

GUIDELINES ON FOOD TRACEABILITY WITHDRAWALS AND RECALLS WITHIN THE FOOD INDUSTRY



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Turkish Cypriot Community Food Safety Project

Funded under the EU Aid Program for the Turkish Cypriot community (TCc), the “TCc Food Safety Project” executed under the contract 2021/423-933 “Technical assistance to improve implementation of food safety standards and disease crisis preparedness”, strives to support faster social and institutional development of the Turkish Cypriot community and higher economic growth of its agri-food chain sector. The aim is to achieve improved food safety, public health, animal health, and protection of the environment, and to mitigate the impact of potential exotic animal diseases, in particular those posing imminent threats. The project started in May 2021 and will be completed in April 2024.

For more information about the project, you can visit the project’s website, follow its social media account and contact the project team through the following communication channels:

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**(for compliance with Articles 14, 16, 18
& 19 of the General Food Law Regulation
(EC) 178/2002)**



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1. BACKGROUND

The “TCc Food Safety Project” executed under Contract 2021/423-933 “Technical assistance to improve implementation of food safety standards and disease crisis preparedness” strives to support a faster social and institutional development of the Turkish Cypriot community (TCc) and a higher economic growth of its agri-food chain sector.

The project aims to achieve improved food safety, public health, animal health and protection of the environment, and to mitigate the impact of an imminent threat of potential exotic animal diseases.

This document was produced within the following project activity:

Prepare guidelines for stakeholders to complement the input delivered in specific trainings, workshops and other capacity building activities.

2. INTENDED AUDIENCE

The intended audience of these guidelines are the food business operators in different food sectors (dairy, meat, honey) within the Turkish Cypriot community.

3. AIM OF THE GUIDELINES

These guidelines aim to assist the actors within the food industry to develop and implement a traceability system that will enable them to respond rapidly to food safety events in line with the EU Food Law.

Via the traceability systems and procedures in place, the food business operators can identify in ‘real time’ production lots and badges in terms of input and in terms of destination, making this information available to the local bodies in charge of control on demand.

The guidelines are also available to the public on the project’s online Food Safety Platform: <http://tccfoodsafetyproject.eu/>. All parties involved in the food and catering sector should find them a valuable tool in their day-to-day operations.

4. INTRODUCTION

The European Union General Food Law establishes the basic principle of traceability being a ‘one step forward and one step back’ process.

According to the General Food Law, the food business operator is responsible for the safety of the food imported, produced, processed, or placed on the market. The principal aim of the Regulation is to protect human health and consumers interests in relation to food. The main requirements are:

- Food must not be unsafe, i.e. it must not be injurious to health or unfit for human consumption;
- Labelling, advertising and presentation of food must not mislead consumers;
- Food businesses must be able to identify the businesses from which they have obtained food, ingredients or food-producing animals and the businesses they have supplied with products, and produce this information on demand;
- Unsafe food must be withdrawn from sale or recalled from consumers if it has already been sold.

In the absence of reliable traceability system, there are potential flaws in control systems which create important risks to both food safety and market stability. Traceability is a business process that enables trading partners to follow products as they move from the field to retail store or food service operator. Each Traceability Partner must be able to identify the direct source (supplier) and direct recipient (customer) of the product.¹ Traceability as a business process can be utilized for a variety of business purposes, including:

- Product recalls/Market withdrawals;
- Regulatory compliance;
- Public health trace-backs;
- Food safety and quality assurance; and
- Process and order management;

Food traceability is an essential element when ensuring food safety.

Regulation 178/2002 defines ‘traceability’ as: **“the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution”**, and contains rules to ensure the traceability of food and food ingredients.

Implementing a traceability system within a supply chain requires that all parties involved will link the physical flow of products with the flow of information about those products. Adopting the standards for traceability processes ensures agreement about identification of the traceable items. This supports the visibility and continuity of information across the supply chain.

An effective traceability system is the means by which a food business operator can track and trace food through the food chain. In the event of a food incident, without a traceability system, a food withdrawal/recall could be more difficult, extensive and time consuming than otherwise necessary. This can damage the food business operator and sometimes damage an entire sector of the food industry. Food business operators are therefore reliant on each other to have efficient and effective traceability systems in place.

¹ Food Traceability-FAO Santiago, 2017© FAO, 2017 ISBN 978-92-5-109876-9

5. KEY STEPS IN DEVELOPING FOOD TRACEABILITY SYSTEMS

STEP 1

THE SYSTEM - The FBO's system must be able to trace food purchased from suppliers and sold to business customers (this does not include food that is sold directly to the consumer).

STEP 2

DEFINING BATCHES OF FOOD - Defining batches of food is essential for good traceability and may help limit the amount of food to be withdrawn/recalled. In the event of a food safety incident, Regulation (EC) No. 178/2002 considers a whole batch, lot or consignment unsafe unless it can be demonstrated otherwise.

STEP 3

TRACEABILITY INFORMATION - Traceability information for food one step back and one step forward in the supply chain is legally required (name and address of supplier/business customer, details of product to enable its identification, and quantity in which supplied the date of the transaction and delivery).

STEP 4

RECORD KEEPING - To ensure that an effective withdrawal/recall can be implemented in the event of a food safety incident, FBOs must have systems in place which allows traceability information to be made available.

In addition, on developing food traceability system FBOs need to:

- Establish procedures for review and testing of the traceability system and to document the traceability system.

The system does not have to involve sophisticated information technology (IT)-orientated tools, but it needs to ensure effective record-keeping processes that follow the one-step-back and one-step-forward principle.

6. OBJECTIVES OF A FOOD TRACEABILITY SYSTEM

There are two objectives of a food traceability system:

1. To identify uniquely, a batch of food and the raw material batches used in its production, in a way which allows tracking the physical flow of the food forwards through the food chain to the immediate customer and tracing of the physical flow of raw materials backwards to the supplier.
2. To create and maintain accurate traceability records that can be provided within a short time period for routine examination or investigation purposes at the demand of the local bodies in charge of control.

Some food business operators rely solely on their purchasing and sales systems to act as their traceability systems. However, experience has shown that in all but small food business operators, such systems are rarely able to meet the objectives above without modification. Whilst most traceability systems will need to utilise at least part of the purchase and sales systems, customisation will be needed because the traceability system needs to track and trace the physical flow of the food rather than the commercial flow of the food, which in some cases, can be different. Additionally, the traceability system must be able to produce accurate and comprehensive traceability records in a short period of time at the demand of the local bodies in charge of control. This is not always possible using the purchasing and sales system alone.

7. SCOPE OF A TRACEABILITY SYSTEM

Food business operators should define the scope of their traceability system before developing it.

Food business operators must determine what needs to be traced. This is commonly referred to as the “traceable item.” A traceable item can be:

- a) a packaged product or traded item (e.g. case/carton, consumer item)
- b) a logistic unit (e.g. bin, container)
- c) a shipment or movement of a product or trade item

There should be an agreement between trading partners on what the traceable item is. This ensures that both partners are tracking the same thing. Otherwise the chain is broken. Each trading partner should define at least one level of traceable item for each shipment.

Traceability systems are composed of one or more of the following three elements, depending on the nature of the food business:

1. Supplier traceability: traceability of the suppliers of food and packaging to the food business operator. Supplier traceability is a legal requirement for all food businesses.

2. Process Internal traceability: traceability of food and packaging through the operations within the food business operator’s establishment whether or not new products are produced. This is not a legal requirement but is a best practice. It is recognized that if businesses are small with single product lines or simple processes, process traceability may not be needed. However, best practice includes process traceability where relevant in the scope of the traceability system, because in many circumstances, food business operators risk more extensive and damaging withdrawals or recalls if their traceability systems do not incorporate process traceability.

3. Customer traceability: tracking the food leaving a food business operator’s establishment to the immediate customers receiving it.

Customer traceability is a legal requirement for all food businesses except when food is only sold directly to the final consumer.

Attention must be given to the interface between the three elements to ensure that the traceability system is seamless.

8. OPTIMAL BATCH SIZE

In operation, traceability systems are designed to trace the ingredients used in a batch of food and track that batch through the food business and onto the immediate customer.

Food business operators should be aware that: whilst bigger batches can simplify traceability systems, the selection of big batches could mean that more food would have to be withdrawn or recalled should a food incident occur, because the General Food Law quoted below considers a whole batch, lot or consignment, unsafe unless proved otherwise.

Article 14 (6) of the General Food Law states, “Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.”

Manufacturers of food delivered in bulk may only be able to define a product batch within a defined time frame such as a day's production. Users of bulk ingredients may only be able to define an ingredient batch in terms of a number of mixed deliveries over a defined date range. However, other manufacturers or caterers may be able to define a batch as a small number of product packs. The majority of food businesses will adopt an approach between these two extremes. A balance must be struck between the complexity and workability of a traceability system and the smallest feasible batch size. This is a commercial decision based on the food business operator's individual risk management approach.

9. TRACEABILITY INFORMATION

Food business operators should identify the traceability information that is necessary for the effective functioning of their traceability system. The traceability information is legally required will depend on the scope of the traceability system. Certain traceability information is legally required and other information is a matter of best practice. Traceability systems should specify the information which needs to be recorded about food and packaging entering a food business. They should detail the information that should follow raw materials and packaging through a process, where applicable, and information that must accompany a batch of food to a customer, either on the label and/or on the documentation accompanying a delivery.

Internal quality control documentation should allow for traceability codes on finished products to be associated with traceability codes on incoming foods and packaging used in the preparation of the finished products.

9.1. SUPPLIER TRACEABILITY INFORMATION

Food business operators shall be able to ensure that foods and packaging they use are traceable to the supplier(s). While Article 18 of Regulation (EC) No 178/2002 does not elaborate on the supplier/raw material information food business operators must keep, there are additional requirements for some food businesses depending on the business being carried out.

To develop a good supplier traceability system, it is recommended that all other food business operators maintain the following information:

- Records of deliveries of food and packaging with all information necessary to maintain traceability of raw materials from the supplier. Examples of relevant information are:
 - Supplier name, address and contact details
 - Nature and description of the food supplied
 - Any supplier batch codes
 - Delivery date
 - Confirmation of acceptance
 - Number of packs in a case
 - Weight of the packs if applicable
 - Number of cases in a delivery
 - Lot number (if any) assigned to the delivery
 - Details of the haulier and vehicle (as applicable)
 - Cross reference to any in-house quality control records associated with the food or
 - Packaging supplied into the food business operator

- Each incoming raw material should carry an identification code as a means of tracing its source of supply, e.g. batch code. In situations where this is not possible, a business should apply its own identification code as soon as the raw material is received.

In the case of delivery of bulk ingredients such as flour, sugar and milk, into bulk storage facilities, it may not be possible to prevent mixing of batches. In addition to the supplier details, the delivery dates, identification of storage facility and weight/volume of the delivery may be the only way of identifying an ingredient. User lot codes can be used to relate all relevant traceability information to a bulk ingredient.

Water is also a bulk ingredient incorporated into foods and details of the immediate supplier and any associated quality records generated by the food business operator should be maintained.

9.2. PROCESS TRACEABILITY INFORMATION

9.2.1. Manufacturers and Mass Caterers

Each food manufacturer or mass caterer should be able to ensure that the ingredients and primary packaging used in foods produced on the premises are traceable back to their suppliers. Manufacturers involved in re-wrapping products for the market should ensure that traceability of the food to the original supplier is maintained.

The following traceability information is appropriate for process traceability:

- Identification of a product batch
- Application of a unique batch code identifier to:
 - Each and every pack comprising the product batch unless the pack is too small to allow for a code to be applied
 - The outer case, if any
 - Internal process documentation associated with the product batch
- Generation of records of the traceability codes of ingredients and primary packaging, e.g. batch codes, lot codes etc., used in the production of the product batch
- Generation of production and quality records with all the necessary information relating to ingredients, packaging and process times to allow traceability to the finished product batch

Examples of relevant traceability information are:

- Product name
- Product batch code
- Date of production
- Time of start and end of production (where appropriate)
- Saleable unit size
- Number of packs per case
- Number of cases
- A means of linking the product batch code to raw material batches used in its manufacture, e.g. via: Reference to any in-house quality control records associated with the product batch and reference to any in-house process control records associated with the product batch.

- Product release procedures by quality assurance staff should ensure that the traceability system has been maintained
- Food businesses engaged in re-work should ensure that the documentation associated with a product batch contains all the information necessary to allow traceability of any rework incorporated

9.2.2. Wholesalers and Central Distribution Centres

These businesses carry out activities that do not involve manufacture or preparation of food but may involve splitting batches of food received and reassembly into new product deliveries, often involving mixed batches of food. Food deliveries that are broken down and/or re-palletised should be handled in a manner that ensures that the batch codes for all foods in the delivery remain with those foods at all times. This ensures traceability information accompanying foods entering a wholesale or retail business is maintained throughout any handling operations that may occur in the premises.

9.3. CUSTOMER TRACEABILITY INFORMATION²

Each food business operator involved in business to business trade must be able to ensure that food leaving the control of the business is traceable to the immediate customer. Food placed on the market must be labelled to facilitate its traceability through documentation or other information. While Article 18 of Regulation (EC) No 178/2002 does not elaborate on the customer traceability information food business operators must keep, there are additional requirements for some businesses depending on the business being carried on.

In addition, these food business operators must also comply, where appropriate, with the more stringent customer traceability information for food of animal origin, including both processed and unprocessed products. As a rule of thumb, a food business operator supplying food of animal origin to another food business operator which has an oval mark (EU plant approval number, e.g. IE 1234 EU) on it requires the additional information. An exception to this is food of animal origin produced in a retail establishment and supplied to another retail establishment which is exempt from Regulation (EC) No 853/2004.

The food business operator shall, as a minimum, keep the following information concerning consignments of food:

- an accurate description of the food
- the volume or quantity of the food
- the name and address of the food business operator to whom the food was dispatched
- the name and address of the consignee (owner), if different from the food business operator, to whom the food is dispatched
- a reference identifying the lot, batch or consignment, as appropriate, and
- the date of dispatch

If any of these food business operators are involved in the production, processing or distribution of sprouts or seeds intended for the production of sprouts they must also comply with Commission Implementing Regulation (EU) No 208/2013. Additional information is not required for sprouts after they have undergone a treatment which eliminates microbiological hazards, compatible with European Union legislation.

² Customer traceability is not required for food business operators who solely sell direct to the final consumer.

9.4. HANDLING RETURNS

It is important to trace non-conforming product as part of the overall traceability system so that a business can be sure of what product is on the market at any one time. Therefore, the traceability system should include food that is returned by business customers and food that is disposed of by the food business operator. It is suggested that the traceability system should record the nature of the returned food, the name and details of the customer returning the food, the date of return and the reason for return. Similarly, the traceability system should document full details of returned food that is disposed of by the food business operator.

10. RECORD KEEPING


The food business operators must keep all relevant traceability records for the period of time specified by the legal requirements. The periods of time that traceability records must be maintained by the food business are laid down in Regulation (EC) No 178/2002 as follows:

Food business operators must maintain traceability records for all food at least until it can be reasonably assumed that the food has been consumed. For food of animal origin, the traceability information must be updated on a daily basis. It must be made clearly and unequivocally available to and retrievable by the food business operator to whom the food is supplied.

The food business operators are required to make information on the traceability of suppliers and customers available to the local bodies in charge of control on demand. Regulation (EC) No 178/2002 requires that traceability records must be available on demand. There is no specific definition in Regulation (EC) No 178/2002 to determine what an appropriate period of time for record retrieval is when local bodies in charge of control demand them. Local bodies in charge of control could make demands to see records during routine inspections or during food incidents, as part of investigations. In both cases, the food business operator must produce the traceability records. Based on experience during food incidents, the speed at which a food business operator must produce traceability records depends on the risk posed by the food that is on the market. Food business operators should provide the traceability records as soon as possible, but in any event, this period should never be greater than one working day after records are demanded. The information on traceability for food of animal origin, sprouts and seeds intended for the production of sprouts must be made available to the local body in charge of control without undue delay.

11. REVIEWING AND VERIFYING TRACEABILITY SYSTEMS

A traceability system should be reviewed at least yearly to ensure that it is delivering the required level of traceability and can produce accurate traceability records in a short period of time and not greater than one working day. A procedure for review should be included in the documentation of the traceability system. Ideally, a multidisciplinary team comprising members from each of the functional areas of the business should report to senior management on the efficiency and effectiveness of the traceability system. The team should audit the traceability system. An audit should consist of a horizontal and vertical assessment of the system. The horizontal check should consist of an audit of several batches at the same point in the process to ensure all identification marks and documentation is correct. The vertical check should follow several batches from the customer to the supplier to ensure all identification marks and documentation is correct. The speed of record retrieval and accuracy should be examined. Based on the audit, areas for improvement that are identified or any non-conformances arising should be addressed. The review should be documented and signed off by senior management.



It is recommended that those food business operators that actively engage in supplier audits or operate supplier approval procedures should seek to verify that the traceability information provided by their suppliers is accurate and sufficient to facilitate traceability of the raw materials supplied to them. Accurate traceability information will limit the damage caused to the food business operator by any withdrawal or recall conducted by their supplier.

12. DOCUMENTING FOOD TRACEABILITY SYSTEMS

The food business operators must document their traceability system. However, it is recommended that all food business operators should document the traceability system and include details of all elements listed above, as well as the roles and responsibilities of staff in the operation, upkeep and maintenance of the system. Such documentation is useful for a number of purposes, including management review and training of new employees.

13. FOOD RECALL/WITHDRAWAL SYSTEMS

In order to comply with legal obligations, food business operators should establish food recall/withdrawal systems that can effectively and efficiently remove affected food from the market. As part of these systems, food business operators should establish a written food recall/withdrawal policy and alert staff to this policy. The policy should be supported by a documented procedure, the contents and testing of which should be guided by elements of this guidance note. There are two distinct processes regarding food recall for food business operators to follow:

Planning: this focuses on the development and documentation of procedures which are necessary for effective food recall/withdrawal and this should be undertaken by all food business operators well in advance of any food incident.

Management: this focuses on the important considerations for identification of unsafe food and its efficient and effective removal from the market during a food recall/withdrawal.

13.1. PROCESS PLANNING

Planning for a food recall/withdrawal includes:

1. Development and documentation of a food recall/withdrawal policy
2. Development and documentation of a food recall/withdrawal plan
3. Review and testing a food recall/withdrawal plan

Food recall/withdrawal systems should be documented and any templates for associated document should be prepared well ahead of any incident. There are a number of advantages to documentation which include: facilitation of management review, crisis support and training of new employees. Documented food recall/withdrawal systems should contain all the information necessary for effective and efficient removal of foods from the market, including any associated communications that are necessary. Hence, it is more likely that a food business operator with a documented product recall/withdrawal system will be able to comply with their legal obligations in this respect. The planning stage should seek to identify and set up the necessary documentation to support the management of a product recall/withdrawal when a food incident occurs. The plan should be maintained in such a way that it is available to appropriate members of staff during and outside working hours.

13.2. DEVELOPING AND DOCUMENTING A FOOD RECALL/ WITHDRAWAL POLICY

All food businesses should develop a food recall/withdrawal policy. This policy demonstrates the food business operator's commitment to protect public health and comply with legal recall/withdrawal obligations. It should clearly state the objective of the food recall/withdrawal plan and the senior management's commitment to providing the necessary resources to ensure successful removal of affected foods from the market. The policy should be clear and unambiguous and should be in place prior to the development of the food recall/withdrawal plan.

13.3. DEVELOPING AND DOCUMENTING A FOOD RECALL/ WITHDRAWAL PLAN

A food recall/withdrawal plan consists of a set of documented procedures and support materials that are designed to facilitate the effective and efficient removal of food from the market and provide the correct information to businesses, consumers and the local bodies in charge of control. A multidisciplinary incident team should develop the plan.

Examples of items that may be incorporated into the plan are:

- Reference to the food recall/withdrawal policy
- List of members of the incident team
- Definition of roles and responsibilities
- Critical contact names and details
- Definitions of withdrawal and recall
- A food recall/withdrawal decision tree
- Mechanisms of notification of a food recall/withdrawal
- A food incident log
- Reference to the company's traceability system
- Guidelines for media contact
- Template press releases
- Template food recall/withdrawal notices
- A food recall/withdrawal plan review procedure
- A food recall/withdrawal plan testing procedure

13.4. ESTABLISHING A FOOD INCIDENT TEAM

The food incident team should consist of the people from the following areas of the food business, where applicable:

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

These areas may be represented by one or more people depending on the size of the company. The responsibilities of the team are to:

- Develop the food business operator's food recall/withdrawal plan
- Manage the testing and adjustment of the plan
- Regularly update the plan
- Manage the food business operator's food incidents

Recommend changes in the operating procedures used by the food business operator that will reduce the possibility of having to remove food from the market. A food incident coordinator should be appointed by senior management to head the food incident team. The food incident coordinator should be knowledgeable about every aspect of the food business operator's operations and should be responsible for the activities of the incident team.

The person should be delegated responsibility by senior managers to make decisions concerning the food recall/withdrawal procedure.

DEFINITION OF ROLES AND RESPONSIBILITIES

Effective food recall/withdrawal requires all employees to be clear about their roles during a food incident and the boundaries of their responsibilities. This is best achieved using a 'role and responsibility' table. Each food business operator should develop its own 'role and responsibility' table to suit its own organizational structure.

CONTACTS LIST

This is an essential feature of any good food recall/withdrawal plan. It is also the element which most quickly becomes inaccurate. Often contact lists are not updated and this will hamper an effective food recall/withdrawal. Updating the contact list should not be an activity that is undertaken during a food incident. Responsibilities for updating the list should be specified in the role and responsibility table and the accuracy of the list should be frequently checked by the incident team. It is suggested that the contact lists available in the food recall/withdrawal plan are split into five sections as follows:

- Incident team and senior management (incl. key personnel if not part of the incident team)
- Suppliers of ALL ingredients (incl. water) and primary packaging
- Distribution company and business customers
- Sources of technical advice and support including laboratory facilities
- Local bodies in charge of control

The lists should also contain references to any files (electronic or otherwise) where further details are kept. Experience has shown that a significant number of food safety incidents occur out of normal business hours. Therefore, food business operators should ensure their contact lists are as comprehensive as possible and include out of hours contact details. They should be kept as an integral part of the food recall/withdrawal plan to facilitate fast and efficient information recovery.

To meet legal notification obligations, food business operators should include the contact details of the local bodies in charge of control.

13.5. DECISION TREE

The food recall/withdrawal plan should contain a decision tree. The decision tree should be designed to clarify the thought processes leading to a final decision on the necessity for food recall or withdrawal. **Annex 2** shows a typical decision tree. Food business operators should adapt the upper part of this diagram to make it applicable to their own business and management structure.

13.6. NOTIFICATION PROCEDURES

Food business operators are often reticent about telling people outside the food business about unsafe food they have inadvertently placed on the market for fear of damaging their business. However, experience shows that clear and accurate communication is essential for the long-term survival prospects of a food business and is, in any event, a legal obligation where unsafe food has left their immediate control. Obligations to notify interested parties can be summarized as follows:

Unsafe food has not reached consumers (Withdrawal):

- Local bodies in charge of control
- Affected food businesses as applicable: suppliers, distributors, wholesalers

Unsafe food has reached consumers (Recall):

- Local bodies in charge of control
- Affected food businesses as applicable: suppliers, distributors, wholesalers, retailers, caterers.
- Consumers

13.6.1. Notification of The Local Bodies in Charge of Control

The food business operators must notify the local bodies in charge of control if they become aware or have reason to believe that they have imported, produced, processed, manufactured or distributed an unsafe food where the affected food has left their immediate control.

The food recall/withdrawal plan should contain procedures to facilitate early consultation with the local bodies in charge of control. Experience has demonstrated that food business operators can sometimes fail to identify unsafe or other non-compliant food due to lack of knowledge of the legal requirements or due to inaccurate risk assessment. Food recall/withdrawal plans should outline the typical information which is required by the local bodies in charge of control, e.g.:

- Name of the food business operator's contact details plus alternative contacts
- Name of the food product(s)
- Pictures of the product(s) and product label(s)
- Batch identification codes
- Product details inc. packaging size and type
- Manufacturers details and date of import where applicable
- 'Use-by' date or 'best-before' date
- Amount of affected food on the market

- Distribution details (is the product exported?)
- Name of the food business operators selling to the consumer
- Nature of the problem affecting the food
- Results of any investigations or tests
- The method being considered for removing food from the market (i.e. withdrawal or recall)
- Plans for public communications
- Timings for food recall/withdrawal and communication

The food recall/withdrawal plan should specify that the local bodies in charge of control must be notified without delay and that in all circumstances notification of the local body in charge of control should be made before executing a food recall/withdrawal and not after it has been completed. The food recall/withdrawal plan should contain procedures to ensure that the food business operator provides frequent updates to the control bodies throughout the incident management process. Procedures are also necessary to 'formally' close the food recall/withdrawal to the satisfaction of the local bodies in charge of control.

13.6.2. Notification of Affected Food Businesses

In the event of a food withdrawal or recall, food business operators should always notify other affected food businesses. Notification of these businesses can involve communication with customers and suppliers. Procedures for notification should contain detailed methods for suspending food distribution or catering usage. Procedures should also ensure that suppliers of foods are notified in situations where their foods are affected or in situations where they have potentially supplied unsafe food. This is particularly important for retailers and distributors who handle many different foods from a broad base of suppliers and are often aware of potential problems with food before the manufacturer due to customer complaints. See Annex 5 for a template of a trade notification.

13.6.3. Notification of Consumers

When food has been identified as unsafe within the meaning of the Regulation (EC) No 178/2002 and has been supplied to consumers, food business operators must effectively and accurately inform consumers of the reasons for its removal from the market. Consumers must be informed in all cases where unsafe food may have reached them. The information provided to consumers must be accurate and effectively inform them of the reasons for the removal of the food from the market.

Food business operators should note that it is a legal requirement to notify consumers if unsafe food has reached them irrespective of whether they are being asked to return or dispose of the affected food or whether the food is outside its date of minimum durability. Food business operators cannot with certainty assume that a food that is past its date of minimum durability is no longer in the possession of consumers. Studies have shown that consumers habitually keep non-perishable food well beyond dates of minimum durability and perishable food is often frozen by the consumer to keep it beyond its 'use-by' date.

13.7. DEVELOPING A FOOD INCIDENT LOG TEMPLATE

A food incident log template is a document that facilitates the capture of all appropriate information about a food recall/withdrawal. A template of a food incident log and procedures for its completion should be part of the food recall/withdrawal plan. The log should have room to list records of communications including phone calls, their time, date, name of the person involved and brief details of the communication. The log also serves as a record of any actions and decisions made by the team and any supporting information. A designated member of the food incident team should be responsible for updating the incident log in a timely manner. All food incident team members should be responsible for passing relevant information to the person responsible for updating the incident log. During a food recall/withdrawal, the food incident coordinator should review the log each day to verify that records are being maintained. The incident log will be useful in three ways in that it will serve as a:

- Reference if facts need to be checked
- Means by which the recall can be reviewed
- Legal document should it become necessary

Food business operators should also create a hard copy and electronic filing system around the food incident log to keep all the detailed records referred to in the log.


13.8. REVIEW AND TESTING A FOOD RECALL/WITHDRAWAL PLAN

The food recall/withdrawal plan should specify the periods for review and the names of the people responsible for the review. In most cases this will be a member of the food incident team. The plan should be examined for inaccuracies, particularly in the contact lists or in light of any changes in the food business operator's food recall/withdrawal policy or trading status. The food recall/withdrawal plan should be reviewed at least once a year following a documented procedure which should also be detailed in the food recall/withdrawal plan.

It is best practice to periodically test a food recall/withdrawal plan to ensure it is valid using a mock exercise. Food business operators that develop plans but do not test them may face problems when a real food safety incident occurs. It is easier and more cost effective to alter a food recall/withdrawal plan when the food safety incident is part of an exercise without the pressures of the real situation. It is recommended that the plan should be tested on an annual basis. It may be worth exploring the possibility of an agreement with customers and/or supermarkets for them to become involved in the test, thereby increasing the value of the exercise. Once the test is completed, a review of the exercise should be carried out by the food incident team to correct and improve the process where necessary and update the plan.

14. MANAGING A FOOD RECALL

During the management of a food recall or withdrawal it is important that food business operators are able to identify when food is unsafe and when it is otherwise non-compliant with legal requirements. This in turn, triggers the legal obligations of food recall/withdrawal governed by the Regulation (EC) No 178/2002. The management of a food recall/withdrawal by a food business operator should be led by a single individual; usually the food incident coordinator and the process should be managed by the food incident team in accordance with the recall/withdrawal plan. The food recall/withdrawal plan should be followed, and all activities should be recorded contemporaneously in the food incident log.



Managing a food recall/withdrawal should follow a clear sequence of events:

1. Initial information management
2. Applying the decision tree and identification of unsafe or other non-compliant food
3. Compilation of information on distribution
4. Removing food from the market and associated communication
5. Closing a food recall/withdrawal
6. Disposal of unsafe food
7. Reviewing the food recall/withdrawal

14.1. INITIAL INFORMATION MANAGEMENT

The incident team should always endeavour to ensure information is accurate and from a reliable source. This prevents the miscommunication that often hampers efficient food recall/withdrawal. The information that is gathered concerning a food safety problem like the product details, the nature of the hazard and the extent of the problem, is vital to good decision making. Initial information on a potential food safety incident can come from a variety of sources but in the first instance, it is likely to come to the attention of only one or two individuals in a food business. The customer complaints system should be linked into the food recall/withdrawal plan so that complaints may be used to highlight potentially unsafe food on the market which, could in turn, trigger a food recall/withdrawal. It is important that staff is aware of the food recall/withdrawal plan and that they take the correct steps to ensure that the incident team is convened. Training of staff will be necessary to ensure that initial information is handled appropriately.

SOURCES OF INITIAL INFORMATION MAY BE:

Internal sources:

- Quality and production records
- Sales representatives
- Employees

External sources:

- Food suppliers
- Packaging suppliers
- Local bodies in charge of control
- Distributors/business customers
- Consumer complaints
- Media reports

Information should be verified at source where possible, by a member of the food incident team. In the case of a consumer claiming illness, full details should be obtained by contacting the customer or the local body in charge of control as appropriate.

14.2. APPLYING THE DECISION TREE AND IDENTIFICATION OF UNSAFE FOOD

The food incident team should follow the food recall/withdrawal decision tree in their plans (see example in **Annex 2**). This requires the food business operator to take initial precautionary measures and to identify the legal status of the affected food by conducting a risk assessment.

Risk assessments should only be carried out by competent technical people. Food business operators are advised to seek suitably competent technical advice and to involve the local body in charge of control as appropriate. However, advice from the local body in charge of control is only as good as the facts provided by the food business operator and will only extend to advice on whether the food poses a public health risk or not. The food business operator will then be expected to take the appropriate risk management action on its own decision, in keeping with their legal responsibilities. Consequently, food business operators should not rely on the local body in charge of control to take the decision on whether to withdraw or recall the unsafe food. However, if the local body in charge of control disagrees with the actions of a food business operator, it has the legal powers to intervene to protect public health.

There is a high probability that information gathered in the early stages of an investigation will be incomplete and inaccurate. This needs to be accounted for when decisions are made as to whether the food is unsafe or otherwise non-compliant with the provisions of the legal requirements. Food business operators should always take a precautionary approach placing the protection of the consumers' health highest on the list of priorities. The precautionary approach requires food business operators to protect public health even when limited details are available. Food recall should not be unduly delayed for want of complete information especially if the food is potentially unsafe.

14.3. COMPILATION OF INFORMATION ON FOOD DISTRIBUTION

Full distribution details are not necessary to initiate the food recall/withdrawal and delay must not result from a desire to have all of the distribution information available. A broad understanding of whether food has, or has not, reached the consumer, is sufficient to decide whether a withdrawal or a recall is appropriate. Further detailed information can be gathered early on after initiating the recall/withdrawal process.

Ultimately the food incident team should aim to collect the following minimum data set on an affected food:

- Food name
- Food description
- Batch codes involved
- Quantity of food implicated
- Distribution details
- Whether the food may have reached consumers

14.4. REMOVING UNSAFE FOOD FROM THE MARKET

The food business operator must take all reasonable steps to remove unsafe food from the market and if the food has left the immediate control of the food business operator, notify the local bodies in charge of control, customers and suppliers as well as the consumer where food has reached the consumer.

Once a food safety incident has been determined and the affected food has left the immediate control of the food business operator, the local bodies in charge of control must be notified without delay. In all circumstances, notification of the local body in charge of control should be made before executing a food recall/withdrawal and not after it has been completed. Notification should follow the procedures laid down in the food recall/withdrawal plan discussed previously and consist, amongst other things, of details of the affected food, its distribution, the food safety concern and the proposed action.

The food incident team should then execute the procedures laid down in the food recall/withdrawal plan with the aim of removing the affected food from the market without undue delay. This will include notification of trade contacts and, in the event that food has reached consumers, notification of the consumer. Where food may have reached the consumer, food business operators may have to work with retail food business operators to notify consumers in an appropriate manner (details on notifying food recalls/withdrawals can be found in Annexes).

When appropriate, food business operators should set up a dedicated phone line on which business contacts and consumers can get advice on the food recall/withdrawal. These are sometimes referred to as customer care lines. Such facilities should be adequately resourced to facilitate communication and information should be channelled through the food incident team.

As the food recall/withdrawal commences, the food incident team should attempt to reconcile food removed from the market against known volumes of affected food distributed, to monitor progress of the food recall/withdrawal and determine when it has ended.

Very often food is not returned to the food business operator but is destroyed by the consumer and/or the retailer/distributor. Nevertheless, the food incident team should attempt to compile accurate figures on the amount of affected food disposed of in this way. However, in a minority of circumstances, affected food may be returned by the consumer and/or other food business operators. The following considerations are important for the control of returned unsafe food:

- Affected food should be returned to one central site or, in the case of a widely distributed product, to major recovery sites.

The recovered food must be stored in an area that is separated from any other food products and identified appropriately to ensure it is not confused with unaffected food.

Accurate records must be kept of the amounts of recovered food and the traceability codes from that food.

During food recalls/withdrawals, particular attention must be paid to catering customers who may use affected food, either whole or as part of meals served to consumers. These businesses have very different procedures from retailers and wholesalers and may require special consideration to ensure that the methods implemented for the recall/withdrawal, storage and disposal of affected food, are practical and ensure consumer protection. The operators of catering franchises must pay particular attention to this aspect.

15. CLOSING THE FOOD RECALL/WITHDRAWAL

To close a food recall or withdrawal, the process must have been effective. To be effective, the food recall/withdrawal notification must have reached as far as the affected food was distributed. The effectiveness of the process should be assessed on the basis of the amount of food accounted for as a proportion of the amount of food that left the manufacturer or distributor, while taking into account the normal market turnover of the food (product reconciliation). During the food recall/withdrawal, progress must be reviewed so that its success can be monitored. If it can be concluded that the public health risk has been reduced to the lowest possible level, the process can be judged to have been a success and brought to an end. However, if there have been few returns or little consumer or customer response to a high-risk problem, without obvious reasons, e.g. food out of date, the food recall/withdrawal procedure should be assessed for its effectiveness. The food recall/withdrawal may then have to be reiterated using different methods to reach all those affected.

A food recall or withdrawal should be 'formally' closed so that it is clear to all parties that the incident has ended. It is recommended that this is done by the food incident coordinator in consultation with senior managers and the food incident management team. Food business operators should remember to notify the local bodies in charge of control when a food incident is closed.

16. DISPOSAL OF UNSAFE FOOD

After a food recall/withdrawal, a food business operator may have unsafe food quarantined that needs to be disposed of. In this case, the affected food must be destroyed or denatured under the supervision of the company management and/or the relevant local body in charge of control, where legally required. Food business operators should consult the local body in charge of control regarding disposal of unsafe food.

17. REVIEWING THE FOOD RECALL/WITHDRAWAL

Every food recall/withdrawal should be viewed as an opportunity to learn and improve the systems used in the food business. The food incident coordinator should initiate a 'formal' review procedure involving the food incident team and any key personnel who were involved. These could be external contacts such as a retailer or caterer. The review should be conducted using the review procedure detailed in the food recall/withdrawal plan.

Some of the elements that should be included in a review are a consideration of:

- Analysis of the cause of the issue, identifying the real issue (not the symptoms) and immediate and long-term actions that will rectify the problems
- Robustness of the recall/withdrawal policy and procedures in the food recall/withdrawal plan
- Effectiveness of the communication strategy
- Working of the management structures and whether reporting or lack of clarity on responsibilities contributed to any problems with the recall process
- Review of the food incident log
- Critical appraisal of the key decisions made during the food recall/withdrawal
- Results of investigations and analysis carried out on returned food
- Consideration of possible improvements to the process

Examples of relevant review questions:

- Was the product recall/withdrawal effective?
- Did the product recall/withdrawal plan drive the process?
- What problems were encountered?
- How effective was the internal and external notification to customers and the local bodies in charge of control?
- Was the media coverage of the incident accurate and what factors affected the coverage?
- Did the customer care line work, was it overloaded, did it cope or crash?
- What was the true cost of the food recall/withdrawal; product, time, communication costs, lost sales?
- Did the food incident team work efficiently and were their roles in keeping with the plan?
- Was the process effective?
- Were the local bodies in charge of control satisfied with the actions taken?

Food business operators should produce a final report of the food recall/withdrawal review to draw all information together in one place and act as a resource for future training and continuing professional development. Such reports may also be useful for the food business operator in the event of litigation.

The final report should include the following:

- Circumstances leading to the food recall/withdrawal
- Extent of distribution of the affected food
- Detailed findings of the review
- Copies of communications to customers and consumers as applicable
- Action taken by the business including any publicity, with names of newspapers in which advertisements appeared
- Method of disposal or otherwise of recalled stock, with certificates of destruction if applicable
- Recommendations for improvement

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

ANNEX 1 : IDENTIFYING 'UNSAFE' FOOD

To understand the applicable legal requirements, food business operators need to be able to accurately identify whether a food is unsafe as defined in Regulation (EC) No. 178/2002 laying down the general principles and requirements of food, or has a different legal status. Article 14 (1) of that Regulation states that **“food shall not be placed on the market if it is unsafe”**.

Article 14(2) states “Food shall be deemed to be unsafe if it is considered to be:

- a) Injurious to health,
- b) Unfit for human consumption.

Article 14(4) states that “in determining whether any food is injurious to health, regard shall be had:

- a) not only to the probable immediate and/or short-term and/or long-term effects of that food on health of a person consuming it, but also on subsequent generations;
- b) to the probable cumulative toxic effects;
- c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.”

Article 14(5) states “in determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.”

Therefore, for a food to be unsafe it must have the potential to cause an adverse health effect or be unacceptable for consumption because of contamination or spoilage or taint. However, this is further clarified by Article 14(7) which states that “food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned”.

Although, Article 14(8) adds a caveat to this generality stating “conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.”

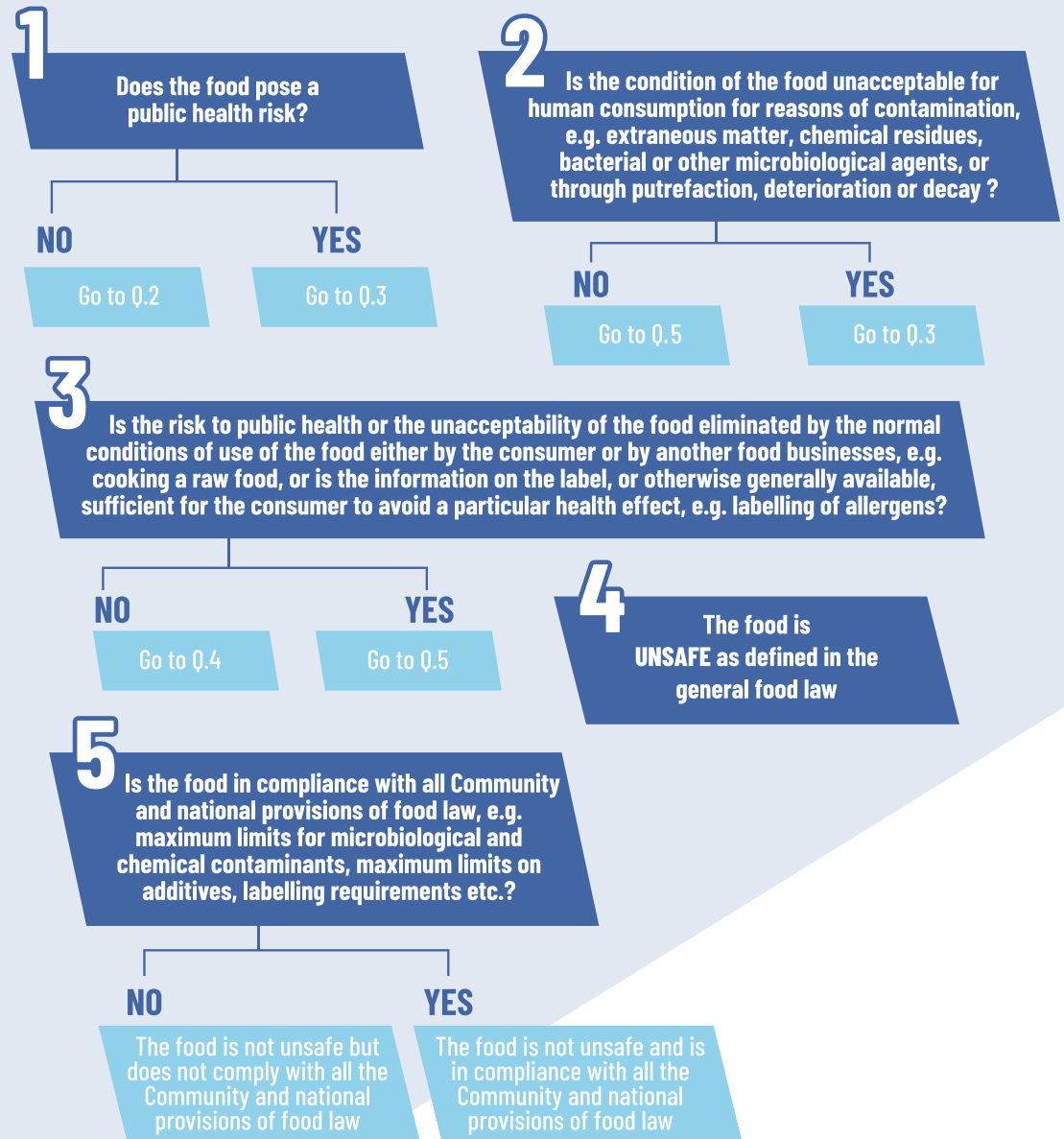
Article 14(3) clarifies some of the factors which must also be considered in identifying an unsafe food, “in determining whether any food is unsafe, regard shall be had:

- a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
- b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific health effects from a particular food or category of foods.”

To determine the legal definition of an affected food, a food business operator should answer the following questions:

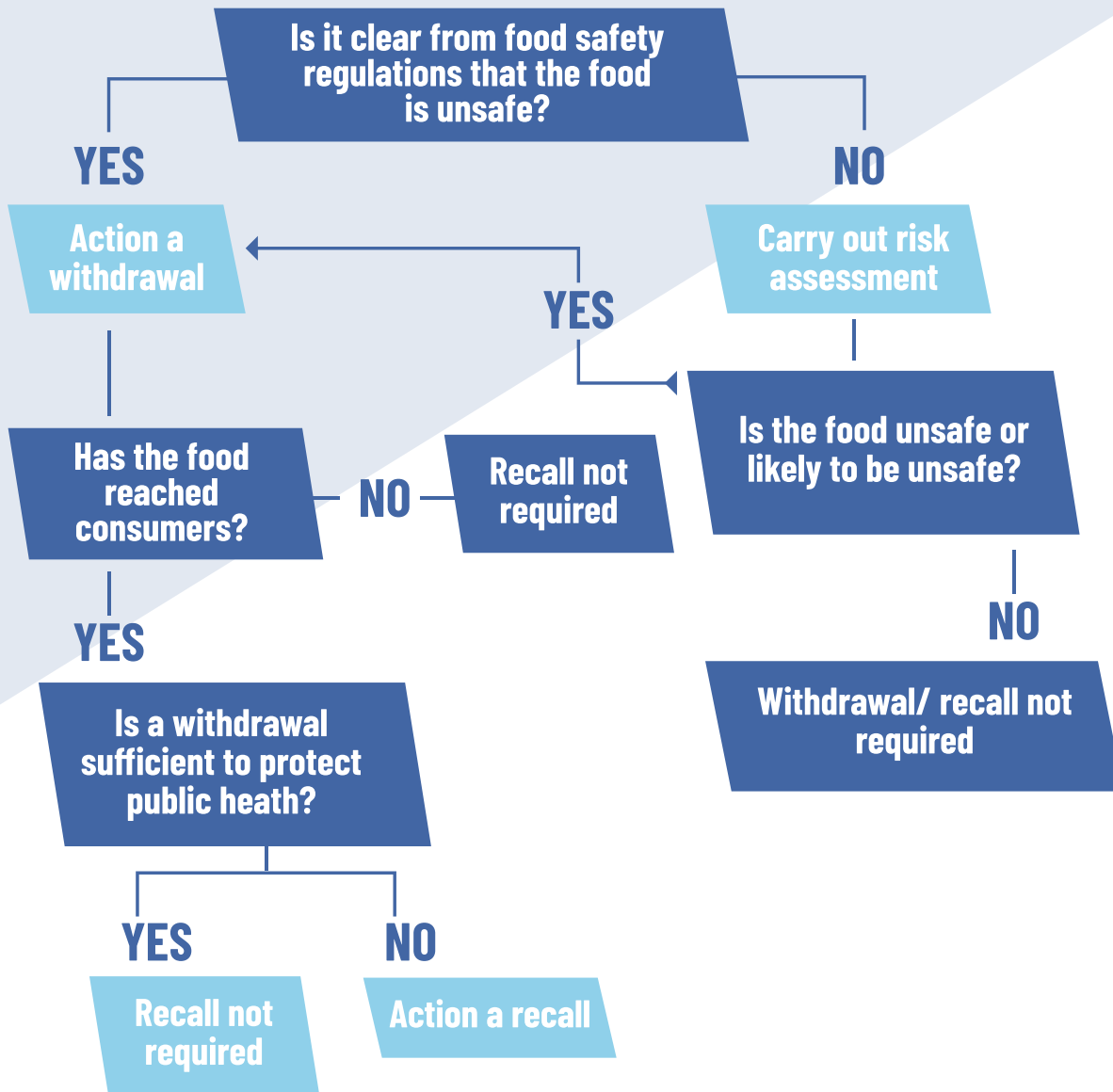
Conduct a risk assessment before answering the 1st question

(public health risk includes a health effect for the general population or a vulnerable/sensitive sub-population whether mild or severe, short-term or long-term including adverse accumulation of chemicals or an infection either of which could manifest itself in later life or even result in a health effect in future generations).



Return to the Decision Tree to determine the appropriate risk management action.

ANNEX 2: FOOD RECALL/WITHDRAWAL DECISION TREE



ANNEX 3: PERFORMING A RISK ASSESSMENT

The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius, each component being integral to the overall risk analysis.

Food withdrawal or recall is a risk management decision that may require food business operators, amongst other things, to be able to identify if a food poses a public health risk. Risk assessment will achieve this aim and should also determine the likelihood and severity of the adverse health effect as well as the affected population profile and size.

Food business operators should follow an accepted model for risk assessment. Codex Alimentarius has developed a model for risk assessment consisting of the following steps:

- 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
- 5. Food business operators should document** their risk assessment and keep records of supporting evidence to inform future review of the incident and also serve as contemporaneous documentation in the event of litigation to support a 'due diligence' defence.

ANNEX 4:

EXAMPLES OF FOOD RECALL/WITHDRAWAL PLAN DOCUMENTATION

RECALL COORDINATOR

CEO/OWNER

Distribution

1. Stop all distribution of questionable material and arrange for return of product to collection points.
2. Prepare inventory and distribution status of product showing where, when, to whom and quantity shipped.

Production & Quality Assurance

1. Prepare batch identification
2. Halt production of product if related problem.
3. Investigate for cause of problem, check all records.
4. Update incident log.

Consumer Affairs

1. Prepare response for consumers.
2. Answer all consumer enquiries.
3. Update contact details list.

Accounting

1. Set up stock reconciliation system to determine cost of recall.

Legal Counsel

1. Handle legal implications.

Public Relations

1. Handle all press releases - all media.

Technical

1. Obtain batch identification and samples.
2. Obtain product analysis to determine if pick-up or destruction necessary.
3. Consult with regulatory agencies if a recall is required.

Marketing

1. Notify sales managers and brokers.
2. Arrange for pick-up at retail levels.
3. Arrange for proper credit to be given.

Regional Sales Managers

1. Aid in contacting customers.
2. Assist in product pick-up and delivery of credit notes.

RECALL PLAN CONTACTS LIST EXAMPLE

COMPANY CONTACTS LIST

CEO / Owner	Name-Surname	Tel: Home Tel: Mobile Tel:	E-mail: Fax:
Recall Coordinator	Name-Surname	Tel: Home Tel: Mobile Tel:	E-mail: Fax:
Recall Coordinator Alternative	Name-Surname	Tel: Home Tel: Mobile Tel:	E-mail: Fax:

SUPPLIER LIST

Supplier Company 1 Main Contact	Name-Surname	Tel: Home Tel: Mobile Tel:	E-mail: Fax:
Supplier Company 2 Main Contact	Name-Surname	Tel: Home Tel: Mobile Tel:	E-mail: Fax:
Supplier Company 3 Main Contact	Name-Surname	Tel: Home Tel: Mobile Tel:	E-mail: Fax:

CUSTOMER/DISTRIBUTOR LIST

Buyer Company 1 Main Contact	Name-Surname	Tel: Home Tel: Mobile Tel:	E-mail: Fax:
Buyer Company 2 Main Contact	Name-Surname	Tel: Home Tel: Mobile Tel:	E-mail: Fax:
Buyer Company 3 Main Contact	Name-Surname	Tel: Home Tel: Mobile Tel:	E-mail: Fax:

COMPETENT INSTITUTION LIST

Competent Institution 1	Name-Surname	Tel: Home Tel: Mobile Tel:	E-mail: Fax:
Competent Institution 2	Name-Surname	Tel: Home Tel: Mobile Tel:	E-mail: Fax:
Competent Institution 3	Name-Surname	Tel: Home Tel: Mobile Tel:	E-mail: Fax:

ANNEX 5:

ADDITIONAL INFORMATION ON RECALL/WITHDRAWAL NOTIFICATIONS

This appendix contains detailed information on different forms of notification procedure that can be considered by food business operators. In addition, it contains examples of relevant documentation that could be included in the food recall/withdrawal plan.

TRADE NOTIFICATIONS

In the event of a food withdrawal or recall, it is essential that food business operators notify other food businesses that may be affected. Initial notification to other food business operators (sometimes called trade notifications) 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 another food business operator to remove the correct food from sale or distribution. Food business operators should include templates of trade notification notices for reference in their product recall/withdrawal plan.

The trade notification notice should be clearly entitled '**URGENT: FOOD RECALL**' or '**URGENT: FOOD 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 in the trade notification notice should facilitate immediate and unambiguous identification of the affected food. 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 food has been distributed to the public'
- 'Notify us immediately if this food has been distributed to other distributors or retail/ catering establishments. Please also notify these businesses of the product recall/withdrawal without delay'


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

- Plans for recovery of the affected food and its disposal
- Notification of quantities of food delivered
- The need to identify and segregate the food from unaffected food
- Other details to facilitate the food recall
- Request for any assistance in notifying the public in the case of a recall

NOTIFICATION OF CONSUMERS

When unsafe food may have reached the consumer, it will be necessary to notify consumers about the removal of food from the market and what action they must take if food is being recalled from them. Information notices must be clear, simple, unambiguous and be displayed where consumers will see them.

It is a legal requirement for food business operators to: accurately inform consumers of the reasons for the removal of unsafe food from the market when it may have reached consumers, and inform them of any actions they need to take if it is decided that the food must be recalled.



Therefore, avoid including unnecessary information about the company or turning the information notice into a marketing opportunity. Wording which downplays the seriousness of the incident should be avoided as this can encourage consumers not to take the action required. Examples of inappropriate wording are “product is not up to our usual quality standards”, “product is being recalled as a precaution” etc. The following checklist should be consulted when writing a consumer information notice:

- Start the notice with a clear indication of what the notice is about, e.g. ‘Warning: Food Recall’ or ‘Warning: Important Safety Notice’.
- Say what the product is (name, brand, description).
- State what is wrong with the product and be specific and truthful, e.g. ‘food may contain harmful bacteria that could cause food poisoning’. Avoid giving information about how the incident happened.
- Avoid ‘downplaying’ the incident.
- Give clear details to help consumers identify the product and avoid confusion with other similar product. Information should also include:
 - Where the food may have been bought
 - The timespan during which the food may have been purchased
 - List of batch codes of the food affected
 - Dates of minimum durability (‘use-by’, ‘best-before’)
- Include a photograph or illustration of the food indicating where the identification information can be found.
- Tell consumers what action to take, if any, e.g. ‘no action required’, ‘stop using’, ‘dispose of...’, ‘return product to shop for a refund’ etc.
- If the health risk is serious, include details of clinical symptoms and include advice to consult a medical practitioner.
- Include details for consumers to contact the company. Free-phone numbers, e-mail addresses and websites are useful. Also include the company’s details.
- Apologize for any inconvenience caused.

IN-STORE NOTIFICATIONS

In-store notifications are displayed by retail stores in a visible and appropriate manner. **The communication with consumers when unsafe food may have reached them must be effective.** Therefore, notifications should be prominently displayed in positions around the store where consumers will see them, e.g. checkout areas, store entrances, on retail shelves where similar food is sold. Display only in customer service areas is not best practice as a minority of shoppers will visit these areas. The notices should carry full details of the food(s) affected, preferably with a picture of the affected food to help people with literacy difficulties identify the food. Similar notices should also be placed on food business operator’s websites, particularly if the food business operator runs an internet shopping business.

However, when food is unsafe because it may be injurious to health, in-store notifications alone are not generally sufficient to meet the legal requirements. In the majority of cases, additional notifications are required, either by paid advertisement in appropriate media or by press release and in certain cases additional dissemination of information via consumer organizations

PAID ADVERTISEMENTS

Paid advertisements prominently displayed in newspapers are also an important way of notifying consumers that an unsafe food may have reached them. They are particularly important in addition to in-store notifications, if the food could be injurious to the health of consumers. Food business operators should include sample newspaper notices in their food recall/withdrawal plan, along with instructions for placing the notices in the appropriate media. The information below should be considered when drafting guidelines for the food recall/withdrawal plan.

It is strongly recommended that notices are placed in the main newspapers and local newspapers.

Food business operators should ensure that they check these deadlines and include them in their recall/withdrawal plans. Food business operators should make every effort not to miss deadlines for newspaper notices. In cases where the unsafe food is a serious hazard and deadlines have been missed, food business operators should communicate the recall information by press release and follow up with newspaper notices the next day.

PRESS RELEASE

In cases where an unsafe food is potentially injurious to the health of consumers and presents an immediate risk, food business operators should communicate the information by press release as well as placing information notices in newspapers. Press releases have the advantage of reaching the print media and electronic media and do not suffer from delays. A copy of a sample press release should be placed into the product recall/withdrawal plan and should take account of the information below. As food business operators cannot rely on the uptake of a press release, this method should only be used as a back up to more targeted notification methods. 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 are recommended. 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 food 'X' due to health concerns
- Place the synopsis of the recall, the food, 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

EXAMPLE FOR PUBLIC HEALTH ALERT FROM USDA FOODS SAFETY AND INSPECTION SERVICE

FSIS Issues Public Health Alert for Salame Stick Products Due to Possible *Salmonella* Contamination

WASHINGTON, Oct. 29, 2021 – The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) is issuing a public health alert because Euro Foods, a Freeland, Penn. establishment, produced ready-to-eat (RTE) Italian-style salame stick products that may be contaminated with *Salmonella*. A recall was not requested because FSIS has not identified a specific contaminated lot or lots, and it is believed that potentially affected products are no longer available to be directly purchased by retail consumers.

The Italian-style salame stick items were produced prior to October 25, 2021. The following product is subject to the public health alert [view labels]:

2-oz packages containing Citterio “Premium Italian-Style Salame Sticks ALL NATURAL” with “best by” dates up to January 23, 2022, located next to the barcode.

The products subject to the public health alert bear establishment number “EST. 4010” inside the USDA mark of inspection. These items were shipped to retail locations nationwide and exported to Bermuda.

FSIS has been working with the Center for Disease Control and Prevention (CDC) and state public health partners to investigate a multistate outbreak of 21 *Salmonella* l 4,[5],12:i:- illnesses in eight states with onset dates ranging from September 18, 2021 through October 3, 2021. The epidemiologic and trace back investigation identified that ill people consumed Citterio Italian-style Salame Sticks produced by Euro Foods Inc. FSIS continues to work with federal and state public health partners to determine if there are additional illnesses linked to these products.

Consumption of food contaminated with *Salmonella* can cause salmonellosis, one of the most common bacterial foodborne illnesses. The most common symptoms of salmonellosis are diarrhoea, abdominal cramps, and fever within 6 hours to 6 days after eating the contaminated product. The illness usually lasts 4 to 7 days. Most people recover without treatment. In some persons, however, the diarrhoea may be so severe that the patient needs to be hospitalized. Older adults, infants, and persons with weakened immune systems are more likely to develop a severe illness. Individuals concerned about an illness should contact their health care provider.

FSIS is concerned that some product may be in consumers’ refrigerators or freezers. Consumers who have purchased these products are urged not to consume them. These products should be thrown away or returned to the place of purchase.

Consumers with food safety questions can call the toll-free USDA Meat and Poultry Hotline at 1-888-MPHotline (1-888-674-6854) or live chat via Ask USDA from 10 a.m. to 6 p.m. (Eastern Time) Monday through Friday. Consumers can also browse food safety messages at Ask USDA or send a question via email to MPHotline@usda.gov. For consumers that need to report a problem with a meat, poultry, or egg product, the online Electronic Consumer Complaint Monitoring System can be accessed 24 hours a day at foodcomplaint.fsis.usda.gov/eCCF/.

EXAMPLE FROM WEB SIDE INFO ABOUT SALMONELLA OUTBREAK

Public health officials in Norway are investigating an outbreak of Salmonella with up to 20 patients. The Norwegian Institute of Public Health reported the outbreak of Salmonella Enteritidis has seen 10 people need hospital treatment.

A dozen people have been diagnosed with the outbreak strain and there are eight suspected cases. Samples were taken from the end of January through the end of February.

Trying to find the source Patients are geographically spread across Norway. Those sick are aged from 11 to 91 years old and 60 percent are women.

The Norwegian Institute of Public Health suspects the source of infection is a widely distributed food but the exact vehicle is not yet known.

Outbreak investigations have been started with the relevant local units, the Veterinary Institute and the Norwegian Food Safety Authority.

Patients are being interviewed and Mattilsynet is taking samples from food products in the homes of those who are infected.

Hilde Marie Lund, from Folkehelseinstituttet, said it was too early to say if it was a limited outbreak or there will be an increase in people affected.

She added the large proportion of patients admitted to hospital may be related to the overall relatively high age of those affected but this is being investigated further.

ANNEX 6: EXAMPLE OF A TRADE NOTIFICATION FORM

The different aspects to consider in creating effective recall messages include:

- style and appearance,
- necessary content,
- effective channels for communicating recall messages to consumers, including best location for displaying point of sale notices.

Communication should be: **Clear and easy to read** (Simple layout, large, legible font that can be read easily, headings and sub-heading for longer notices), **Bright and eye catching** (use red colour and iconography - exclamation mark, associated with alert and risk if possible, use of banners, boxes and bordering to draw attention), **concisely worded** (lay out information in clear, simple language with, use of bullet points).

URGENT FOOD RECALL ALERT

FOOD RECALL (OR WITHDRAWAL)

Company Name: _____

Food Name: _____

Food Details: _____

Batch Identification: _____

'Use-by' or 'Best-before' Date: _____

Reasons for the Recall:

Action Required:

Contact Details: _____

Alternative Contact Details: _____

ANNEX 7: EXAMPLE OF AN IN-STORE NOTIFICATION OR PAID NEWSPAPER ADVERTISEMENT

WARNING !

FOOD RECALL

Food picture of
illustration of food

Company Name: _____

Food Name / Description: _____

Pack Size: _____

Batch Identification: _____

Company Address and Contact Details: _____

Details of What Is Wrong With The Product
(Use clear title to indicate what this is and what the danger or risk to consumers is)

Actions The Consumer Should Take
(Do not eat this product; Return the product to the store where you bought it from, How to obtain a refund)

We apologize for any inconvenience!!!

ANNEX 8: APPROPRIATE CONTROL ACTIONS FOR FOOD THAT IS NOT UNSAFE BUT IS NEVERTHELESS NON-COMPLIANT WITH THE LEGAL REQUIREMENTS

The following control measures are based on enforcement measures for local body in charge of control laid down in Article 54 (2) of Regulation (EC) No. 882/2204 on official controls performed to ensure the verification of compliance with feed and food, animal health and animal welfare rules. These control measures should be used as a guide to food business operators needing to take some form of control action when a food they have placed on the market is not unsafe, within the meaning of the Regulation (EC) No 178/2002 but is nevertheless non-compliant with applicable provisions of other legal requirements. This is not an exhaustive list:

- Restriction or suspension of distribution of the affected food,
- Withdrawal or recall of the affected food,

- Diversion of affected food for other purposes for which it complies, e.g. use of cracked eggs in the production of liquid pasteurised egg,
- Notification of customers and consumers of the reasons why the affected food is noncompliant, e.g. minor labelling errors,
- Apply sanitation procedures or any other action deemed necessary to ensure the food, is brought into compliance with the provisions of legal requirements.

Food business operators should consult with the local bodies in charge of control to determine the most appropriate control action in light of the particular circumstances and non-compliance.

ANNEX 9: KEY TRACEABILITY AND RECALL DEFINITIONS AND ELEMENTS

Traceability is defined as the ability to discern, identify and follow the movement of a food or substance intended to be or expected to be incorporated into a food, through all stages of production, processing and distribution.

Product Recall is defined as the action to remove food from the market at any stage of the food chain, including that possessed by consumers (the removal of an unsafe food from the market when it may have reached the consumer and the notification of the consumer).

Withdrawal is the removal of an unsafe food from the market before it has reached the consumer.

Unsafe food is food that is injurious to health or unfit for human consumption as detailed in Article 14 of Regulation (EC) No.178/2002 or relevant local legal texts.

Consumer is a member of the public in receipt of a food who will not use the food as part of any food business operation or activity.

Market is all the applicable parts of the supply chain where an affected food may be located.

Placing on the market is the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves.

Food business operator is the natural or legal persons responsible for ensuring that the legal requirements for food safety are met within the food business under their control.

Hazard is a biological, chemical or physical agent in or condition of, food or feed with the potential to cause an adverse health effect.

Product batch is a clearly identified unique volume of product consisting of one or more saleable units sharing a common process, common ingredients, packaging and services.

BATCH/LOT NUMBERS AND SERIAL NUMBERS

Lot or Batch Number means a reference number assigned by a food business operator to a series of similar goods, or goods produced under similar conditions. For crops, the lot number is the crop harvesting date, as decided when the crop/harvest starts. Lot and batch are defined/used synonymously and interchangeably.

All suppliers should assign Batch/Lot Numbers or Serial Numbers to case-level products they create. The content, syntax, and format of the batch or lot number itself typically varies from one company to another, depending on company practice and the precision desired. For example, a lot can represent all products produced in a day at one facility or the product produced in one hour from an individual packing line or it could represent a unique recipe run. In addition to the Batch/Lot Number, some suppliers also assign a unique Serial Number to each case and record the beginning and ending case Serial Numbers for each batch or lot.

It is important to remember that the range of products assigned to a single Batch/Lot Number also defines the minimum amount of product that may need to be removed from the supply chain in the event of a recall. This needs to be considered when defining your company's standard practice for setting the scope of each Batch/Lot Number for each type of product that is produced.

Serial Numbers can be assigned to each case or pallet at the time of packing by the supplier. The format of the Serial Number may include a code representing the production facility and production date and time. Suppliers that use a case Serial Number for product tracking in place of a Batch/Lot Number must manage the Serial Number in a way that it affords a similar level of traceability as would be provided by a Batch/Lot Number.

RECORD KEEPING

It is the act of creating a permanent piece of information constituting an account of something that has occurred. Normally, records are relevant traceability information that link final products (outputs) with ingredients, raw material and packaging material through their batch numbers. The information may be recorded using:

- Paper
- Pre-printed paper forms (examples in the last section of this document)
- Copybooks or farm books
- Excel sheets
- Software (Management software, ERP, Traceability software)

PRODUCT LABELS

In the European Union, the labelling rules enable the citizens to get comprehensive information about the content and composition of food products. Labelling helps consumers make an informed choice while purchasing their foodstuffs.

Product labels are elements that physically identify traceable items, such as a tag, a sticker, or printing on product packaging that provides information about the product inside. Usually, they are attached to the packing of every packed product but also can be printed or affixed. Normally product labels include the following information: Business Identification Number (BID), Product Identification or Description, Batch number, Additional information (best before date, harvesting date, weight, quantity, price), Bar code (if required by customer).

Traceability and product recall are important as they enable food businesses to respond quickly to food safety/quality incidents thereby ensuring that consumer exposure to the affected product is prevented or minimised. A good traceability system ensures that withdrawals/recalls are limited to implicated products, thereby minimising disruption to trade and company finances.

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