



Industry Recall Guideline

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Industry Recall Guideline

1. Introduction

The ability to remove products from the market rapidly and effectively is vital to every producer and distributor. A recall programme is a written action plan that is carefully constructed, tested and evaluated to ensure efficiency. It is a safety net that can prevent consumers from buying or consuming potentially unsafe products.

Whilst a number of organisations have detailed consumer recall processes, there is an inconsistent approach to consumer product recalls within the South African market. Yet all consumers need to be able to trust that our industry will recall products with a potential or actual consumer safety risk and that recalled unsafe products will be managed appropriately. When there is transparency by the organisation with regards to the recall, consumers develop trust in the brand and organisation gains in customer loyalty.

Organisation's internal standards, conformity assessments and regulations are designed to help ensure that products are safe for the consumer to use, but from time to time defects do occur, or hazards are identified after the product has been introduced to the marketplace. In these instances, recalls need to be undertaken by the organisation to protect the safety of the consumer.

The purpose of this document is twofold; firstly, to provide guidance on the protection of South African consumers by building capability in terms of recall processes within the industry. Secondly, to protect the reputation of the industry, who must be seen to act decisively with regard to the safety of their products.

This document does not dictate how one should go about making the recall decision that is up to the individual organisation to decide. That decision is based upon the assessment of the risk to the consumer, and it is critical that this risk assessment is undertaken by qualified individuals. This is a merely a guideline to organisations as to a minimum standard for the Industry and best practices.

2. Legislation *

The following Acts and Regulations listed were also taken into consideration.

- Consumer Protection Act 68 of 2008
- NCC Draft Guidelines on Product Recalls
- Foodstuff, Cosmetics and Disinfectants Act 54 of 1972
- Fertilizers Farm Feeds Agricultural Remedies and Stock Remedies Act No. 36 of 1947
- SANS 10049 food safety management system – requirements for a prerequisite programme (PRP) system
- ISO 10393 Guidance standard on consumer product recall and corrective action: Code of good practice (draft)

- HACCP Europa
- Directive 2001/95/EC of the EU Parliament: General Product Safety
- ASA Code of Good Practice
- Pet Food Industry Code of Good Practice

3. Scope*

This document covers a recall process for products which are considered a safety risk to the consumer. The scope is limited to (add industry) intended for (add industry use), as well as (any other inclusions). These include imported products which have actual or potential consumer safety risks (hereafter referred to as "suspect (food) products") which need to be removed from the South African market place.

This document does not provide guidance on products exported from South Africa. In cases of the latter, the exporting company should consult with the relevant sector regulator for guidance. e.g. National Regulator for

4. Organisation responsibilities

A recall guideline for products pre-supposes that certain factors are in place at the organisation which produced the suspect product, namely:

- The organisation has adopted the principle of commitment and accountability of the management to the health and safety of the consumers of their product
- The organisation has adequate resources available (or will make adequate resources available) to manage the recall and associated actions
- The organisation has adopted a principle of continuous improvement
- The organisation complies with relevant national and local legislation and regulations
- The organisation has a structured decision-making process for risk-assessment, recall decision, management and communication of a consumer safety recall
- The organisation can identify the suspect product(s) (via traceability and quality system management) or, understands that all of the products which are potentially suspect must be recalled;
- The organisation system needs to be geared to allow for recall of specific products/batch and not entire SKU and
- The organisation understands and acts upon collateral damage where relevant, i.e. grasping the extents to which other batches or products may be potentially or actually affected via cross-contamination or association or some other reason, which could necessitate a recall procedure.

5. Definitions

5.1 Consumers /Customers

Consumers - In respect of any particular goods or services, means- a) a person to whom those particular goods or services are marketed in the ordinary course of the supplier's business; b) a person who has entered into a transaction with a supplier in the ordinary course of the supplier's business, unless the transaction is exempt from the application of the Consumer Protection Act by section 5(2) or in terms of section 5(3); c) if the context so requires or permits, a user of those particular goods or a recipient or beneficiary of those particular services, irrespective of whether that user, recipient or beneficiary was a party to a transaction concerning the supply of those particular goods or services and d) a franchisee in terms of a franchise agreement to the extent applicable in terms of S 5(6)(b) to (e) as per the Consumer Protection Act of no 68 of 2008.

Customers -

5.2 Consumer Safe Product

A product that does not pose any risk to consumer health or safety.

A safe product is compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of consumers, taking into account the following points in particular:

- The product and process characteristics of the product, including its composition, packaging, instructions for use and storage. The effect on other products, where it is reasonably foreseeable that it will be used with other products
- The presentation of the product, the labelling, date markings, any warnings and instructions for its use and disposal, and any other indication or information regarding the product; and
- The categories of consumers at risk when using the product, in particular children, pregnant or breastfeeding mothers and the elderly. (Directive 2001/95/EC of the EU Parliament" General Product Safety)

5.3 Product Recalls: Trade in relation to the Consumer

Trade: Removal of the suspect product(s) from the marketplace (trade, customer or distribution centres) to ensure consumer health and safety, followed with appropriate corrective actions. This is also sometimes referred to as a product withdrawal.

Consumer: Recall of the suspected product(s) from the consumer, or the consumer is advised to take appropriate action, for example to return or destroy the particular product.

Product blocked or stopped whilst still in the control of the supplier whether in their factory or in their warehouse not be considered a recall. This is the usual “quarantine” or “QA Held” process followed by manufacturers or suppliers.

5.4 Recall Triggers

Triggers that indicate a potential or actual consumer safety risk in a product which may or may not lead to a recall decision are numerous. Examples are:

- Foreign matter/objects
- Contamination, including chemical and microbiological and allergen
- Reports of illness, injury and adverse reactions, e.g. allergenic reactions
- Incorrect or wrong packaging or labelling
- Accidental, negligent or malicious contamination
- Sources of triggers could be, but are not limited to:
 - Notifications from warehouses, sales representatives, employees, distributors, customers or authorities that the food product poses a risk to consumer health and/or company reputation
 - Regulators notification
 - Notifications from packaging, ingredient or processing aid suppliers
 - Consumer or customer complaints
 - Media reports
 - Notification from manufacturing units
 - Internal records
 - Etc.

5.5 Corrective Action

Generally includes any type of remedial action taken by an organisation. This may include multiple measures that are necessary to protect consumers. (ISO 10393 draft)

5.6 Consumer Safety Risk

Shall mean any risk, where, based on the information available, where there are concerns about actual or suspected risks in relation to the safety of the product; the result of which could affect the consumer, including those where the effects are not immediate. (Directive 2001/95/EC).

5.7 Harm

Harm: means physical injury or damage (including illness) to the health of people.

5.8 Safety Hazard /Defective Goods

5.9 Brand Protection and Consumer Safety Protection

In the context of this document, the above refers to the product being damaged and/or contaminated in such a manner that the product itself cannot be consumed, or its packaging cannot protect the product in any manner. It is considered unfit for consumption and shall be disposed of.

5.10 Consumer Safety Risk

Means the combination of the probability of occurrence of harm and the severity of that harm.

5.11 Risk Assessment

Risk assessment, in this context, is the determination of the risk related to a concrete situation and a recognized threat/hazard. Risk assessment requires calculations of two components of risk: the *severity* of the potential threat/hazard and the *probability* that the threat/hazard will occur.

Risk assessment consists of an objective evaluation of risk in which assumptions and uncertainties are clearly considered and presented. Part of the difficulty of risk management is that measurement of both of the quantities in which risk assessment is concerned. Severity of the threat/hazard and probability of occurrence can be very difficult to measure. The chance of error in the measurement of these two concepts is large; hence experienced, qualified individuals should undertake the risk assessment.

5.12 Traceability

Traceability means the ability to trace any finished product, its raw materials, its ingredients and its packaging that will be used for consumption, through all stages of production, processing, distribution and storage.

It is vital that when an organisation identifies a risk, they can trace it back to its source in order to swiftly isolate the suspect product and prevent the suspect product from reaching consumers. In addition, traceability allows targeted withdrawals and the provision of accurate information to the public, thereby minimising disruption to the trade.

5.13 Documentation and Records Management

All documentations and recorded data related to the recall shall be maintained and managed, including: Activities arising out of a recall for continuous improvement, data analysis, due diligence and to facilitate incident investigation, product and process identification and traceability.

5.14 Root Cause Analysis (RCA)

Root cause analysis (RCA) is a class of problem solving methods aimed at identifying the root causes of problems or events. The practice of RCA is predicated on the belief that problems are best solved by attempting to address, correct or eliminate root causes, as opposed to merely addressing the immediately obvious symptoms. By directing corrective measures at root causes, it is more probable that problem recurrence will be prevented. However, it is recognized that complete prevention of recurrence by one corrective action is not always possible. Conversely, there may be several effective measures (methods) that address the root cause of a problem. Thus, RCA is often considered to be an interactive process, and is frequently viewed as a tool of continuous improvement.

RCA is typically used as a reactive method of identifying event(s) causes, revealing problems and solving them. Analysis is done *after* an event has occurred. While one follows the other, RCA is a completely separate process to Incident Management, but is often included in the Incident Management procedure as a process to be conducted when investigating the cause of a suspect product and the corrective actions required eliminating a repeat occurrence.

5.15 Living Standards Method (LSM)

The South African Advertising Research Foundation (SAARF), Living Standards Measure (LSM), developed by the South African Advertising Research Foundation (SAARF) has become the most widely used market research tool in South Africa. The SAARF LSM is a unique means of placing the SA market on a continuum by cutting across race and other outmoded techniques of categorising people, and instead, groups people according to their living standards using criteria such as degree of urbanisation and ownership of cars and major home appliances.

5.16 SWOT Analysis

A SWOT analysis must first start with defining a desired end state or objective, which in this case relates to the recall of the suspect product. A SWOT analysis is best incorporated into the initial recall planning stage.

Strengths: characteristics of the business or team that gives it an advantage over others in the industry, in this particular recall situation.

Weaknesses: characteristics that place the organisation at a disadvantage relative to others.

Opportunities: *external* chances to make greater positive impact in the recall environment.

Threats: *external* elements in the recall environment that could cause distress for the organisation.

Identification of SWOTs is essential because subsequent steps in the process of planning for achievement of the selected objective (in this case the defined recall objective/end state) can be derived from the SWOTs.

5.17 Collateral Damage

The extent to which other products or batches of products may also be potentially or actually affected, via cross contamination or association, or some other reason, (e.g. suspect batch cannot be isolated from others, and require to be recalled).

5.18 Stakeholders

Include, but are not limited to:

- Customers
- Suppliers
- Manufacturers
- Regulators
- Consumers
- Insurance companies
- Competitors

6. Recall Process

It is recommended a team, rather than one individual, manages the consumer safety recall to ensure all aspects are appropriately addressed. Owing to the swiftness at which a consumer recall develops, it is very

easy to lose control of the situation, resulting in the organisation's recall being scrutinised by the media or the authorities.

Another important factor to consider when deciding on the scope of how much, and what product will be included in the recall notice, is the fact that the market will often (grudgingly) accept one recall notice for a particular product, but is unlikely to accept a second recall notice.

Only if the organisation is unsure of the scope (product type and quantity), in which to include a recall notice, it is preferable to recall all products of the brand or type identified. The returned products can always be sorted as to minimize losses in terms of separate affected products from non-affected products.

To widen the scope of the recall, a second recall notice could be required if all affected products were not recalled, once the first recall notice was published or communicated.

6.1 Recall Team

All team members need to understand and appreciate that a consumer safety recall takes precedence over all their other activities.

The team must represent the different functions within the organisation that are impacted by the recall, for example:

- Product Recall Co-ordinator
- Customer/sales
- Production
- Supplier
- Retailer
- Marketing
- Quality
- Purchasing
- Consumer Services
- Outbound logistics/warehousing/transport
- Reverse logistics

Satellite expertise must also be available to the team as required, for example medical, legal, finance and public relations.

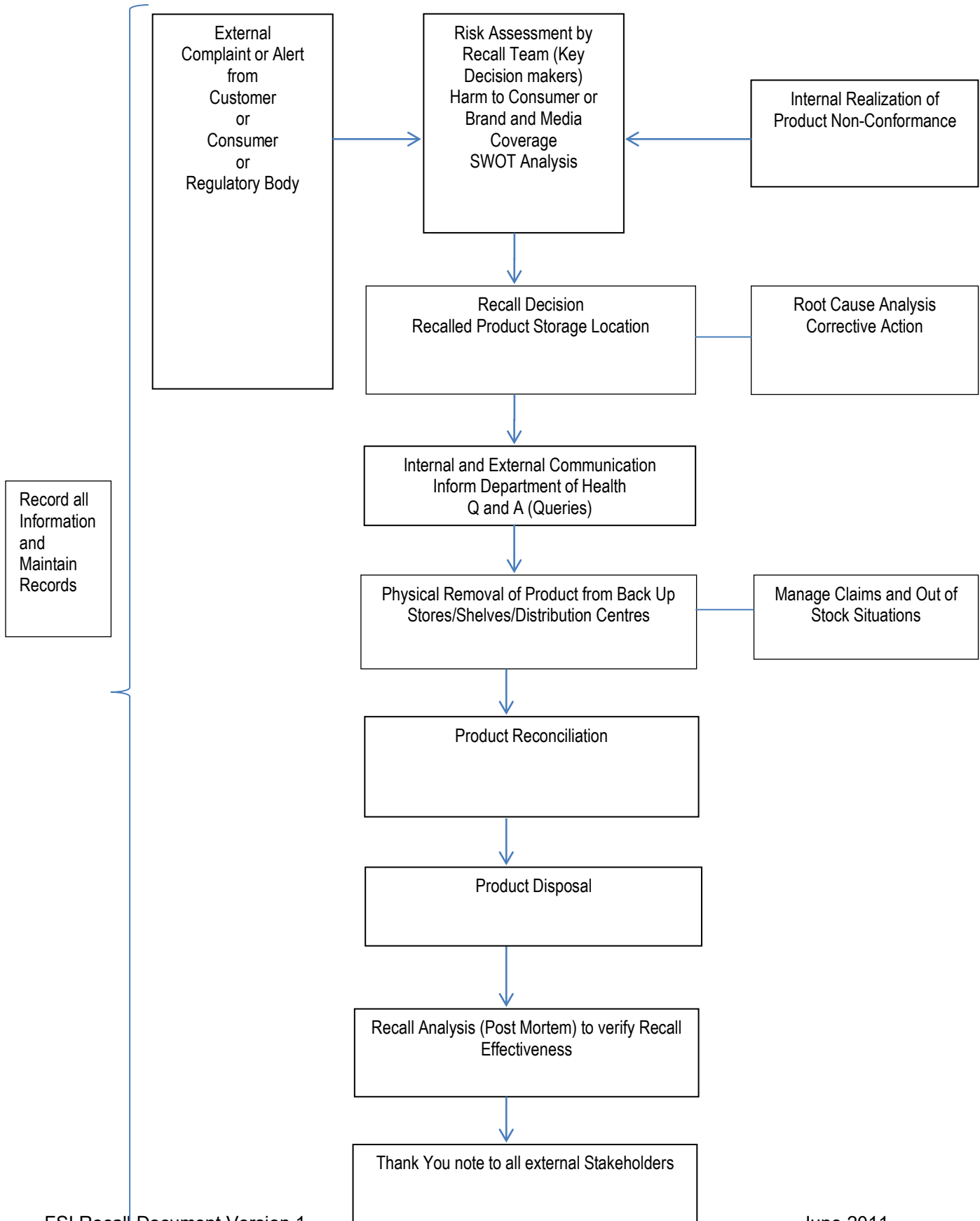
In smaller organisations one individual may be responsible for more than one of these functions, and in larger organisations these functions may be split even further.

The purpose is to have individuals present at the team meetings who can make immediate decisions as regards their responsible functions. It is also recommended that deputies are nominated to stand in for these team members where necessary; however it is essential for deputies to have the authorisation to make key decisions.

In some circumstances, it may facilitate quicker responses if the team is split into a core team with sub teams all reporting to the core team chair:

- Recall core/key team through which all information flows
- Recall communication team who manages communication to the consumer, customer and media
- Trained individuals who can manage standardised answers to queries
- Recall investigation team (usually manufacturing based) who commence the RCA
- Recall customer team who facilitate the arrangements with customers, particularly when a consumer recall is being planned

7. RECALL PROCESS FLOW





Verify effectiveness of Corrective Action
Implemented

8. Recall Facilities & resources

Should you be conducting a recall it is recommended that the team be assigned a room/or area, with amongst others, the following:

- Direct line telephone as well as one directed through the switchboard
- Copier/scanning equipment
- Computer facilities
- Flip charts and appropriate stationery

that can be locked and left “as is” at the end of a day.

- The individuals nominated to handle consumer, customer and media queries will require access to:
 - Direct line telephones and computers to receive queries and to feed the information through to the recall team on a daily basis
 - It is strongly recommended that these telephone and email lines are switched through to appointed individuals’ cell phones to deal with afterhours queries
 - Receptionists/Switchboard Operators/Security including those people at satellite offices need to be alerted and advised on how to deal with enquiries (document consumer details for example)

All team members must share their cell phone numbers, and cell phones should not be switched off for the duration of the recall period.

- The individuals nominated to handle consumer, customer and media queries will require access to:
 - Direct line telephones and computers to receive queries and to feed the information through to the recall team on a daily basis
 - It is strongly recommended that these telephone and email lines are switched through to individuals’ cell phones to deal with afterhours queries

Emergency Telephone Contact Lists

These lists need to be maintained and kept updated in order to enable the prompt implementation of the recall plan. These lists should include the members of the various teams involved in product removal, and their functions and designations. The mentioned lists should also include contact details for both office hours and after hours.

Emergency numbers of external partners should be well maintained (Forensic Department, Microbiologist and Courier Contacts etc.)

9. Recall Decision

It is recommended the first order of business for the recall team, after a recall decision was made, is to conduct a SWOT analysis of the situation.

This can be used as the basis of any future actions or messages to stakeholders and the consumer, and also ensures all future actions and communications project the same message.

Conflicting public messages and actions merely demonstrate that the organisation lacks (1) knowledge of the situation and (2) control of the situation.

The decision to recall is one made by each individual organisation, in consultation with the relevant authorities where necessary, once a consumer safety issue has been identified.

The decision to recall must be supported by the risk assessment and clear scientific facts, if available.

It is essential for management to have established a series of steps that the recall team should consider to make sure that the organisation makes a structured decision based on available and reliable information.

Whilst this document supports a risk based approach, it is critical that the risks in question are assessed by qualified individuals.

To clarify the recall decision making process, refer to the example in Figure 1 below. (This is merely an example, not a definitive process).

STRUCTURED RECALL DECISION MAKING PROCESS: AN EXAMPLE

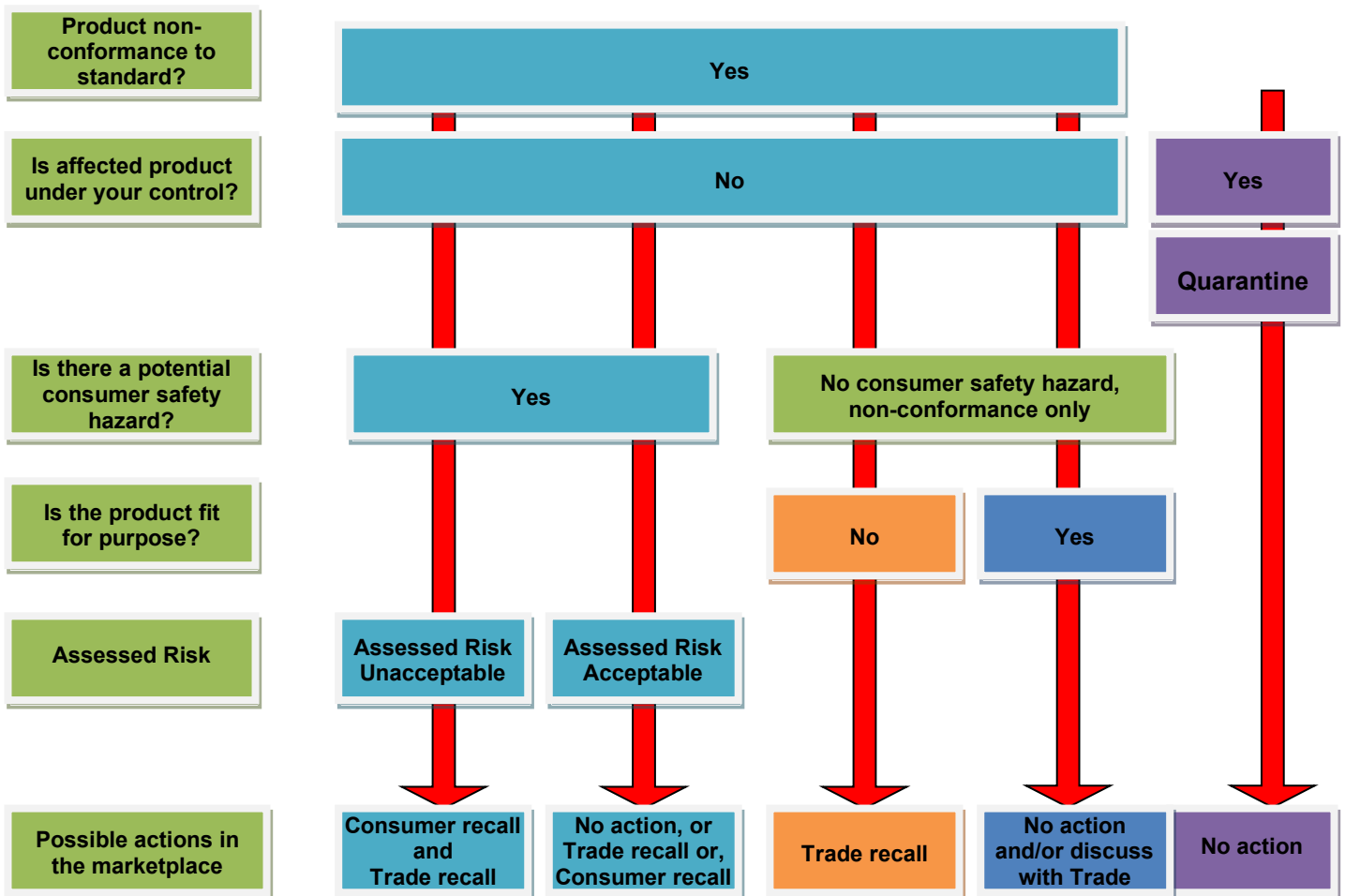


Figure 1

A consumer safety recall, while usually an individual company decision, can be dictated to the organisation, for example by:

- The National Department of Health, Directorate: Food Control; or
- The Consumer Commission who draws their authority from the Consumer Protection Act, or
- A customer of the organisation

Under these circumstances, the organisation should immediately initiate a recall of the suspect product (which may have already commenced based upon instructions issued to the market place by these Authorities)

10. Physical Retrieval of Product

- The organisation needs to specify as to whether they want the consumer to dispose of the suspect product and merely retain some proof that it was purchased, e.g. a barcode from the packaging, the date marking of the packaging, the empty packaging etc. or whether they wish to collect all of the suspect products to ensure it is fully removed from the marketplace and thereby not at risk to cause any harm.
 - The organisation needs to have a plan in place as to how they will collect suspect products from all of their customers, including spaza stores and pavement traders as well as consumers. They need to advise if they will do the collecting themselves, or will they request the customers to return the products/ proof of products. If they are collecting they need to indicate how frequent the collections will be.
 - The organisation must specify whether they wish the product or proof of product to be returned to where it was purchased, or do they wish the suspect products be returned to the organisation via post.
 - In certain circumstances, the organisation may choose to retrieve product from consumer's homes and need to advise the consumer of the necessary arrangements and logistics (including resources) around the collection.
- Organisations need to get agreement from customers that they are willing to receive the returned products / proof thereof and whether they will need handle returns or will they use their own resources.

11. Communication Strategy

In order to have an effective recall programme, communication should be clear, timely, transparent and accurate.

The team managing the recall must appreciate that the South African consumer is neither practised nor used to product recalls. Whilst some SA consumers might have been exposed to the odd recall, there have not been that many recalls to the consumer level in South Africa.

Owing to this, the organisation must be well prepared for consumer queries or complaints, as well as some anticipated level of confusion as to which actual product is involved in the recall. It is essential that all communiqués carry a photograph of the suspect product, together with an indication of products that are not affected by the recall.

It is recommended the recall team adopts the approach that *all* communications, whether internal or public, be made public at some point in time.

It is critical that the organisation does not attempt to conceal any information. A consumer product recall tends to invoke considerable interest in a market unused to them. Any concealed information will invariably become public at one stage or another, and it is preferable for the organisation to control the release of information, rather than be reacting to it.

It is also critical that all press releases and written communications are vetted by legal and communications experts before they are released. This will assist in protecting the organisation from various potential legal comebacks.

Note: It is advised not to (hastily) communicate scientific facts if such facts are not clear and verified. Rather state that the facts will be made public once all scientific data is verified.

11.1. Queries

It is recommended that the organisation appoints at least one person to respond to queries from the media, and others to assist with queries from consumers. It is important to clearly instruct employees to direct respective queries to these appointed individuals.

It is also important that these individuals reserve an opinion on the matter until further notice, rather than making arbitrary statements. (If the facts are not yet clear, it is advisable to say that the facts will be made public, once confirmed). It is equally important that such persons obtain the answer to the query, and respond to the enquirer as soon as possible.

It is recommended that queries from the media are requested via fax or e-mail, and responded to in writing, so as to avoid any misunderstandings.

11.2 Public Media

When issuing a recall notice to consumers via the media, do ensure that sufficient, relevant information is included in the notice (see Figure 2 below). It is recommended that a photograph of the suspect product, as purchased by the consumer, is included in the recall notice.

These could also be issued to the organisation's customers, requesting them to display it at the appropriate spot in store.

It is recommended, that in order to be effective in terms of prominence, that the advert (communication) should be placed as an A5 minimum size in publications.

Figure 1

PRODUCT RECALL	
ABC Hot and Steamy Microwaveable Pizza	... what is the action?
<p>Quality Assurance checks revealed that a number of the foil trays in ABC Hot and Steamy Microwaveable Pizzas are defective. They risk overheating, which in certain cases causes the tray to burn.</p> <p>As a precautionary measure, ABC is advising all consumers to check if they have purchased any of the mentioned product with the Best Before Dates of ddmmy and/or batch number xxxxxx.</p> <p>The Best Before Dates can be found in the coloured panel on the side of the pack.</p>	... what is the product?
NO OTHER ABC PRODUCTS ARE AFFECTED	... what is the problem?
WHAT YOU, THE CONSUMER, SHOULD DO IF YOU HAVE PURCHASED OR RECEIVED THIS PRODUCT	... what should the consumer do?
<p>Discard the contents of the packaging in such a way that neither animals nor people would be able to get into contact with the affected product.</p> <p>Please send the packaging together with your contact details to: ABC, Whitehall road, Rathfarnham, Durban 6230.</p> <p>We will contact you as soon as possible to replace the product.</p> <p>We apologise for any inconvenience caused by this incident and would like to thank all consumers in advance for their understanding and co-operation.</p>	... where consumer finds the identifying info
ABC CARELINE 1850 6273 08976	... KEY MESSAGE !
	... eye catching instruction
	... consumer's action
	... apology
	... further information

The Afrikaans media, e.g. the Rapport newspaper, will not publish an English advert (communication); thus the need to translate the recall notice in Afrikaans as well.

Figure 2

PRODUKHERROEPING ABC Hot and Steamy Microwaveable Pizza	<p>... wat is die aksie?</p> <p>... wat is die produk?</p>
<p>Gehalteversekeringstoetse het getoon dat 'n aantal foelieverpakkings van bogenoemde produk foutiewelik funksioneer tydens verhitting. Onder sekere omstandighede, is daar die potensiële risiko dat die produk kan oorverhit en dus brand.</p> <p>As voorsorgmaatreël, versoek maatskappy ABC dat alle verbruikers wat bogenoemde produk gekoop het, sal sekermaak of die gekoopte produk(te) die volgende "Best Before" datum bevat: ddmj en/of vervaldatum xxxxxx.</p> <p>In geval van bogenoemde produk word die datum aangedui in die gekleurde paneel aan die een sykant van die verpakking.</p>	<p>... wat is die probleem?</p> <p>... wat moet die verbruiker doen?</p> <p>... waar kan die verbruiker die inligting vind</p>
GEEN ANDER ABC PRODUKTE IS GE-AFFEKTEER NIE	<p>... KERNBODSKAP!</p> <p>... prominente instruksie</p>
<p>WAT U, DIE VERBRUIKER, MOET DOEN INDIEN U HIERDIE PRODUK GEKOOP OF ONTVANG HET</p> <p>Gooi die inhoud weg; liefs op 'n wyse en plek waar geen dier of mens daarmee in kontak kan kom nie.</p> <p>Stuur asseblief die verpakking, tesame met u naam en volledige kontakbesonderhede aan die volgende adres: ABC, Whitehall road, Rathfarnham, Durban 6230.</p> <p>Ons sal spoedig met u in kontak tree en poog om die produk so gou moontlik vir u te vervang</p> <p>Ons vra om verskoning vir enige ongerief wat u mag ervaar weens hierdie insident en wil graag al ons verbruikers by voorbaat bedank vir hul samewerking in hierdie verband.</p>	<p>... verbruiker se aksie</p> <p>... verskoning</p> <p>... verdere inligting</p>
ABC KLIENTE DIENS NOMMER 1850 6273 08976	

The team must also consider the most appropriate medium to spread the recall message, depending on the target market of the suspect product. For example, consumer recall notices could also be issued via electronic media:

- Twitter
- Facebook
- Company website
- FSI website
- Radio
- SMS
- TV

Bear in mind that in the current South African context, Radio and SMS could possibly reach a greater spread in the LSM 1 – 3 consumer base.

In addition, the organisation should decide what they wish the consumer should do with the suspect product. Ideally, the organisation should also have obtained relevant agreements if customers or third parties are involved.

11.3 Trade/Customer

The organisation's customers need to know how to identify the suspect product so they can remove it from their shelves, back of stores and/or their Distribution Centres (DCs).

In addition, being the organisation's stakeholders and partners in selling the product, they need to know precisely what is wrong with the product. They also need assurances that no other product made by the organisation will be affected by a similar cause.

If the team is conducting a Consumer Recall in addition to a Trade Recall or Product Withdrawal, it is recommended that they advise their customer's buyers as soon as they know when the public advertisements will be displayed. No customer wishes to find a product they have on their shelf as being recalled, without their having had an opportunity to investigate and act on the matter themselves.

To ensure the correct Customer Head Office individuals are notified in the event of a recall, they must be telephoned and the said conversation should be confirmed in writing as well.

An updated recall contact list for customers must be available within office hours, and after hours contact numbers should also be available and be kept updated.

Note: notification directly to Customers Distribution Centre is not an ideal route to follow, as it is the customer's duty to communicate with their respective DCs.

11.4 Stakeholder Communications

Local, National and Provincial Authorities: The Authorities which require notification of the product removal activity should be identified as well as further information requested by these authorities.

It is suggested to use the Department of Health's Communication Document.

Furthermore, it is advised to also inform the CGCSA's Food Safety Initiative Manager

11.5 Employees

When a consumer recall is taking place, it is recommended the organisation notifies their employees as soon as possible to prevent misunderstandings and to emphasize the communications policy. (Only authorised staff can communicate with customers, consumers and media).

In addition, employees need to be advised that all queries related to the recall must be directed to the nominated individuals. This process will assist that all recall communications carry the same message.

11.6 Re-introduction of the Product

In the event of a consumer recall, a consumer notice is issued after the recall has been conducted and investigated. Such a notice attempts to give reassurance that the suspect product is no longer in circulation; it thanks the consumer for their co-operation; and it advises the consumer that good product is available for them to enjoy.

Where relevant, the supplier should notify the customer that they are ready to re-introduce the product and obtain agreement from the customer as the customer may require the supplier to be re-audited /complete questionnaires/give further assurances/re-testing before re-introduction takes place.

12. Reimbursement of Customer and/or Consumer

12.1 Customer

This is usually an accounting transaction for those customers who have purchased goods on credit.

For cash and smaller stores however, which might be a table on the pavement or a spaza store, the organisation has to make arrangements with such stores' sourcing retailers or wholesalers in order to accept the returned products, and either offer replacement products or a credit.

The organisation needs to advise the customer as to a) What proof of the suspect stock in hand is required before a reimbursement is given.

b) Whether or not the organisation can arrange for transportation to the spaza or pavement stores, to replace their goods.

c) What particular conditions the goods are to be stored under.

d) Whether they will offer cash, vouchers or products as a refund

12.2 Consumer

This is usually a refund or replacement transaction, via product, voucher or cash. However, an alternative compensation method needs to be established for those consumers who refuse replacement.

The organisation needs to arrange for returns and same-time reimbursement of the consumer-held product, either via their customers, themselves, or a third party (see customer above).

If retrieving the product from the consumer, it is appropriate for the retriever to reimburse the consumer at the same time.

The organisation needs to advise the consumer as to a) What proof of suspect stock is required before a reimbursement is given to the consumer

b) Will they offer cash, vouchers or product as a refund?

c) Whether they will be reimbursed for any expenses incurred when sending the product back.

13. Reporting

A structured investigation must be undertaken, followed by corrective actions, to ensure a re-occurrence of the situation does not arise. This will reassure customers and/or consumers that the organisation will prevent a consumer safety risk in future.

One of the structured investigation tools available is a formalised root cause analysis which, if conducted properly, ensures the cause, and not the symptom is clearly identified with associated corrective actions to eliminate or control the said cause.

Continuous improvement occurs when the organisation ensures a robust, sustained implementation of the identified corrective actions. Without this, the chances of the consumer safety situation re-occurring is high.

14. Future Strategy

The decision to stop or continue production when a consumer safety risk is identified must be made by the Recall Management Team, based on the issue at hand and the related risk assessment.

Whatever the decision, the organisation needs to instil confidence in their customers and consumers that it has robust practises in place to ensure that the suspect product has been removed and disposed of, and that no other product deliveries are affected.

It is critical that the suspect product being withdrawn is not confused with other/similar non-affected products awaiting despatch. It is recommended that a separate secure warehouse is used for storage of the returned suspect product.

14.1 Insurance

Whilst insurance cover cannot cover all costs associated with a recall, it will assist in ensuring the business has some protection from financial ruin. Businesses should discuss Product Recall and Contamination cover, including salvage of goods, incidental risks such as brand protection, business interruption, and other associated and expenses with their broker, insurer and finance division.

- 14.1.1 It is important businesses understand and outline **all the risks** it faces as a result of a recall, determine the impact of these and discuss with their broker or insurer.
- 14.1.2 Items to consider in the discussion as to what the insurance policy should cover with regards to recall are listed, but not limited to the ones, below.
- 14.1.3 Potential Harm: The product, or batch of product, has been identified as one that could likely/*potentially* cause injury or damage. The product does not necessarily have to cause injury or damage but must have the potential to cause injury / damage.
- 14.1.4 Actual Harm: The product or batch of product has already caused harm to a consumer. In this case, the Department of Health may also intervene and direct that a recall is conducted by the government or public authority.
- 14.1.5 The business must understand to what extent the insurer will offer cover if the recall is initiated by the government / public authority, the business, your customer, your principal or the brand owner.
- 14.1.6 Associated Risks of a Recall (not covered by a Products Recall policy):
 - Delayed harm: The product or batch of product may not cause harm at the time it was consumed, but result in later harm to the consumer e.g. toxin damage, a bacterium with a long incubation period etc. Whilst this is not covered by the recall policy itself, it is a risk associated with a recall
 - Psychological harm: The consumer claims damages owing to being psychologically affected by consumption of the product being recalled. Again, a scenario which is not covered by a recall policy, but an indication of risks associated with a recall
 - Brand Damage: This is probably one of the greatest threats to a business. Whilst brand protection cover is not easily available, some specials markets can provided limited cover with regards to brand protection
- 14.1.7 Collateral Damage: The extent to which, other products, or batches of product may

also be potentially or actually affected via cross contamination or association or some other reason (e.g. suspect batch cannot be isolated from others) and also require to be recalled.

- 14.1.8 Disposal of Salvage: To protect their brand, many companies refuse to allow an insurer or third party to salvage their products, preferring to pay for environmentally sound destruction of the product. In the event insurers insist on retaining salvage, business should agree a value on the salvage (and reduce a claim by the salvage amount).

However, usually products are recalled due to their potential to cause injury/damage. These are destroyed and not sold as salvage.

- 14.1.9 Destruction: Depending on the circumstances, the product may require specialised destruction due to the nature of the product or to protect the brand or the population that may retrieve goods from dumpsites. This specialised destruction is usually expensive.
- 14.1.10 Business Interruption: A recall may cause the business to lose revenue.
- 14.1.11 Third Party Recall: The business may supply a product which is an ingredient to another (company's) product. The ingredient may be the cause of the recall (due to its potential to cause injury or damage) and the company may recall its product and recover its recall costs from the business. This must be discussed with your broker so that the extent of risk and coverage is clearly understood.
- 14.1.12 Advertising, Media and other costs: Usually business will incur costs for a recall so that public is made aware of the potential dangers (if any) associated with the products and can assist with returning the products.
- 14.1.13 Transportation costs associated with return of products.

15. Disposal of Suspect Product

There are a number of options for disposal, for example (provided it is safe to do so) via:

- Rework: if reworked in different packaging there should be no food safety risk during the process, and the appropriate date marking, must be the same date as the original date marking. Traceability on the reworked batch must be verified
- Donation to welfare
- Destruction by consumer, customer or distributor

In all cases other than rework, one of the primary risks is that the suspect product is not disposed of via the nominated route, but re-introduced into the supply chain.

It is therefore critical that whatever disposal route is chosen, it is overseen by a responsible organisation employee, photographs are taken, and the method of disposal ensures consumer and brand protection.

Given the South African situation of dump pickers at municipal waste sites and in the streets going through consumer's waste, disposal of suspect product via these municipal routes is strongly discouraged.

If choosing to use the warehouse, customer or organisation waste route, the said disposal must be in line with the relevant local or national regulations. In particular for customer or organisation waste disposal, it must be determined whether the suspect product is hazardous or non-hazardous waste and disposed of correctly.

Depending on the nature of the recall, National and Provincial Authorities may need to be consulted on the safe disposal of the recall product.

15.1 Destruction (Uplift and Safe Disposal) Certificate

A Destruction Certificate (uplift and safe disposal) must be issued by the local authority or waste management company, and should indicate:

The name of the product being destroyed (frequently a collated list is referred to, and the waste site merely weighs the product rather than counting it)

- The quantity of products that have been destroyed
- The method of destruction
- Where the destruction took place
- The date the destruction took place
- And preferably co-signed by the company's witness present at the destruction
- And preferably accompanied by photographs of the destruction

The Destruction Certificate is the assurance to the owner of the goods that the product has actually been destroyed appropriately. Without it, there is no proof whatsoever that the product has been destroyed in an appropriate manner and place rather than being disposed of in an unknown manner elsewhere.

15.2. Hazardous and Non-hazardous Waste

According to the National Waste Management Act 59 of 2008, the following is defined:

"General waste" means waste that does not pose an immediate hazard or threat to health or to the environment, and includes:-

- (a) Domestic waste;**
- (b) Building and demolition waste;**
- (c) Business waste: and**
- (d) Inert waste**

"Hazardous waste" means any waste that contains organic or inorganic elements or compounds that may, owing to the inherent physical, chemical or toxicological characteristics of that waste, have a detrimental impact on health and the environment.

"Inert waste" means waste that:-

- (a) Does not undergo any significant physical, chemical or biological transformation after disposal;**
- (b) Does not burn, react physically or chemically biodegrade or otherwise adversely affect any other matter or environment with which it may come into contact; and**
- (c) Does not impact negatively on the environment, because of its pollutant content and because the toxicity of its leachate is insignificant**

It is essential that one team member is appointed as the Recall Administrator.

Their role is to:

- Maintain a daily diary of all activities (meetings, telephone calls etc.)
- Maintain all records referenced during the investigation
- Maintain a record of all communication approvals
- Maintain a record of all media questions and replies given, and comments in the public arena including those radio and TV clips, twitter, Facebook etc.
- Ensure responses to media and authorities are timely with the correct information
- Compile a lessons-learned document and corrective actions re the recall process itself
- Identify any corrective actions for other products arising from the recall investigation e.g. manufacturing, warehousing

All documentation should be kept for a period of 5 years.

16. Closing the Recall Incident

A recall is closed with a final report which is used for:

- Insurance claims
- Lessons learnt
- Continuous improvement

All relevant parties involved in the process of retrieving product must be notified that the recall is now closed.

The following data should be prepared for inclusion in the final incident report and re-introduction of the product into the market (if relevant):

- Final figures (%) of recovered product to determine the financial loss and recall effectiveness when consolidating with original product volumes
- Write-off data prepared for accounts
- The instruction to destroy the product is issued and certificates of such obtained
- A meeting with the relevant insurers
- The relevant Purchasing Manager is briefed to lodge claims with suppliers if necessary
- An agreement is obtained from Marketing within 2 weeks of recall commencing as to whether product can be re-introduced into the market or whether restrictions are required owing to the brand damage sustained by the recall event
- Formally agree with customers what measures are necessary to re-introduce the product into the market and ensure these are met on time in full. Evidence of same to be included in the final incident report
- Agree the communication plan to reintroduce the product to the market
- Review the incident and complete the Incident Review Document. A Recall Incident review document is required, covering:
 - An approximation of damage to consumers (cases of illness/injury) Refer to Risk Analysis
 - The management of publicity regarding the recall
 - The affect the recall has had on brand and corporate image
 - The effectiveness of the early warning system to the company
 - The time necessary to get the incident committee together
 - The speed and accuracy of the product and raw material traceability system
 - The speed and effectiveness of the advice and support from within and without the organization
 - The effectiveness of the SWOT analysis and risk assessment of the product
 - The effectiveness of any public warning issued
 - The time taken to retrieve product from the trade and consumer
 - The amount of product retrieved
 - The costs involved, including destruction costs
- Members of the Recall Management Team to identify root causes, and what measures are required to prevent it happening again. Some of these answers may already be available from the initial investigations and an audit of procedures to identify whether man, machine, and material or method failure. These measures must be included in the above Incident Review Document
- Complete a summary, including liability and insurance aspects
- Issue learnings document for both the product itself and the recall process, including who is responsible for implementing corrective action

16.1.1 Further complaints

There is always the possibility that not *all* affected product will be retrieved.

In the event a recall product complaint is received post the recall incident being closed, an immediate visit to the complainant must be made to retrieve the product.

Every effort must be made to discover where and when the product was obtained in order to communicate with and remove product from that source and any other customers they may have sold the product to.

16.1.2 Continuous improvement

The Organisation should apply continuous improvement principles to safety in design, production and the marketplace such as processes for:

- Hazard identification,
- Product incidents investigation,
- Risk assessments,
- Product recall implementation and
- On-going monitoring

Fundamental to effective and efficient improvement, is making informed decisions on the basis of data analyses and the incorporation of lessons learned. The organisation should define objectives for the improvement of its products and processes through the analysis of data.

The improvement processes should follow a structured approach, such as the “Plan-Do-Check- Act” (PDCA) methodology. Improvement activities can range from small-step continuous improvements at a work place to significant improvements of the entire organisation or its supply chain.

The organisation should ensure that continuous improvement becomes established as a part of the organisational culture such as by:

- Providing the opportunities for people in the organisation to participate in improvement activities,
- Providing the necessary resources,
- Establishing recognition and reward systems for improvement, and
- Continuous improvement of the effectiveness and efficiency of the improvement process itself
- Providing a closed loop system to ensure on-going monitoring of the changes and their effectiveness
- Incorporating best practices through training and information exchange with experts
- Whether they be internal or external ideas and recommendations for continuous improvement may be obtained from a variety of sources such as (but not limited to) the following:
 - Analysis of incident and complaint data
 - Analysis of injury data
 - Employees
 - Suppliers and contractors
 - Evaluation of recalls and corrective actions
 - All applicable legislation, regulations, legal guidelines and standards
 - Technology advancements
 - Supply chain partners such as original design, manufacturers(ODM) and contract manufacturers (As per recommendation re: ISO DRAFT DOC)

16.4.2.1 Cost Summary

Costs associated with recalls include, but are not limited to:

- Advertising and communications
- Retrieval, testing, rework (if relevant) and disposal of affected product
- Reimbursing consumers, including any collateral consumer costs
- Any charges paid by customer outlets returning suspect product to their DCs

- Any additional resource charges related to customers reimbursing consumers
- Reimbursing customers with replacement product
- Recall management team costs (travel, loss re: day to day business, Consultants, etc.)
- Overtime for call centres and associated resources required
- Loss of sales
- Brand damage and associated costs of these actions where applicable
- Regulatory fines
- Cost of disposal

16.1.2.2 Product Quantities Produced, Retrieved and Destroyed

It is critical for the Recall Team to appreciate how much of the suspect product was not retrieved, and if there will be any short term and or long term risk associated with the recall

A full reconciliation needs to be completed:

Product reconciliation refers to the extent to which affected product and potentially affected product can be identified and accounted for throughout the value chain.

Reconciliation of affected product is a key pre-requisite for an effective recall. Product reconciliation should be considered effective when 100% of product has been accounted for. Reconciliation should include:

- 16.4.2.2.1 The amount of affected product still under the direct control of the organisation i.e. in production, warehouses, etc.
- 16.4.2.2.2 The amount of affected product under the control of the organisations, distributors
- 16.4.2.2.3 The amount of affected product under the control of the organisation's customers that may be used in subsequent manufacturing
 - a) The amount of affected product under the control of retailers but not yet sold
 - b) The amount of affected product that is in market or in the hands of consumers
 - c) The amount of affected product likely to have been consumed or used
 - d) The amount of affected product remaining in the market

Note that in the event of affected product that has been sent to a customer for subsequent manufacturing (16.4.2.2.3) and that product has actually been used in subsequent manufacturing, this product needs to be obtained from the customer(s). In the event that customers have supplied finished product to the market, the customer is responsible for the recall, however the customer must appraise their supplier of the situation if that supplier's product is implicated in the recall.

16.1.3 Mock/Dummy Recall Testing

- 16.1.3.1 Product Recall procedures must be verified by conducting annual testing or more frequently, if relevant. This is referred to as a 'mock' or 'dummy' recall, and is conducted in exactly the same manner as a genuine recall. To avoid questions in the marketplace however, it is recommended that the business and customers are advised that this is a mock/dummy recall to test the preparedness and recall procedures.

As most actual recalls happen after hours/public holidays, it is recommended that a mock recall should also be performed after hours.

- 16.1.3.2 The output of the verification exercise must be a formal identification of any improvements, gaps or anomalies that exist, and must include allied

information, for example contact lists up to date, changes in consumer safety policies, new routes to market, etc. together with the plan to close out these identified items.

16.1.3.3 A second verification exercise is recommended shortly after to ensure the gaps identified are corrected.

16.1.3.4 The mock recall should be conducted in the same manner as a proper recall. The same communication routes should be followed.

16.1.3.5 Should an actual recall have taken place that year, and there are identified improvements, it is not necessary to repeat the exercise other than to verify the close outs have occurred.