

<i>HACCP</i> Europa.com	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 1 of 16</i>	

PURPOSE: To ensure that systems are in place to limit liability for corporate negligence, which can cause costly legal penalties and to improve or avoid damage to publicity.

RESPONSIBILITY: It is the responsibility of the management to ensure that the following procedures are adhered to and understood by all relevant personnel and the personnel follow State or local health department requirements.

CLASSIFICATION OF THE LEVEL OF PRODUCT RECALL

There two levels of product recall:

- **Recall:** This is the removal of unsafe food from the market and extends to food distributed to the final consumer and therefore involves communication with consumers (a recall should be initiated when a foodstuff is identified as potentially injurious to health and has been supplied to consumers)
- **Withdrawal:** This is the removal of an unsafe foodstuff from the market up to and including the point of retail sale (a withdrawal should be initiated when a food is identified as unsafe but it can be demonstrated that the unsafe food remains wholly in the distribution chain and has not reached the final consumer).

The above classification should always be used in communication with other businesses and competent authorities to avoid confusion.

INSTRUCTIONS:

The product recall team

1. The product recall team will consist of the people from the following areas:

- Production
- Quality
- Purchasing
- Marketing
- Sales
- Legal services
- Distribution and supply chain
- Consumer affairs/public relations.

<i>HACCP</i> Europa.com	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 2 of 16</i>	

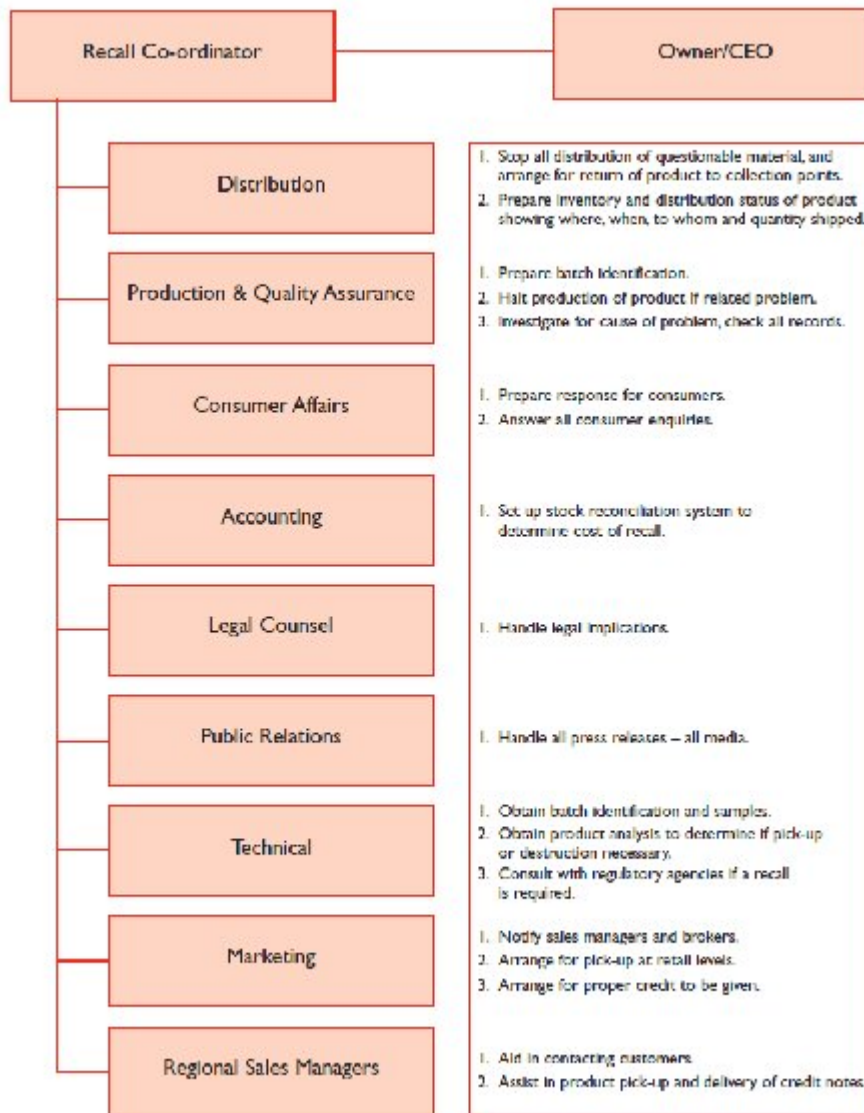
2. The team will be responsible for:

- developing the company's product recall plan
- managing the testing and adjustment of the product recall plan
- regularly updating the product recall plan
- directing the company's product recall activities
- recommending changes in the operating procedures within the company that will reduce the possibility of having to remove unsafe foodstuffs from the market.

3. The team must appoint the product recall coordinator.

4. The product recall coordinator will be responsible for the activities of the product recall team and will be authorised to make decisions concerning the product recall procedure.

HACPEuropa.com	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 3 of 16</i>	



Product recall contacts list

1. Product recall team will be responsible for updating product recall contact list:
2. The contact lists must be available in the product recall plan are split into five sections as follows:

HACCP <i>Europa.com</i>	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 4 of 16</i>	

- The product recall team and senior management (incl. key personnel if not part of the recall team)
- Suppliers of ALL ingredients (incl. water) and primary packaging
- Distribution company and business customers
- Sources of technical advice and support including laboratory facilities
- Competent authorities (including certification bodies)

The lists should also contain references to files (electronic or otherwise) where full details are kept along with the contact details of the persons responsible for the files.

Company Contacts List

CEO/Owner	Mr.A	Tel (work) Tel (home) Tel (mobile)	E-mail: Fax:
Recall co-ordinator	Ms. B	Tel (work) Tel (home) Tel (mobile)	E-mail: Fax:
Recall co-ordinator alternative	Ms. C	Tel (work) Tel (home) Tel (mobile)	E-mail: Fax:

Supplier List

Packs 'R' Us Main contact	Mr.A	Tel (work) Tel (home) Tel (mobile)	E-mail: Fax:
Packs 'R' Us Alternative contact	Mr. B	Tel (work) Tel (home) Tel (mobile)	E-mail: Fax:
Raw Products Inc. Main contact	Ms. C	Tel (work) Tel (home) Tel (mobile)	E-mail: Fax:

Customer/Distributor List

I Buy Ltd. Main contact	Mr.A	Tel (work) Tel (home) Tel (mobile)	E-mail: Fax:
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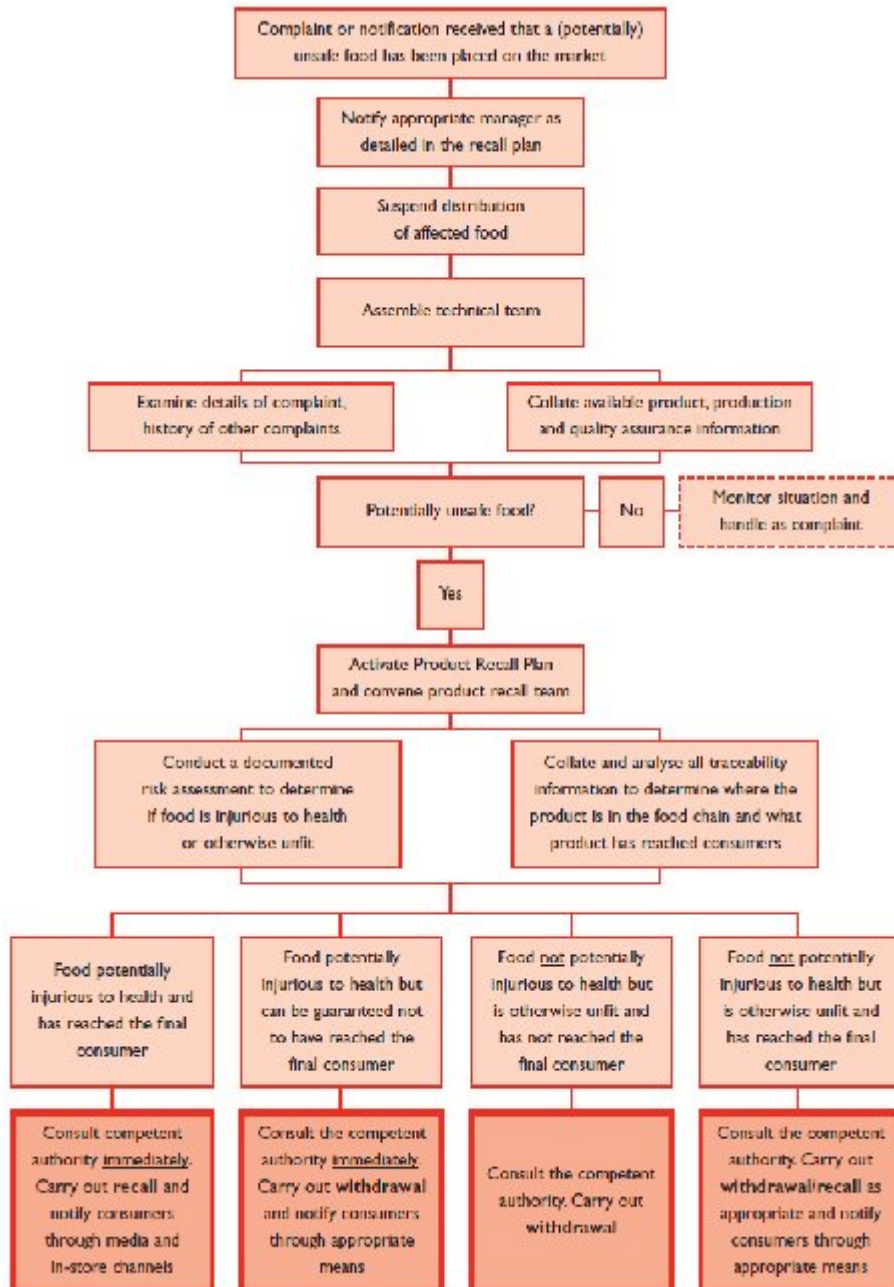
HACCP Europa.com	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 5 of 16</i>	

I Buy Ltd. Alternative contact	Mr. B	Tel (work) Tel (home) Tel (mobile)	E-mail: Fax:
We Distribute Inc. Main contact	Ms. C	Tel (work) Tel (home) Tel (mobile)	E-mail: Fax:

Product recall decision tree

1. The decision tree must be designed to clarify the thought processes leading to a final decision on the necessity and extent of the product recall.
2. Risk assessment must be carried out with the cooperation of, a person who is technically competent to evaluate the severity and impact of food safety hazards in foods.
3. The risk assessment must be carried out in recognition of the precautionary principle and in consultation with the competent authorities.

HACPEuropa.com	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 6 of 16</i>	



<i>HACCP</i> Europa.com	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 7 of 16</i>	

MANAGING PRODUCT RECALL

1. The management of a product recall must be managed by product recall co-ordinator.
2. The product recall must involve the product recall team.
3. The product recall should follow the product recall plan.

Identification of unsafe food

1. Sources of initial information may be:
 - Internal
 - Quality and production records
 - Sales representatives
 - Employees
 - External
 - Ingredient suppliers
 - Packaging suppliers
 - Competent authorities
 - Distributors/business customers
 - Consumer complaints
 - Media reports.
2. Information must be verified at source where possible by the product recall team.
3. In the case of a consumer claiming illness, full details should be obtained by contacting the customer or the EHO as appropriate.
4. The product recall team must aim to collect the following minimum data set on a suspected food safety incident:
 - Product name
 - Product description
 - Batch codes involved
 - Quantity of product implicated
 - Distribution details
 - Whether the product has been sold to the final consumer
 - The nature of the product fault.
5. These data must be verified and fed into the risk assessment process that in turn informs a risk management decision on the level of product recall, the need to inform the competent authorities and the urgency/resources required.

HACCEuropa.com	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 8 of 16</i>	

Risk assessment

The Codex Alimentarius model for risk assessment must be followed:

1. **Hazard Identification:** the identification of known or potential health effects associated with a particular agent
2. **Exposure Assessment:** the qualitative or quantitative evaluation of the degree of intake likely to occur
3. **Hazard Characterisation:** the qualitative or quantitative evaluation of the nature of the adverse effect associated with the hazard
4. **Risk Characterisation:** the integration of hazard identification, hazard characterisation and exposure assessment into an estimate of the risk and its associated uncertainties.

The process is best understood using the following example:

The Production Problem: The pH of an acid preserved food is too high. The product is distributed at ambient temperature, has a shelf-life of one year, does not require reheating and has been on sale for one month.

Hazard Identification: The bacterium *Clostridium botulinum* could grow during product distribution. *Cl. botulinum* causes botulism, a condition where a person who eats food where *Cl. botulinum* has grown and produced toxin can die.

Exposure Assessment: The product conditions and shelf-life are suitable for *Cl. botulinum* to grow and produce toxin. There is no re-heating to degrade the toxin. The consumer is likely to have bought the product. The chances of exposure to *Cl. botulinum* toxin are high.

Hazard Characterisation: *Cl. botulinum* toxin is one of the most potent neurotoxins known. If the toxin is ingested the chances are high that the consumer will develop severe breathing difficulties and may die.

Risk Characterisation: The chances of exposure are high and the consequences of exposure potentially lethal. A severe adverse public health effect is likely. It is not possible to quantify the risk or the uncertainties associated with the risk.

Managing the product recall

1. The recall team must keep an incident log of the actions taken during the product recall as it proceeds.
2. The incident log should consist of a list of communications including phone calls, their time, date, who made them and brief details of the communication. Notes

HACCP <i>Europa.com</i>	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 9 of 16</i>	

must be maintained of any actions and decisions made by the team and any supporting information.

3. All product recall team members are responsible for completing the incident log. The product recall coordinator must review the log each day to verify that this is happening.
4. The product recall team is responsible for notification of the competent authorities is essential in the case of food that is potentially injurious to health and in other circumstances. Notification must be made before executing the product recall and not after it has been completed.
5. The product recall team must attempt to reconcile recovered stock against known volumes of affected food distributed.
6. The product recall team must ensure that arrangements are made with business customers to segregate unsafe foods in a safe manner, in isolation from unaffected foods when they are being held outside of the control. Recalled or withdrawn food must be labelled 'not for consumption' to distinguish it from unaffected stock.
7. Unsafe food returned directly from consumers, returned from retail outlets, returned via the distribution chain or product already in stock must be:
 - Returned to one central site or, in the case of a widely distributed product, to major recovery sites
 - Stored in an area that is separated from any other food products
 - Accurate records must be kept of the amounts of recovered product and the codes of that product.
 - If the recovered food is unfit for human consumption, it must be destroyed or denatured under the supervision of the company management and/or the relevant competent authority where legally required
 - If the food safety risk can be safely removed from the recovered food through relabelling or reprocessing this must be done once it is clear that public health will be protected and the relevant competent authority permissions are obtained.

NOTIFICATION

The four levels of notification are:

- Internal
- Food supply chain (where applicable)
- Suppliers

<i>HACCP</i> Europa.com	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 10 of 16</i>	

- Distributors
- Wholesalers
- Retailers
- Caterers
- Competent authorities
- Consumers.

The first three are applicable to product recalls and product withdrawals. However notification procedures for consumers are only applicable to product recalls.

Trade notification

Initial notification should be via telephone but this should be followed up by written notification, preferably sent by fax and/or e-mail. The written notification should contain all the information necessary to allow removing the correct product from sale or distribution. It should include templates of trade notification forms for reference in the product recall plan.

The trade notification should be clearly entitled '**URGENT: PRODUCT RECALL**' or '**URGENT: PRODUCT WITHDRAWAL**' as appropriate, in bold large lettering to ensure that the notification is acted upon quickly. Avoid making the notification look like a business letter or it may not be dealt with urgently. The details included should facilitate immediate and unambiguous identification of the unsafe food in question. The 'action required' part of the notification should clearly state:

- 'Remove from sale/distribution' or 'do not use' in the case of a caterer.
- 'Notify us immediately if this product has been sold to the public'.
- 'Notify us immediately if this product has been distributed to other distributors or retail/catering establishments. Please also notify these businesses of the product recall without delay'.

This part of the notification can also be used to specify:

- Plans for recovery of product and disposal
- Notification of quantities of stock recovered
- The need to identify and quarantine the product
- Other details to facilitate the recall/withdrawal of product
- Request any assistance in notifying the public in the case of a recall.

HACCP <i>Europa.com</i>	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 11 of 16</i>	

URGENT

Product Recall (or withdrawal)

Company Name _____

Product Name _____

Product Details _____

Batch Identification _____

'Use by' or 'BB' date _____

Reasons for the Recall

Action Required

Contact Details

Alternative
Contact Details

Paid advertisements

Product recall notices must be clear, simple, unambiguous and in a prominent position in the newspaper. Avoid including unnecessary information about the company or turning the product recall notice into a marketing opportunity. Wording which downplays the seriousness of the recall should be avoided as this can encourage consumers not to take the action required in the recall notice. Examples of such wording are “product is not up to our usual quality standards”, “product is being recalled as a precaution” etc. The following checklist must be consulted when writing a product recall notice:

1. Start the notice with a clear indication of what the notice is about, e.g. ‘Warning: Food Product Recall’ or ‘Warning: Important Safety Notice’

HACCP <i>Europa.com</i>	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 12 of 16</i>	

2. Say what the product is (name, brand, and description)
3. State what is wrong with the product and be specific and truthful, e.g. 'product may contain *Salmonella* bacteria that could cause food poisoning' NOT 'product is not up to our usual quality standards'. Avoid giving information about how the incident happened
4. Avoid 'downplaying' the incident because this may not prevent consumers eating the affected product.
5. Give clear details to help customers identify the product and avoid confusion with other similar product. Information should also include:
 - Where the product may have been bought
 - The time span during which the product may have been purchased
 - List of batch codes of the products affected
 - Dates of minimum durability ('use-by', 'best-before').
6. Include a photograph or illustration of the product indicating where the identification information can be found
7. Tell consumers what to do with the product, e.g. 'stop using', 'dispose of...', 'return product to shop for a refund' etc
8. If the hazard is serious then include details of clinical symptoms and include advice to consult a medical practitioner
9. Include details for consumers to contact the company. Free-phone numbers, e-mail addresses and websites are useful. Also include the company's details
10. Apologise for any inconvenience caused.

HACCEuropa.com	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 13 of 16</i>	

WARNING
Food Product Recall

<p style="text-align: center;">Company name</p> <p style="text-align: center;">Product name/description</p> <p style="text-align: center;">Pack size</p> <p style="text-align: center;">Batch Identification</p>	<p>Product photograph or illustration</p>
<p>Details of what is wrong with the product</p>	
<p>Actions the consumer should take</p>	
<p>We apologise for any inconvenience</p>	
<p>Company address and contact details</p>	

Notes on notifications to the competent authorities

Management should ensure that the following information will be supplied to the competent authorities:

- Name of the company and contact details plus alternative contacts
- Name of the product
- Batch identification codes
- Product details inc. packaging size and type
- 'use-by' date or 'best-before' date
- Amount of unsafe product on the market
- Distribution details
- Names of the companies/outlets selling to the consumer

<i>HACCP</i> Europa.com	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 14 of 16</i>	

- Nature of the food safety risk
- Results of any investigations or tests
- The level of product recall being considered (i.e. **Recall** or **Withdrawal**)
- Plans for public communications
- Timings for product recall and communication.

Press release

In cases where an unsafe food is potentially injurious to the health of consumers and presents an immediate risk, product recall team must communicate the recall by press release as well as placing recall notices in newspapers.

It is important to include local radio news desks, especially if the product recall is isolated to specific areas. Follow-up phone calls to media must be made. To encourage journalists or editors to pick up on a press release, the following approach to writing the release should be taken:

- write 'Press release - for immediate release' at the top of the page in bold print
- compose a title, e.g. Company 'A' recalls product 'X' due to health concerns
- place the synopsis of the recall, the product, the problem and what is being done into the first paragraph and the use the proceeding paragraphs to flesh out the details
- include quotes from the company that the journalist can use in the article.
- finish the release with 'ENDS' to signify conclusion
- keep press releases to a single page if possible
- include all the information required in the paid advertisement.

Closing the product recall

The product recall team must decide on the basis of stock reconciliation and monitoring of the progress of the recall, whether all unsafe food has been removed from the market and consumers

A product recall must be formally closed so that it is clear to all parties that the incident has ended. The product recall coordinator in consultation with senior managers is responsible for closing the product recall.

The product recall team must also notify the competent authorities in writing when a product recall is closed.

Final report

The final report must include the following:

- A copy of the product recall notification (or fax) to customers

HACCP <i>Europa.com</i>	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 15 of 16</i>	

- The circumstances leading to the product recall
- The action taken by the business including any publicity, with names of newspapers in which advertisements appeared
- The extent of distribution of the relevant batch in Ireland and overseas
- The method of disposal or otherwise of recalled stock, with certificates of destruction
- Action proposed for the future to prevent a recurrence of the problem
- Any difficulties experienced in conducting the product recall.

The final report is signed off by the senior management who should ensure that any recommendations are acted upon within an appropriate timescale.

REVIEWING AND TESTING THE PRODUCT RECALL PLAN

Product recall plans must be verified on an annual basis or more frequently if appropriate. The plan must be examined for errors, particularly in the contact lists or in light of any changes in the company product recall policy or trading status. The product recall plan must be reviewed at least twice a year.

Simulation Exercises

1. Simulation exercises play a vital role within the Product Recall Plan. It will greatly assist in providing an insight into the performance of a company in the event that serious product safety issues were to occur. It is important that these exercises are carried out regularly.
2. The exercise should include all potentially affected staff and be as close to reality as is practical. It can include participation by "selected" customers and suppliers to add realism and provide factual stock information. There may also be relationship and PR benefits.
3. The exercise should simulate reality as closely as possible so design the scenario around potential issues your company may face e.g. .. the presence of a particular contaminant or temperature abuse or failure.
4. Restrict information on the date and time when the simulation is be carried out to a small number of staff. It is better not to tell the IMT.
5. PR statements and adverts should be produced for internal use and assessment. The simulation is to determine areas of weakness and identify training needs. It should expose areas where outside resources may be required, e.g. PR agencies, specialist laboratories, recall insurance and call centers.
 - Give staff practical experience of what is required & provide them with training
 - Test the Product Recall Plan

<i>HACCEuropa.com</i>	QUALITY SYSTEMS MANUAL	<i>Issue: 1</i>	<i>Ref No:</i>
		<i>Issued by:</i>	
	Product Recall Management	<i>Approved by:</i>	
		<i>Issue date:</i>	
		<i>Approval date:</i>	
		<i>Page: 16 of 16</i>	

- Identify shortcomings
- Demonstrate commitment to customers
- Test associated processes e.g. complaint handling

DOCUMENTATION RETENTION:

The records applied to this procedure are to be kept on file for a minimum of 10 years.