be familiar with the supplier's product recall plan and have the capabilities and personal attributes needed to implement the recall.

Planning, training and conducting recall simulations will help to better prepare people for a recall and also increase the likelihood that agreed processes are implemented quickly and effectively under conditions that can be stressful. In addition, these activities may be required to meet contractual, legal and insurance requirements.

Table 1 — Typical expertise required for product recall

Expertise required	Activities or responsibilities
Recall coordination and leadership	First point of contact for incidents
	Initial sorting and escalation of the incident
	Ensure notifications are made to appropriate people
	Gather people with the appropriate expertise
	Facilitate meetings and ensure required actions are carried out
	Ensure information needed is collected in a timely manner and appropriate people are updated regularly
	Ensure timely decisions are made
	Ensure all communications are consistent and controlled
	Ensure appropriate external notifications and briefings are performed
	Ensure all required reports are prepared and distributed
	Facilitate continual improvement process and ensure follow up responsibilities are delegated
Technical/Engineering	Lead the investigation of the recall incident
	Review internal records, quality systems and traceability of the affected product
	Establish contact with laboratories and testing authorities and other experts performing the risk analysis or risk assessment
	Lead the risk analysis or risk assessment process
	Act as a liaison with suppliers
	Provide technical advice about the product to the team
	Participate in the recall decision
Operations	Gather distribution records, ensure they are accurate and create distribution register
	Manage collection, retrieval, replacement, repair and disposal of product
	Ensure accurate records are kept to measure recall effectiveness
	Manage the logistical requirements necessary to remove product from the marketplace, to repair or replace product in the marketplace and to destroy defective product that was the subject of the recall
Sales and marketing/ Accounts	Establish and maintain liaison with affected consumers
	Ensure consumer enquiries and concerns are addressed in a timely manner
	Establish consumer needs for replacement products and arranges credits, refunds, or replacements for the subject product
	Participate in the recall decision
Finance/ Risk management	Estimate costs of proposed actions, sources of funding and potential impact on business
	Notify insurer where required
	Establish budget and monitor costs
	Keep records for claims
	Work with sales & marketing/accounts to arrange credits and refunds
	Participate in the recall decision

Table 1 *(continued)*

Expertise required	Activities or responsibilities
Legal counsel	Ensure compliance with regulators' requirements Ensure compliance with contractual requirements with buyers and licensors Provide advice to minimize organization's liabilities arising from recall decision and from day-to-day execution of recall plan Participate in the recall decision
Communications	Identify key audiences, with special focus in vulnerable groups Assist in the development of the communication strategy and key messages Establish and manage resources to handle enquiries (call centre, product recall consultant) Prepare communications and gain approval for release Monitor clarity and usefulness of communications and recommend any changes necessary to improve effectiveness.

A supplier should do the following:

— identify the people and organizations that may be needed to carry out recall activities, provide them with the recall plan and make them aware of their responsibilities and authority to act during a recall;

— train people so that they understand their responsibilities and have the skills to carry out those responsibilities during a product recall,

— practise the implementation of the recall plan through a simulated recall, in order to verify that the recall plan is likely to be useful in a real recall situation;

— document and implement what has been learned from the simulation to improve the recall programme;

— conduct ongoing reviews of the recall programme and simulations, in order to keep it current and effective and to retain and improve skills for preventing and managing recalls.

It may be difficult for smaller organizations to conduct a recall simulation. In such cases, key managers should review their recall plan annually and discuss potential incidents and how the plan will be implemented if a recall becomes necessary. This should include involvement of an external consultant or advisor whose expertise has been identified as necessary (see Table 1).

5 Assessing the need for a product recall

5.1 General

In order to determine the need for a product recall, the supplier should have in place a process for acting upon receipt of information that a product has created harm, or has the potential to create harm, in accordance with 5.2 to 5.6, as illustrated in the flowchart in Figure 2, and the timeline required by the applicable regulatory requirements.

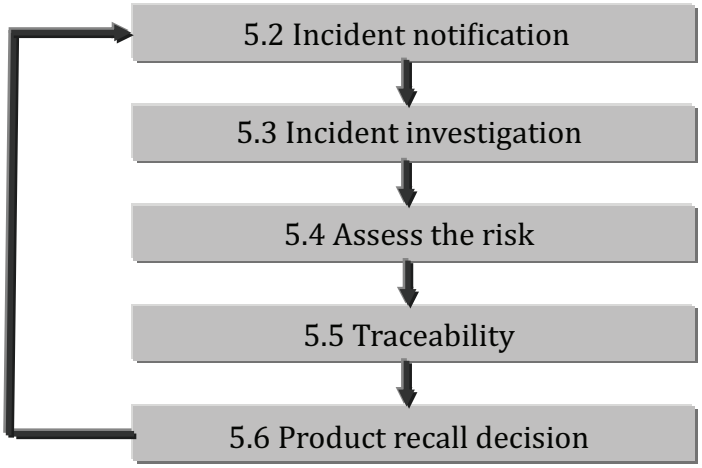


Figure 2 — Assessing the need for product recall

For situations where very serious injury or substantial property damage could occur, consideration should be given to implementing a product recall, even if the probability of risk cannot be accurately determined.

5.2 Incident notification

Suppliers should have in place a system for collecting information on product incidents and communicating these to stakeholders, as necessary.

As required by regulatory requirements and contractual obligations, the supplier should notify regulators, certification bodies and other organizations of reports that a product has created harm, or has the potential to create harm.

5.3 Incident investigation

The supplier should establish a process for investigating product incidents or potential incidents. The process will generally include the following steps:

— document the key elements of the investigation, including the findings and the actions taken;

— conduct an initial assessment to determine the urgency and the priority of the investigation;

— assign competent staff to conduct the investigation;

— determine if the incident report is valid and accurate, which could also involve acquiring the actual product or a sample to use for testing and review purposes;

— determine if the product report is valid and accurate, which could also involve acquiring the actual product or a sample to use for testing and review purposes, in accordance with appropriate sampling procedures;

— identify the root cause for the defect that created the harm or potential harm, and use this information in the continual improvement process outlined in ISO 10377; in addition, the supplier should determine if the defect is common to other products and therefore require that similar recalls be implemented;

— assess the risk in accordance with 5.4;

— determine if there have been any other incidents regarding the product in question, including those related to similar products.

5.4 Assess the risk

There are various methods for assessing the risk of harm in consumer products (see Bibliography).

The supplier should establish a process for assessing the risk of harm, which generally includes the following steps:

a) identify the product involved, including details such as product name, brand, model number, type, unique global identifier, lot, batch, source of components used in the products or date of production;

b) identify the likely population groups that will use or come into contact with the product, particularly vulnerable consumers (see Bibliography);

c) identify whether the incident occurred during foreseeable use or foreseeable misuse of the product;

d) identify the hazards and severity of harm that may occur during installation, use, maintenance, repair or disposal of the product (see Annex A);

e) estimate the probability of the harm occurring, taking into consideration consumer behaviour and the frequency and duration of use of the product (harm could be caused by the product not functioning correctly, as in the case of a smoke alarm that fails to detect smoke);

f) estimate the risk to each of the identified user groups from the hazards identified (see Annex A) and, when determining the level of risk, consider the following:

   — vulnerability of users;

   — general knowledge of the risk within communities;

   — possibility of taking precautions against the risk;

   — obviousness of the risk;

   — ability of the user to avoid the risk;

   — available warnings or notices of the risk;

   — effectiveness of warnings;

   — effectiveness of safety measures;

g) determine the impact on level of risk if the assumptions change;

h) identify the number of products in the marketplace to determine the accumulated risk to society, and document the assessment;

i) have the assessment and conclusions verified by independent experts.

5.5 Traceability

5.5.1 General

Suppliers should be aware of the one step down/one step up traceability principle referred to in ISO 10377. Product traceability will facilitate the recall process by allowing the supplier to determine quickly where the affected product was sold and to be able to target the recall notification to the appropriate audience.

The traceability attributes will also help consumers verify whether the product they are using is impacted by the recall, thereby avoiding a situation where all of the supplier's products are perceived as defective.

5.5.2 Affected product

The recall notification should clearly identify the product or products that are within the scope of the recall. This identification should be as precise as possible and should distinguish the key characteristics of the affected product.

Examples of key characteristics can include product variants, e.g. lot, colour, size, amperage, formulation or product packaging. Each recalled product should be uniquely identified. Ideally, this identification should be globally unique. Examples of globally unique product identification include the Universal Product Code (UPC) and the Global Trade Item Number (GTIN).

5.6 Product recall decision

Once the assessment of risk has been completed, the supplier should determine if the level of risk exceeds the tolerable risk (see ISO 10377 for guidance). If the level of risk does exceed the tolerable risk, the supplier should make a determination on the need for a product recall. There is no automatic link between an identified level of risk and implementing a product recall, as decisions should be made on a case-by-case basis using all available information.

The supplier should consider all the relevant facts and circumstances that influence the probability of harm, the nature of the potential harm and the severity of the potential harm. In particular, they should consider the impact of the recall, including the following:

— potential risks created by the product recall;

— the practicality of implementing the product recall;

— the anticipated success of the product recall;

— the ability to maintain or sustain the product recall;

— the ability of consumers and the supply chain to adequately identify the affected product;

— the suitability of the product recall to achieve the intended objective;

— whether there are alternative means of achieving the objective.

For situations where very serious injury or substantial property damage could occur, consideration should be given to implementing a product recall, even if the probability of risk cannot be accurately determined.

Experts may be consulted to help determine the risks, the practicality, the impact and the effectiveness of the product recall. As new information becomes available, it should be used to review the decision and the processes used.

The decision to recall should be made in consultation with relevant regulators. In some countries, regulators have the authority to require a product recall under specific circumstances.

6 Implementing a product recall

6.1 General

When the decision is made that a product recall is necessary, the supplier should communicate with the supply chain to determine the supplier responsible for the recall. In some countries, the supplier responsible for the recall may be specified by regulation. The decision to implement a recall is based on the process outlined in Clause 5.

Once a decision has been reached to implement a recall, the processes described in 6.2 to 6.7 should be followed, as illustrated in the flowchart in Figure 3.

6.2 Initiate the recall action

6.2.1 General

The recall action should provide guidance on the processes to be used and resources that are needed to achieve an effective recall. It should provide guidance to those implementing the recall on the approach to be taken, what objectives are to be met and when they are to be achieved. It should provide criteria for determining the effectiveness of the recall and guide the decision on when the supplier responsible for the recall can cease active recall operations.

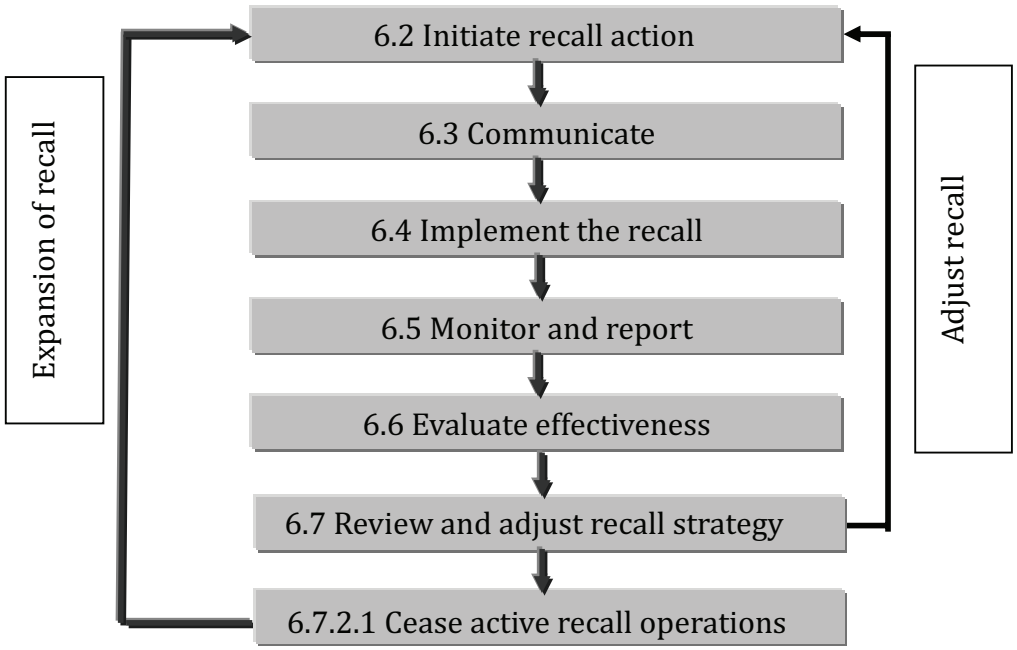


Figure 3 — Implementing the recall

There are generally four key elements to a recall action plan:

a) the recall strategy;

b) the recall objectives;

c) the recall process;

d) identification of the financial resources required to implement the recall.

6.2.2 Recall strategy

The recall strategy should provide a clear overview of the reasons why the recall action is being taken, what is to be achieved by the action, how the supplier responsible for the recall will communicate with affected consumers, supply chain and appropriate regulatory authorities. It should outline the actions that should be taken to reduce the risk associated with the product.

In some countries, the regulator may require the supplier responsible for the recall to discuss the proposed recall strategy and communications with it prior to taking action.

The recall strategy should include an explanation of the following:

— the nature and scope of the hazard in terms that are easily understood by someone without a technical background;

— the likely distribution of the affected product, and an assessment of where and how much of the product is affected;

— what caused the hazard, and what actions the supplier is taking to address the hazard;

— the risk that the hazard poses to the or consumer of the product, and how the intended consumer can reduce the risk;

— identification of the affected stakeholders, and how the supplier responsible for the recall will communicate with them;

— any legal and regulatory requirements, and how the supplier responsible for the recall intends to comply.

6.2.3 Recall objectives

The objectives should outline what is to be achieved by the recall actions and by when they are to be achieved.

Recall objectives should generally include the following:

— inform affected suppliers, consumers and appropriate regulators about the nature and scope of the hazard, and provide clear guidance on what actions they should take to reduce any risks related to health or safety;

— quarantine the product in order to prevent any further distribution or sale of affected product;

— arrange for the removal, repair or replacement of affected product as quickly as possible;

— rework the affected product to reduce the risk;

— dispose of, or destroy, the affected product to ensure that affected product cannot re-enter the market;

— return unaffected or replacement products to the market as quickly as possible.

6.2.4 Recall process

The process for retrieving, repairing, modifying or replacing should be designed to make it as easy as possible for the supplier and the consumer to take the recommended action. Using a simple process will make it more likely that affected consumers will be willing to take the requested action, and therefore make the recall more effective.

The sorts of processes that could be used include the following:

— return product to place of purchase: the consumer returns the affected product to the place of purchase and receives a replacement or refund;

— return product to repair facility: the consumer returns the affected product to a repair facility that is appropriately qualified to modify or repair the product;

— prepaid mail/postage: the consumer is sent a prepaid, stamped self-addressed package to return the affected product;

— retrieval service: a retrieval service is used to physically collect a consumer's affected product;

— repair: a qualified technician repairs the affected product at the point of use.

The recall process should be designed to enable all affected parties to identify the key elements of the recall. These include the following:

a) the recall notice;

b) the product or products affected;

c) the party issuing the recall.

Each product recall notice should be uniquely identified. This ensures that the recall can be distinguished from other product recall in the market. This is accomplished by assigning a globally unique identifier to the original recall notice.

Similarly, as necessary recall updates or modifications are communicated, each update should also be uniquely identified. Examples of updates include changes to the scope of products involved or the provision of supporting documentation (e.g. media releases, disposal or return instructions, product specifications). Assigning a unique identifier to product recall updates enables all affected parties to maintain a record, or audit trail, of changes over the life of the recall.

An updated product recall notification should clearly state that it supersedes the previous notification.

In designing the recall process, the supplier responsible for the recall should consider vulnerable consumers.

6.2.5 Financial resources

The recall plan should identify how the costs of a recall will be met. The costs of product recalls can sometimes be covered by a comprehensive product recall insurance policy.

The primary costs associated with a product recall can include the following:

— costs of advertising and communications;

— costs of retrieval, repair, modification, installation and disposal of affected product;

— production and distribution costs of replacement product;

— costs of compensating consumers for losses, including, if applicable, the costs of medical care;

— costs associated with business interruption and any short term alternative supply/production costs;

— loss of income during interruption;

— costs of consultants and advisors;

— costs of additional call centre and communications facilities;

— loss of market share;

— costs of discovering the cause of the accident;

— legal costs;

— costs of additional staff for recall.

6.3 Communication

6.3.1 General

Communication is critical to the effective implementation of a recall. The supplier responsible for the recall should ensure that its communications are clear, consistent and accurate. Communication should be designed to meet the needs of the various stakeholders that are affected by the recall, so that they understand the risk and what action they should take to minimize the risk. The communication plan should also allow for affected stakeholders to communicate with the supplier responsible for the recall.

6.3.2 Develop the communication plan

The supplier responsible for the recall should provide a means for consumers to contact it to carry out the instructions they are given, or to address any questions or concerns they may have. For a consumer level recall, this may involve establishing a call centre, with an appropriate means of communication

for all geographical locations where the product is available. This may include a contact number and a contact form on the supplier's website. Appropriate resources should be identified in the recall plan.

In a larger scale recall, the supplier responsible for the recall may receive a very large number of enquiries from consumers and, potentially, the media. Consideration should be given as to how it will cope with a large increase in enquiries, and this may include identification of third party call centres and communication support.

Communications should be distributed as soon as possible after the decision to recall is made. Appropriate arrangements should be in place before communications are released, and all affected parties should be fully briefed on the recall strategy and the actions they should take to support the recall. In some countries, it is appropriate to discuss the content, the intended audience and the timing of the communication with the regulator prior to release.

The recall plan should provide a list of the audiences that should receive communications, the most appropriate means for these communications and the people who will be responsible for those communications. See Annex B for examples of product recall posters and press releases. An example of a product recall checklist for a recall plan is given in Annex C.

6.3.3 Communication with regulators

There is a legal requirement in many countries to notify and provide required information to a regulator at various stages of the recall.

6.3.4 Communicate with supply chain

The supplier responsible for the recall should identify who received the affected product and establish a process for:

— recording when it is contacted;

— detailing how much affected product it still has under its control;

— confirming that it has quarantined affected product, or otherwise taken action to prevent further distribution.

The process for retrieving, replacing or destroying the affected product, as well as a method for recording receipt, destruction or other agreed action, needs to be established.

6.3.5 Communication with consumers

The objective of communicating with consumers is to ensure that they understand the risk associated with the affected product and to give them clear guidance or instructions on what actions they should take. Well-designed communications will be a key factor in making sure the recall is effective.

Where direct contact cannot be made with the consumer, contact should be made using the most appropriate channel for the target audience. While traditional means of communicating a recall notice is often through a newspaper advertisement, a number of other effective channels exist. Some of the channels that should be considered include the following:

— social media or blogs;

— announcements on websites;

— electronic or printed newsletters, direct mails;

— loyalty programmes, e.g. frequent shopper programmes;

— specialist magazines;

— radio and television.

In designing recall communications, consideration should be given to consumers that have special needs, e.g. consumers living in isolated areas, or those with disabilities. In addition, there may be support organizations that can assist in communicating with consumers that have special needs.

6.3.6 Recall notice

The recall notice should include the following:

— a globally unique identification number for the recall message;

— a clear description of the affected product;

— a clear identification of the product numbering schemes (e.g. model type), part numbers (e.g. GTIN/UPC code), serial numbers, batch or lot codes;

— a photograph or image of the product;

— where and when the affected product was sold and distributed;

— a description of the problem with the product and the risk it poses to the consumer, in language that is easy for the consumer to understand;

— a clear explanation of the actions the consumer should take, both immediately (e.g. stop using the product) and subsequently (e.g. return to place of purchase for a refund or replacement);

— contact details for the supplier responsible for the recall for any enquiries and to arrange for replacement or repair.

6.4 Implement the recall

6.4.1 General

A supplier responsible for the recall should give clear instructions to the supply chain to stop the sale of the affected product, and should store the product securely to prevent its sale or distribution until retrieval can be arranged.

6.4.2 Retrieve, replace and repair affected product

Retrieval of products could be accomplished through using an internal distribution system, an internal sales and delivery network, or through using an external retrieval service. Consideration should be given as to how additional stock, parts or other components will be arranged for replacement. In addition, authorized installers or repairers should be arranged if modifications or repairs are necessary.

Where the consumer is expected to return the product to place of purchase, arrangements need to be made for the retailer to collect and store the product securely to prevent resale. In the event of consumers returning the product by mail or courier, the supplier responsible for the recall should arrange for pre-paid stamped self-addressed packaging, and a facility established to collect and dispose of the product and arrange replacement.

Depending on the amount of affected product, there may be a requirement for temporary warehousing.

6.4.3 Destroy or dispose of the affected product

Recalled products that are not to be repaired, reworked and redistributed through authorized channels should be destroyed, preferably using recycling, where possible. This reduces the risk of recalled products being inadvertently reused or resold, or shipped into other markets. Verification or objective evidence of destruction or recycling may be appropriate.

Affected product should be destroyed or disposed of in an appropriate manner consistent with any and all applicable environmental regulations. If verification is required, a signed statement describing the

method, place, date, and number of products should be obtained from those responsible for the product's disposal or destruction. The supplier responsible for the recall should also consider the environmental consequences of destroying the product and obtain advice on appropriate destruction methods.

Recalled products should not be exported to other countries or markets unless:

a) the product does not create a hazard as determined by the assessment of risk;

b) it is specifically authorized by the relevant regulators in both the exporting and importing countries or markets.

6.5 Monitor and report

6.5.1 General

The progress of the recall should be carefully monitored to ensure that the recall is effective and achieves the objectives. It is important to collect accurate and up-to-date information that can be used for internal and external reporting.

6.5.2 Manage information

The supplier responsible for the recall should establish a process for continually monitoring the implementation of the recall, in order to ensure that the objectives are being achieved and to provide regular reports to senior management and, where required, to regulators.

Data collected should be sufficient to measure the progress of the recall against previously agreed objectives, and may include the following:

— the time, date and media used for communications;

— the time, date and method of contact with consumers;

— the response rate for communications, e.g.

  — replies to direct contact with consumers;

  — the number of calls received;

  — the number of website views;

— the number of complaints, reports of injuries or requests for compensation;

— the amount of affected product identified and held at each stage in the supply chain;

— the amount of affected product returned, replaced, repaired, modified or disposed of at each stage of the supply chain;

— the amount of affected product returned, replaced, repaired, modified or disposed of from consumers.

6.5.3 Establish reporting requirements

Where reporting to a regulator is required, the frequency of reporting should be agreed at the start of the recall action, and the report deadlines should be met. In instances where there is a higher risk to public health or safety, more frequent reporting may be required.

6.6 Evaluate effectiveness

6.6.1 General

It is important to evaluate effectiveness continually in order to ensure that objectives are being met and, if necessary, to adjust the recall strategy to improve effectiveness. For more information, refer to Annex D on recall effectiveness.

6.6.2 Locating affected product

The supplier responsible for the recall should be able to identify and confirm where it distributed all affected product. The supplier should also confirm that notice of the recall has been received and understood by consumers.

6.6.3 Return rate

The return rate refers to the amount of affected product retrieved, repaired or modified. The return rate will be affected by a number of factors, and therefore determining an actual rate as "effective" will vary depending on the product, its distribution and the characteristics of users, and on the cost and ease of return. Historical data for similar types of products may be useful in providing a guide for appropriate return rates.

The supplier responsible for the recall should measure the effectiveness by monitoring and verifying that affected product has been removed from various parts of the supply chain, e.g. warehouse and retailers.

6.6.4 Disposal rate

This refers to the amount of product that has been appropriately disposed of, or destroyed. In the case of higher risk product, particularly one which poses significant public health or safety risk, or where disposal may cause an environmental hazard, independent certification and verification of disposal may be appropriate.

6.6.5 Injury rate

If injuries have occurred as a result of the product incident, the reduction and eventual elimination of injuries is a key measure of effectiveness.

6.6.6 Enquiry rate

Enquiry rates are generally high in the early stages of a recall. A significant reduction in enquiry rate can be used in conjunction with other measures as an indicator of effectiveness.

6.6.7 Communication

The effectiveness of communication is an important measure. Direct and targeted communication is the most the effective means of informing people of the recall and will improve the effectiveness of the recall. Where there are low levels of response, more direct, targeted communications will help to improve the response.

The supplier responsible for the recall may measure the effectiveness of communication by sampling target groups to determine whether they are aware of the recall, whether they have the affected products and whether they know what actions they should take.

6.7 Review and adjust recall strategy

6.7.1 General

If monitoring indicates the recall is not meeting objectives, the recall strategy may need adjustments to improve effectiveness. Adjustments that could be made to improve effectiveness may include the following:

— including additional media or increasing coverage in existing media channels;

— better targeting of communications;

— improving the ease of response, because consumers are reluctant to respond if it is difficult or time-consuming to do so;

— offering incentives to respond.

6.7.2 Recall operations

6.7.2.1 Cease active recall operations

Before active recall operations cease, the supplier responsible for the recall should consider the following:

— that the objectives of the recall have been met;

— that there is a high level of confidence that a large proportion of affected consumers have received the recall notice and have had the opportunity to make an informed decision on the actions they should take;

— that there are no longer reports of injuries or illness;

— that there are appropriate levels of returns, given the type of product and the nature of the risk;

— that, where applicable, the regulator agrees that the supplier responsible for the recall has taken reasonable and appropriate steps to inform affected consumers and has provided the opportunity for them to take recommended actions.

Once the recall objectives have been met, a decision can be made to cease active recall operations. In countries where there is oversight by government authorities or a legal requirement to do so, this decision may need to be made in consultation with the regulator.

The decision to cease active recall operations should not preclude the resumption of the recall if it becomes clear that affected product posing a health or safety risk remains in the marketplace. In addition, consumers should continue to be able to return defective products that pose a health or safety risk at any time. The supplier responsible for the recall should therefore continue to provide the capability to receive products that are subject to recall, even though active recall operations have ceased.

6.7.2.2 Adjustment of the recall

The decision to adjust a recall should be taken if no changes have been made to the original recall notification and the affected products. The process should follow the steps indicated in Figure 3, starting with 6.2.

6.7.2.3 Expansion of the recall

If additional products need to be added to increase the scope of the original recall, a new recall notification should be created and a new unique notification number assigned. This is to ensure that only one active recall notification exists for a product at any one time and that the actions taken are easily audited (see Figure 3).

7 Continual improvement of recall programme

7.1 General

Continual improvement should be a permanent objective of the supplier. The supplier should continually improve its recall procedures by reviewing the communication plan, operations and other activities, the results of risk assessment and the effectiveness of recalls.

Fundamental to effective and efficient improvement is making informed decisions on the basis of data analyses and the incorporation of lessons learned. All continual improvement activities and their outcomes should be regularly documented and reviewed by management in order to ensure that continual improvement is occurring and that changes do not inadvertently cause another safety problem.

Figure 4 illustrates continual improvement for product recall.

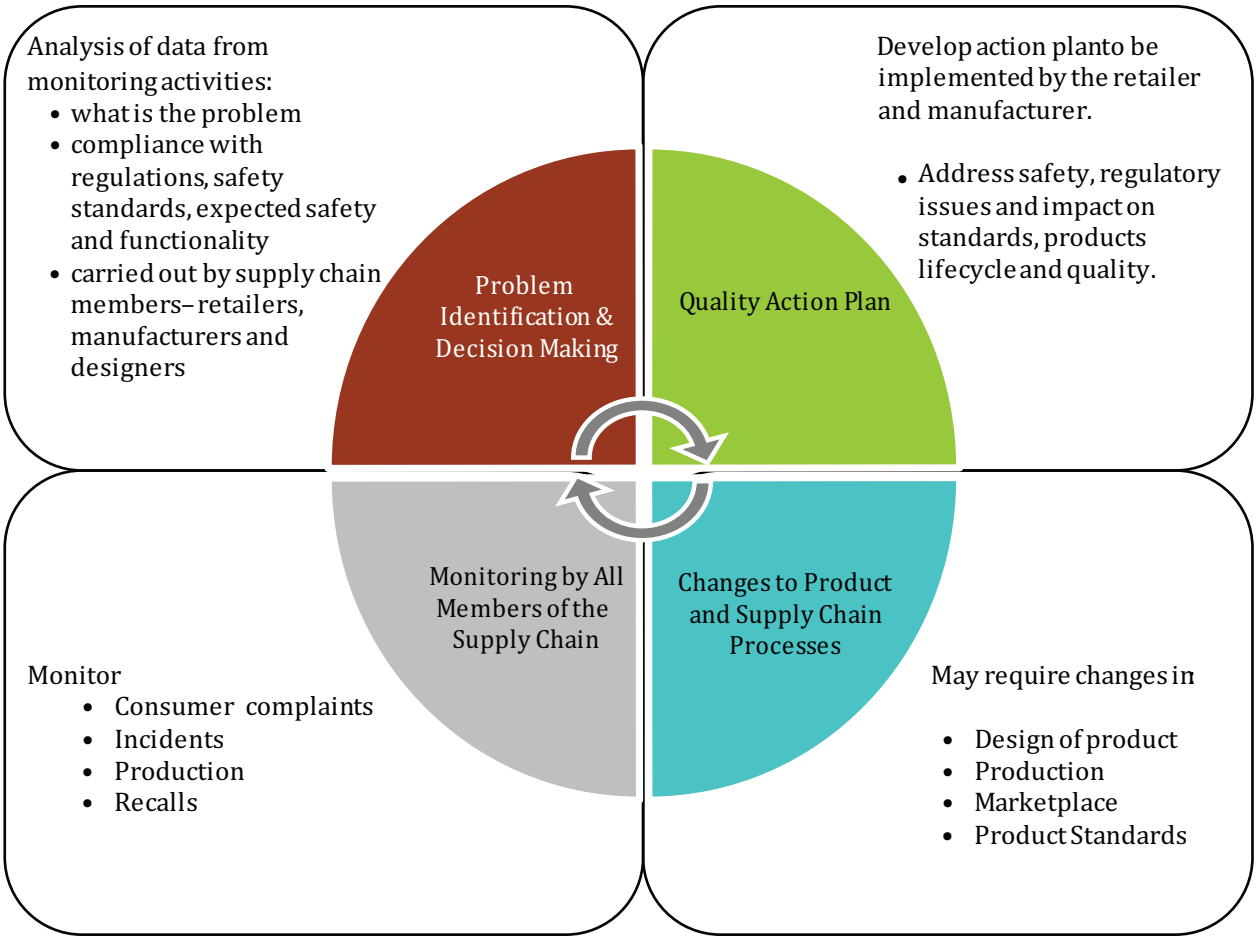


Figure 4 — Continual improvement for product recall

7.2 Reviewing the recall

After the recall, the supplier should document its observations and experience, and a meeting should be held to discuss opportunities for improvement.

A member of staff should be assigned responsibility for ensuring that opportunities for improvements are implemented.

7.3 Corrective actions to prevent reoccurrence

The supplier should implement corrective actions to reduce the probability of the incident reoccurring. This can be accomplished by initiatives such as redesigning the product to remove the potential harm, identifying the kind of materials during the manufacture and redesigning labels and instruction manuals.

The supplier should periodically review the effectiveness of the corrective actions that were implemented in accordance with 6.5 in order to address the identified root causes. If the corrective actions have not reduced the probability of the incident reoccurring to the desired level, then the supplier should consider implementing additional or revised corrective actions.

The supplier should also periodically review all root causes to identify trends or patterns in product safety, in order to determine if additional or revised corrective actions should be implemented to the same or similar products.

Corrective actions include changes in the following**:**

— materials;

— design;

— production process;

— production monitoring;

— product safety standard;

— packaging;

— shipping;

— storage;

— product markings;

— instructions.

Annex A
(informative)

Hazard and risk evaluation

Risk evaluation is the logical identification and evaluation of any hazards that a product may pose, and the determination of the likelihood that a consumer or user will be exposed to them. Once the potential hazards and their cause have been identified, it is then possible to determine the risk posed and, if required, to redesign the product or add protective devices before the product is produced or reaches the consumer. In some instances, but not all, it may be necessary to carry out research or obtain knowledge and expertise in order to help with the evaluation.

Table A.1 provides a number of examples to illustrate how hazards are identified.

Table A.2 provides examples of how hazards are evaluated.

Table A.3 provides examples of different types of use and misuse of products.

Table A.1 — Identification of hazards

Hazard	Product property	Injury scenario	Injury
Abrasion	Rough surface	Person slides along rough surface; this causes friction and/or abrasion	Abrasion
Adhesion	Exposed adhesive	Traumatic removal of skin that is attached to a product by an adhesive.	Avulsion, laceration
Avulsion	Catch points	Teeth or fingernails caught in narrow channels	Removal of tissue (e.g. teeth, nails) by tearing
Burn (cold)	Cold surfaces	Person does not recognize the cold surface and touches it; the person sustains frostbite	Burn
Burn (thermal)	Hot surfaces	Person does not recognize the hot surface and touches it; the person sustains burns	Burn
Burn (thermal)	Hot liquids	Person handling a container of liquid spills some of it; the liquid falls on the skin and causes scalds	Burn, scald
Burn (thermal)	Open flames	A person near the flames may sustain burns, possibly after clothing catches fire	Burn
Burns (chemical)	Chemicals with caustic properties	Burn caused by a caustic or corrosive chemical contacting the skin.	Burn
Burns (cold)	Objects or areas with greatly reduced temperatures	Burn caused by contact with a cold solid, liquid, or gas.	Burn
Burns (thermal)	Objects or areas with elevated temperatures, hot liquids and steam	Including scald burn caused by contact with a hot liquid or steam, hot surface burn caused by contact with a hot solid, and electrical burn or tissue damage caused by electric current passing through the tissue.	Burn

Table A.1 *(continued)*

Hazard	Product property	Injury scenario	Injury
Burns (thermal)	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
Chemical	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
Drowning	Holds liquid and is large enough to admit the head or face	Obstructing the passage of air by submersion of mouth and nose in a fluid.	Drowning, anoxia
Electric shock	Accessible electric current	Sudden stimulation of the nerves or convulsion caused by the passage of electric current through any portion of the body.	Cardiac Arrest, muscle damage, electric shock
Electric shock	High/low voltage	Person touches part of the product that is at high voltage; the person receives an electric shock	Electric shock
Entrapment	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
Ergonomic strain	Components or products which are not sized or shaped to their purpose	Poor body mechanics during tasks	Strains and fatigue in muscles, joints and tendons.
Explosion	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
Explosion (chemical)	Violent chemical reaction	Sudden release of chemical energy in a sudden and often violent manner, usually with the generation of high temperature and release of gases.	Impact, Burn
Explosion (mechanical)	Parts under spring tension	Sudden release of mechanical energy in a sudden and often violent manner.	Impact, laceration
Fall	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
Foreign object insertion (non-airway)	Small or slender products or components	Objects lodged in ears or other non-airway body cavities.	Irritation Infection, discomfort
Impact	Slippery surface	Person walks on surface, slips and falls	Bruising; fracture, concussion
Impact (moving object)	Pressurized 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)
Impact (moving object)	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
Impact with moving object	Significant kinetic energy	Force or impetus transmitted to the body by a collision from a moving object.	Fracture or bruising

Table A.1 *(continued)*

Hazard	Product property	Injury scenario	Injury
Infrared	Electromagnetic radiation with wavelength between 780 nm and 1 mm.	Sufficient time exposure to intense infrared light, e.g. heat lamps. Hazard is dependent on time and intensity.	Tissue damage through a thermal mechanism (burn).
Interference with safe activity	Small eyeholes, ill-fitting footwear, loud sounds or dim lights	Sensory distraction or masking leading to the creation of a hazard condition.	Various injuries
Internal airway obstruction	Product is or contains small part	Person (child) swallows small part; the part gets stuck in larynx and blocks airways	Choking, internal airway obstruction
Internal airway obstruction/ aspiration	Small light aerodynamically shaped objects	Inhalation of (a) small object(s) into the airway.	Acute (anoxia) or chronic (infection)
Internal airway obstruction/ choking	Small parts which fit in the mouth	Objects lodged in the mouth or oral airway.	Anoxia
Internal airway obstruction/ insertion	Small parts which fit into the nostrils	Objects lodged in the nasal passages.	Infection or aspiration.
Laceration	Sharp edge	Person touches sharp edge; this lacerates the skin or cuts through tissues	Laceration, cut; amputation
Microwave	Electromagnetic radiation with wavelength between about 1 mm and 1 m.	Ineffective shielding on microwave transmission and generating devices	Tissue damage through heating or of interfering with implanted medical devices.
Noise-induced hearing loss	High Intensity impulsive or continuous noise	Person is exposed to noise from the product. Tinnitus and hearing loss may occur depending on sound level and distance	Permanent or temporary complete or partial loss of hearing
Positional asphyxia	Tilting infant environments/ conditions	Children's heads may tilt forward placing their airways under compression.	Anoxia
Puncture	Sharp corner or point	Person bumps into sharp corner or is hit by moving sharp object; this causes a puncture or penetration injury	Puncture
Puncture	Sharp points	Penetration injury of the skin caused by contact with a sharp point.	Bleeding open wounds
Repetitive motion	Poor design of control interfaces	Human interface requiring repetitive motion, e.g. frequently repeated tasks	Carpal tunnel syndrome muscle and joint strain. Nerve damage
Strangulation (neck)	Strings, cord or edges of products that can come into contact with the throat.	Caused by external pressure obstructing the passage of air through the airway or by preventing the flow of oxygenated blood to the brain.	Anoxia
Suffocation	Flexible films and circular cross-section rigid containers that can cover the nose and mouth	Caused by obstructing the passage of air by sealing the mouth and nose with an external object (example: plastic films, containers).	Anoxia
Suffocation	Product is impermeable to air	Product covers mouth and/or nose of a person (typically a child)	Suffocation

Table A.1 *(continued)*

Hazard	Product property	Injury scenario	Injury
Ultraviolet	Electromagnetic radiation between about 100 nm and 400 nm.	Exposure to intense UV for sufficient duration,, e.g. tanning booths.	Tissue damage through photo-chemical effect.
Ultraviolet	Ultraviolet radiation	Skin or eyes of a person are exposed to radiation emitted by the product	Burn, scald; neuro-logical disorders; eye injury; skin cancer, mutation
Vibration	Eccentrically mounted motors	Hand-Arm Vibration (HAV) (usually associated with the use of vibrating hand tools) and Whole-Body Vibration (WBV), which is experienced when the operator or driver sits on or in a vibrat-ing machine, usually a vehicle such as a forklift, or one of muscle and joint strain. Nerve damage the numerous kinds of vehicles used in agriculture, transport, materials handling, mining and forestry.	Muscle and joint strain. Nerve dam-age

Table A.2 — Hazard evaluation

Nature of hazard	Cause of hazard	Type of injury	Product ranges and model	Consumer groups/supply chain members affected by haz-ard	Quantity of products on market/in supply chain
Suffocation	Impermeable packaging material used by children due to attractive ribbon attached to the assist repacking. Pack-ing material has no warning.	Death of one 2-year old and hospitalization of two 2-year olds.	All XXXX character range	Children age between 2 years and 4 years	10 000 units sold only in the state of XXXXXX
Drowning	Top loading washing machine cover does not come with safety switch or lock which stops operation when top cover opened during opera-tion. (Case in China: A woman was washing clothes and her mother-in-law was reading newspaper. When the woman was answering a phone call, her 2-year old daughter was drowned in a top-loader when she stood on a stool beside the washing machine and lost her balance.)	Death by drown-ing of two tod-dlers less than 2 years old	All top load-ing range produced before year XXXX	Toddlers between 2 years and 5 years	2,5 million

Table A.3 — Examples of different types of use and misuse

Examples of reasonable user behaviour (use)	Examples of unreasonable user behaviour (misuse)
Product used as manufacturer intended: — purpose (utility) — operating environment (temperature, humidity, moisture, pollution) — market (industrial/commercial/consumer) Product used as promoted	Product used for purpose expressly excluded by manufacturer Product modified for other than recommended use Product subjected to degrading environment Product used to produce deliberate harm
All product instructions are followed: — hazard avoidance (cautions and warnings) — assembly — installation — proper operation, including duty cycle — maintenance — repair — disposal	Interacting with product (assembly, installation, operation, maintenance or repair) while judgment impaired by alcohol/drugs Warnings disregarded Instructions disregarded Safeguards bypassed or removed Product used while obviously damaged Product abused to destruction Product disassembled other than as recommended in manufacturer's instructions Product repaired other than as recommended by manufacturer Failure to comply with installation, inspection and disposal regulations Secondary use without instructions or warnings Toaster is used to bake pizza Toaster thermal switch safeguard is disabled to allow for use at higher temperatures Toaster is used in a bathroom near water Toaster lever is forced into engaged position Toaster is repaired at home with a knife or by a person without experience Toaster is discarded in a landfill

Annex B
(informative)

Examples of product recall posters and press releases

SAFETY RECALL

ABC Company Recalls the following items:

XXXXXX

UPC's XXXXXXX & XXXXXXX

Reason for Recall:

Insert Product Picture Here

Insert Product Picture Here

Consumers should stop using this product immediately and return the product to your nearest point of sales for a full refund.

For any inquires, please contact:

XXXXXXXXX

Post Until XXXXXXX

Figure B.1 — Example 1

Sample Press Release:

NEWS from CPSC

U.S. Consumer Product

Safety Commission

www.cpsc.gov

OFFICE OF INFORMATION AND PUBLIC AFFAIRS

WASHUINGTON D.C. 20207

FOR IMMEDIATE RELEASE

January __, 2010

Release # AA-XXX

ABC Company Recall Hotline: (888) 888-0000

CPSC Recall Hotline: (800) 638-7722

CPSC Media Contact: (301) 504-7908

ABC Company Media Contact: (xxx) xxx-xxxx

The CPSC, Health Canada and ABC Company recall the [subject product], , due to potential flammability hazard from mixed ingredient, which may ignite and cause personal injury or death.

WASHINGTON, D.C. & OTTAWA, ONTARIO, CANADA - The U.S. Consumer Product and Safety Commission (CPSC) and Health Canada, in cooperation with ABC Company, today announced a joint, voluntary recall of the **[subject product]**. Consumers should stop using this product immediately and return to them for a full refund.

Name of Product: [subject product],

Units: Approximately 110,000 in the United States and Canada.

Retailer: XYZ Retailer (USA) and Stoney River Stores (Canada).

Hazard: Mixed ingredient may ignite during use due to extreme flammability of raw material substance, which poses a risk of personal injury and death to product users.

Incidents/Injuries: Two (2) incidents without injury reported. No injuries reported.

Figure B.2 — Example 2

Description: **[product description, including UPCs, model numbers, container identification numbers and product ingredients]**

[1st product picture & description]	[2nd product picture & description]

Sold: United States and Canada from March xxx until December xxx, 2009.

Manufactured in: United States

Remedy: Consumers should stop using this product immediately and return it to the nearest retailer for a full refund.

Consumer Contact: For additional information, contact ABC Company toll-free at (888) 888 0000 between 7 a.m. and 7p.m. (CT) CT) Monday through Friday, or between 10 a.m. and 6:30 p.m. (CT) on Saturday, or visit the website at www.abccompany.com.

The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of serious injury or death from thousands of types of consumer products under the agency's jurisdiction. The CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical, or mechanical hazard. The CPSC's work to ensure the safety of consumer products—e.g. toys, cribs, power tools, cigarette lighters and household chemicals—contributed significantly to the decline in the rate of deaths and injuries associated with consumer products over the past 30 years. To report a dangerous product or a product-related injury, call CPSC's hotline at (800) 638-2772 or CPSC's teletypewriter at (800) 638-8270, or visit CPSC's website at www.cpsc.gov/talk.html. Consumers can obtain this release and recall information via Internet gopher services at cpsc.gov or report product hazards to info@cpsc.gov. To join a CPSC email subscription list, go to https://www.cpsc.gov/cpsclist.aspx.

Figure B.3 — Example 3

RECALL NOTICE TEMPLATE

RCLYY-NO.

Month Day, Year

Month Day, Year

Subject of the recall

Location – The Company Name. is notifying the public that Company Name has announced a voluntary recall of the following consumer product. Consumers should stop using recalled products immediately.

Name of Product:

Units:

Manufacturer/Importer:

Hazard: Provide description of the potential hazard and associated risk.

Incidents/Injuries: Provide the number and type of injuries or damage reported.

Description/Models: Provide distinguishing features, batch or serial number, retail cost, colour, etc.

Sold by:

When was distributed:

Manufactured in:

Remedy: The suggested steps and remedial action that the consumer should take to protect themselves and what is being done to correct the problem or defect.

Consumer Contact: Provide Contact name, number (preferably toll-free) and address for further information.

Remarks:

Provide Picture for the Recalled Product

Figure B.4 — Example 4

Annex C
(informative)

Product recall checklist

Table C.1 provides an example of a product recall checklist, once the decision to recall is made.

Table C.1 — Example of product recall checklist

Action/step	Responsibility of supplier	Responsibility of retailer
Has your organization reviewed all applicable legislative, regulatory and standard requirements for recalls, in all markets where the defective consumer product is produced in or sold?	Y	Y
Have you determined the full range of products affected? (e.g. range of sizes, colour or flavours)	Y	
Has your organization uniquely identified the affected products? These can be identified by: — unique product identification (e.g. UPC codes), or — unique product identification and production batch/lot, or — unique product identification and serial number (range)	Y	
Has your organization identified all the affected retailers and potential consumers?	Y	
Has your organization determined whether other product recalls may need to be referenced in the recall notification? While referencing other product recalls is necessary to maintain visibility to the chain of events that have resulted in the current recall.	Y	
Has your organization stopped sale and further distribution of the affected product(s)?	Y	Y
Has your organization followed the supplier's instructions for product removal from the supply chain or directly from consumers?		Y
Has the product recall changed since its initial initiation? (e.g. additional affected product, new product handling instructions, copies of media releases) If so, has your organization issued an updated notification and assigned a new unique recall notification identifier?	Y	
Is your organization maintaining an audit trail of all changes made to the original recall notification?	Y	Y

Annex D
(informative)

Improving recall effectiveness — Examples

D.1 Monitoring and reporting system

As noted in 6.6, it is important to monitor the effectiveness of the recall to ensure it is meeting the objectives. During a recall, the supplier responsible for the recall will receive a variety of information from a range of stakeholders including consumers. In order to monitor the effectiveness of consumer communications, an efficient system for enabling consumers to contact the supplier needs to be established. In addition, information on the number of consumer enquiries and how the consumer found out about the recall will help to determine whether communications were effective. The questions and examples in Clauses D.2 to D.6 may assist in ensuring that a recall is effective.

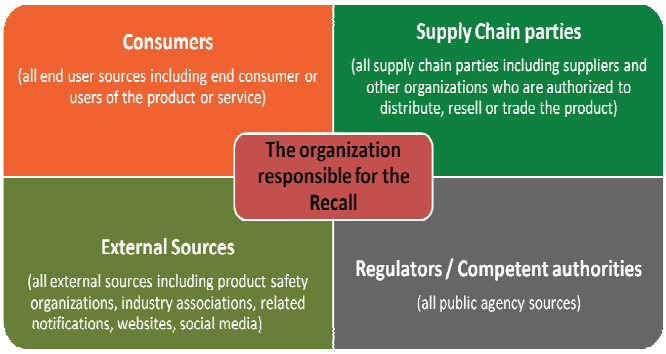


Figure D.1 — Sources and channels of information to assess recall effectiveness

D.2 Is the recall notice clear?

It is important that suppliers responsible for a recall provide clear guidance and use a variety of communication methods to make consumers are aware of the recall. For example, clear instructions, the use of large lettering and thick red borders around the notice will help make recall notices stand out, as the sample Australian recall notice in Figure D.2 demonstrates.

Figure D.2 — Example - Sample recall notice

Photographs and diagrams within the notice can also draw attention to key information.

Example – Use of photographs

A manufacturer of a metal drink bottle had sold a product with two different forms of a plastic caps. One form was found to be defective and the other was acceptable. Including a colour photograph in the recall notice clearly showing the difference between the affected cap and the cap that was not affected by the recall reduced confusion and helped ensure that only faulty caps were returned.

D.3 Can the consumer identify the affected product or hazard?

It is sometimes very difficult for consumers to know whether they have the affected product when the problem is not immediately obvious. In those circumstances, the supplier responsible for the recall may have to have qualified technicians available to answer questions, or to inspect the product.

Example – Technical assistance

Consumers that had purchased a product used in exterior home renovations had difficulty identifying whether they had a product that had been recalled. The manufacturer arranged for experienced employees to visit the homes of those consumers to help identify whether they had purchased and installed the affected product.

Example – Retailer support

The manufacturer of a baby stroller recalled the product after a defective part was found. The company had a very large amount of contacts after the first newspaper advertisement but these contacts very quickly reduced. With the cooperation of the retailer, the company started a free inspection and repair process via a point of purchase campaign which increased the enquiry rate and return rate.

After sale information, such as warranty information, or contacting installers can also be used for more effective recalls.

Example – Use installers

A manufacturer of a home appliance recalled a product using newspaper, radio and TV advertisements. As consumers registered products for warranty purposes, some were able to be contacted by direct mail. In addition, the installers of the appliance were able to contact the consumer to let them know about the recall.

D.4 Is the communication targeted?

Traditionally newspapers advertisements have been the primary means of communicating with consumers. Consumers however obtain information through a variety of sources and these sources can vary considerably depending on the characteristics of the consumers. The methods used to communicate should be appropriate to the user of the product.

Example – Target user group

Motorcycle helmets were found to be defective and had to be recalled. Advertisements were placed in newspapers but found to be less than effective. Advertisements were placed in motorcycle journals and, as one important user group were teenage boys, information distributed through high schools. This improved the response rate dramatically and no further incidents were reported

Example – Target specific user group

A manufacturer of oil heaters recalled a product after a defect was found. Notices were placed in newspaper, TV and radio advertisements however incidents still occurred. The company extended their notification to companies leasing cottages and villas as short term accommodation and improved the enquiry and return rates.

D.5 Is the media used appropriate to the consumer?

The media that consumers use to gather information about products can also be used to communicate a recall. Increasingly consumers use social media, particularly if the product has some unique qualities or attract groups with specific needs. In the following examples, companies used the internet effectively to communicate a recall.

Example – Use of social media

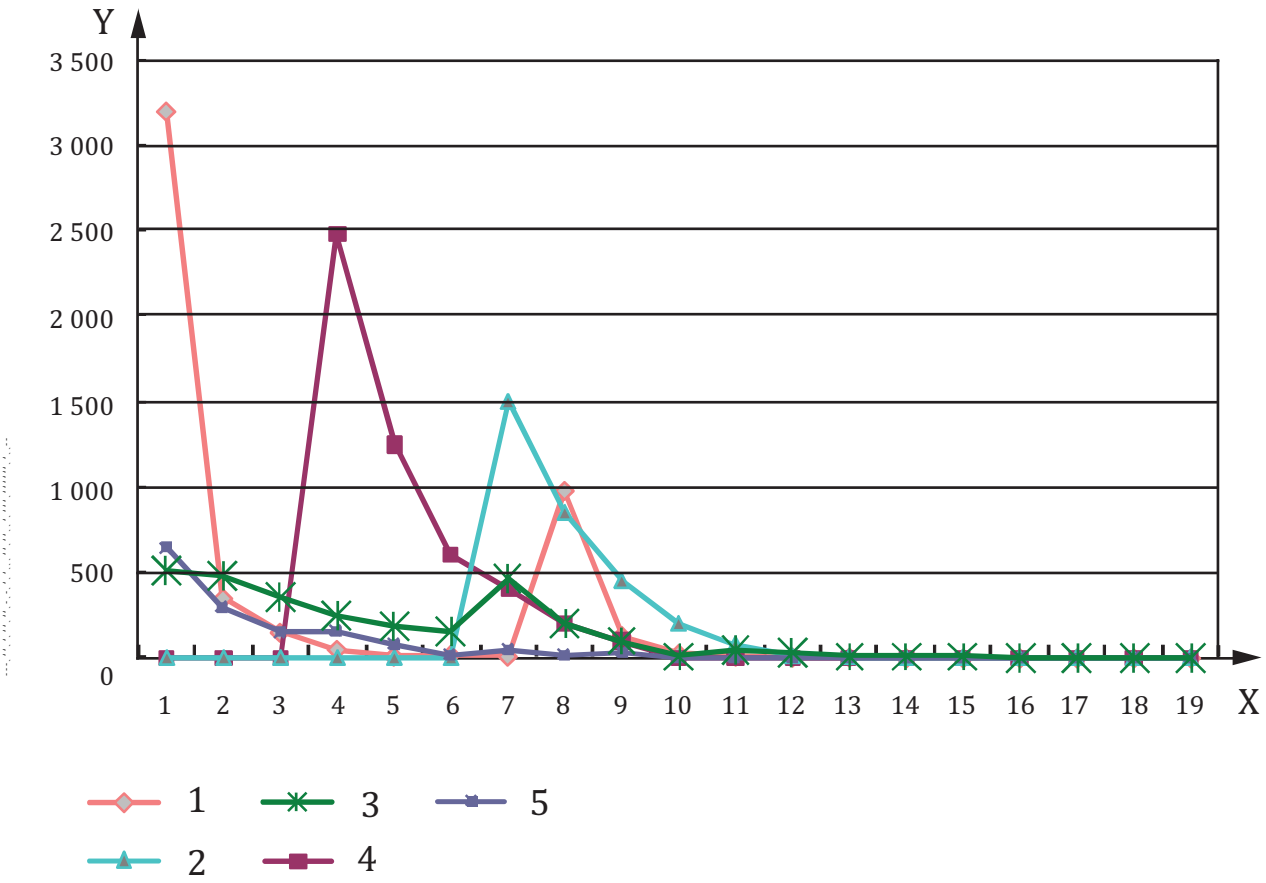
A manufacturer of organic food products had developed a strong following by health conscious consumers on a weblog devoted to healthy products. When the manufacturer decided to recall a product as a result of a faulty ingredient, it used the website to announce the recall and to assure consumers that it had found and resolved the problem and to apologize for the inconvenience. The use of open honest communication actually strengthened the relationship with its consumers.

Example – Online retailers

A quality problem with a popular recreational product led to a recall in a supplier's home market. The regulator in another country contacted the supplier and requested they also conduct a recall in that country even though the supplier had no formal distribution system there. The product had been sold by small online retailers and had built a strong following among active, environmentally conscious consumers. The supplier responsible for the recall contacted those small online retailers and arranged for them to send emails to their customers notifying them of the recall and providing instructions for the return and replacement of the product. This method resulted in a very high percentage of consumers being notified and a positive response in related social media.

D.6 Are a variety of communication methods used?

In the example in Figure D.3, a manufacturer of home electrical products used a variety of methods to communicate the recall and tracked the number of enquiries it received from those sources.



Key

X	Week
Y	Number of contacts by each notification method
1	Announcement by newspaper
2	Leaflet
3	Website
4	Direct mail
5	POP (point of purchase)

NOTE Source: Product Recall Handbook of Japan (2010).

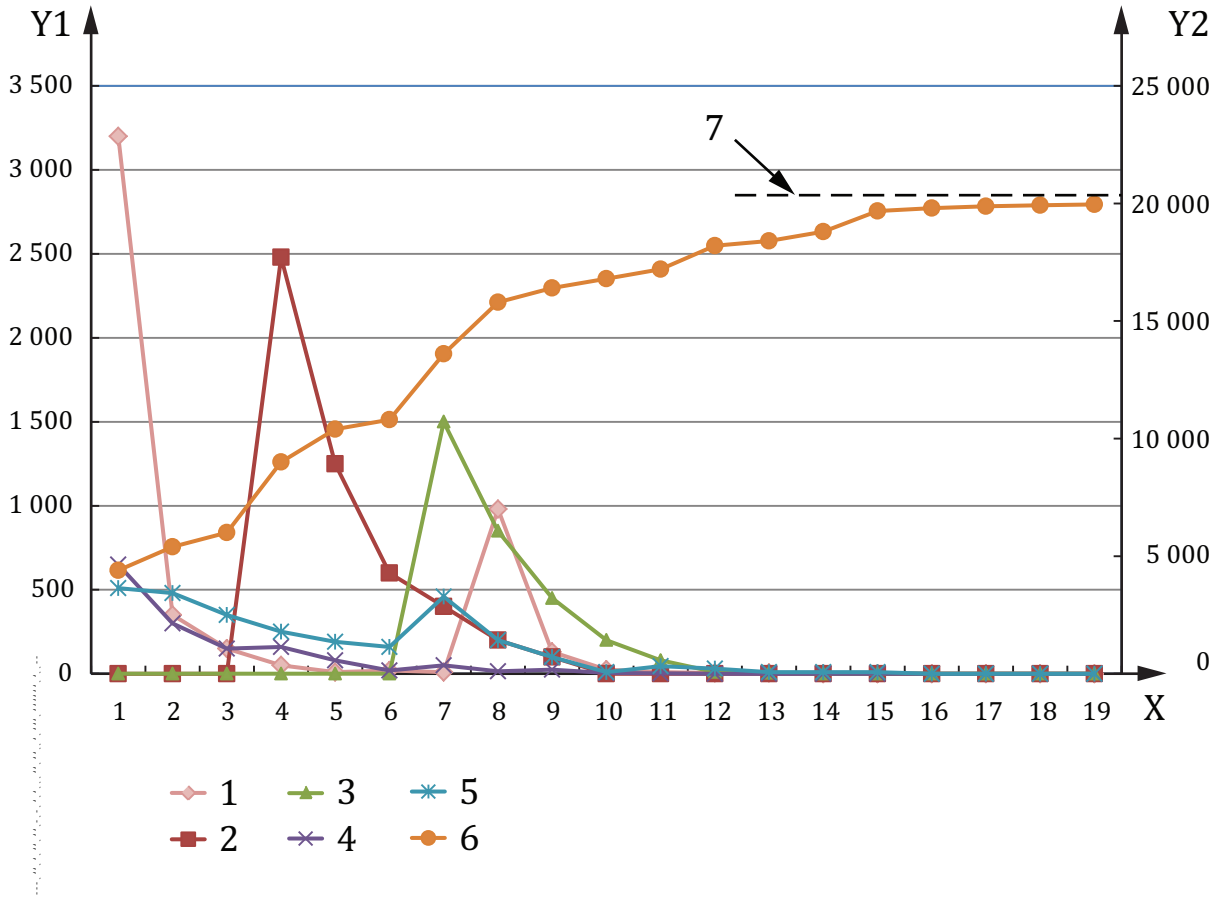
Figure D.3 — Example - Consumer contacts after various methods of communication

The first newspaper announcement triggers a high level of response but the number of contacts quickly reduces. Direct mail to consumers using warranty cards provides an additional peak of contacts. Further methods (e.g. point of purchase notices, leaflet drops and additional advertisements) are used which result in gradually reducing peaks of consumer contact.

This pattern is typical of enquiry rates after announcements of a recall, but that does not necessarily mean that the recall is effective.

D.7 Evaluation of the recall

The graph in Figure D.4 shows the same information but also shows the total accumulated number of contacts on the right axis.



Key

X	Week
Y1	Number of contacts by each notification method
Y2	Total number of contacts
1	Announcement by newspaper
2	Direct mail
3	Leaflet
4	POP (point of purchase)
5	Website
6	Total of the accumulated numbers of consumer contacts received by the organization up to each week after taking various methods of notification
7	Effectiveness evaluation at the seemingly ending stage

NOTE Source: Product Recall Handbook of Japan (2010).

Figure D.4 — Example - Accumulated contacts

Measuring the accumulated number of contacts shows there is a gradual tapering off in the number of contacts shown by the dotted line. This information could indicate the recall has been effective and that active recall operations can cease. The supplier responsible for the recall should however take other information into account before making that decision.

In the graph, the accumulated number of contacts is around 20 000. If the actual number of affected products in the marketplace was also around that number, the recall could be considered effective as long as incidents are no longer occurring. However, if the total number of affected units in the marketplace is

much higher than 20 000, it may not have been effective, particularly if incidents are still occurring. The supplier responsible for the recall may have to consider additional communication methods to improve the effectiveness of the recall.

Monitoring reports of incidents causing illness or injury is particularly important for determining whether the recall has been effective. While accidents and injuries are still occurring, the recall cannot be considered effective.

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