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10

GUIDANCE NOTE

Product Recall and Traceability (Revision 3)

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Product Recall and Traceability
(Revision 3)

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GLOSSARY OF TERMS

Central distribution centre	A food distribution unit that is either owned by a retailer or operated by a third party on behalf of a retailer
Codex Alimentarius	(Latin for food code) is the joint food standards programme of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO)
Competent authority	The central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country
Consumer	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	All the applicable parts of the supply chain where an affected food may be located
Food law	The laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food producing animals
Food business	Any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food
Food business operator	The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control
Hazard	A biological, chemical or physical agent in or condition of, food or feed with the potential to cause an adverse health effect

Immediate customer	The next person or business one step up in the supply chain who handles or sells the foodstuff produced by the food business
Immediate supplier	The person or business one step down in the supply chain who supplies raw materials into a food business
Ingredient batch	A clearly identified unique volume of ingredient from a single supplier that is either identified by a traceability code applied by the supplier or is identified as a single delivery
Placing on the market	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
Product batch	A clearly identified unique volume of product consisting of one or more saleable units sharing a common process, common ingredients, packaging and services
Risk	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard
Recall	The removal of an unsafe food from the market when it may have reached the consumer and the notification of the consumer
Traceability	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
Unsafe food	Food that is injurious to health or unfit for human consumption as detailed in Article 14 of Regulation (EC) No.178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Withdrawal	The removal of an unsafe food from the market before it has reached the consumer

FOREWORD

Since 2002, the Irish food industry has developed traceability and recall systems and has built up considerable expertise in this complex area. Likewise, the Food Safety Authority of Ireland (FSAI) has been involved in many diverse food withdrawals and recalls and has also gained experience in food traceability systems. This revision is designed to ensure that the guidance in this document is consistent with current interpretations of the legal requirements on food recall/withdrawal and traceability, and reflects current best practice.

In light of experience from a number of large scale pan European food incidents, the legal requirements for traceability were strengthened by the introduction of additional specific provisions for products of animal origin and for sprouts and seeds intended for the production of sprouts. This revision is designed to ensure that the guidance in this document reflects recent changes in the law and current best practice.

INTRODUCTION

Even within the best managed food business, an issue involving the safety and suitability of a food may occur. This may be the result, for example, of a packaging defect, a product formulation error, a manufacturing or storage problem, a problem with the food ingredients. It is important that food business operators are aware that food safety issues can arise with their products and therefore, recognise that there is a need to plan ahead.

Irish and European Union (EU) food law requires all food business operators to be able to trace the food they receive back to the immediate supplier of that food. Then, following food handling, preparation or processing, food business operators must be able to track the distribution of food, forward from their own business to their immediate customer. In addition, food business operators are required to withdraw unsafe food from the market where it has left their immediate control and, if it has reached the consumer, inform consumers of the reason for the food being removed from the market and if necessary, recall the affected food from them. Therefore, food business operators should develop documented food traceability and food recall/withdrawal systems and integrate them into their 'food safety management' systems.

SCOPE

This guidance note is a reference document for the food and beverage industry (hereafter referred to as 'the food industry'). It aims to clarify and standardise procedures for the identification and removal of unsafe and, where necessary, other non-compliant food from the food chain.

It outlines the legal requirements for the traceability of food and recall/withdrawal of unsafe food within the meaning of Regulation (EC) No. 178/2002 on the General Principles of Food Law and implementing Regulations as transposed by relevant national food law (hereafter referred to as the General Food Law). In addition, it outlines the more specific requirements for the traceability of products of animal origin, sprouts and seeds intended for the production of sprouts. It also covers food that is not unsafe but is nevertheless non-compliant with European and Irish provisions governing food safety.

Guidance is provided on what is considered best practice for the development of traceability systems and management of food recalls or withdrawals.

Other traceability requirements are contained in European and national food law relating to food packaging, origin and provenance of foods, e.g. beef labelling. However, these are outside of the scope of this guidance note.

NOTE on legal requirements vs best practice

Legal requirements are highlighted throughout the document and detailed in bold black italics. **Some legal requirements direct food business operators to carry out very specific actions, e.g. specific traceability records they must keep or specific time periods for record keeping. Other legal requirements are less prescriptive and do not specify how a food business operator might comply with the requirement, e.g. food business operators must be able to trace food to suppliers and customers. Where legal requirements are not prescriptive, this document outlines best practice which, if followed by food business operators, will in most circumstances, be accepted as compliance with the legal requirements by the competent authorities.**

PART 1. FOOD TRACEABILITY

INTRODUCTION

This part of the guidance note addresses the main issues concerning the traceability of food. It outlines the legal requirements and the role of the competent authorities and food business operators as well as considering legal requirements and best practice for establishing traceability systems.

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.

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 immediate 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 competent authorities

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 competent authorities. This is not always possible using the purchasing and sales system alone.

THE RESPONSIBILITIES OF FOOD BUSINESS OPERATORS IN FOOD TRACEABILITY

Food business operators are responsible for establishing food traceability systems that, as a minimum, comply with the General Food Law. However, to ensure the highest standards of food safety and public health protection, food must be traceable throughout the entire food chain. Therefore, every food business operator, at every step in the food chain, has a role to play in the traceability of food. Consequently, food business operators should pay particular attention to the effective and efficient transfer of accurate traceability information to their immediate customers. The interconnectivity of traceability systems throughout the food chain is so important for the protection of the consumer and protection of the food industry, that it is highly recommended that food business operators determine that their immediate suppliers and immediate customers also have effective traceability system in place prior to establishing trading relations.

Food industry trade bodies may also have a role in developing more specific detailed guidance based on this document for the food sector that they represent.

THE RESPONSIBILITIES OF THE COMPETENT AUTHORITIES

Under Article 17 of the General Food Law, Member States of the EU are required to enforce food law. This is elaborated in Regulation (EC) No 882/2004 on the official control of foodstuffs. In Ireland, food law is enforced by the FSAI. Enforcement activities are carried out by authorised officers in official agencies under service contract agreements with the FSAI. Collectively, the FSAI and the official agencies are referred to in this document as 'competent authorities'.

The activities that are carried out by the competent authorities are called 'official controls'. Official controls are carried out to verify that food business operators are complying with the food law. Enforcement powers of authorised officers and offences for breaches of legal requirements by food business operators are laid down by Irish food law that implements the European food law. The General Food Law lays down the principal requirements for traceability. These requirements have been transposed into Irish law by two Statutory Instruments that are used by authorised officers working for different official agencies under service contract to the FSAI.

In broad terms, the Health Service Executive (HSE) enforces the General Food Law, through its environmental health officers (EHOs) in all retail food businesses and all food businesses processing foods of non-animal origin and in certain food businesses that process products of animal origin. The HSE conducts its official control activities under the European Communities (Official Control of Foodstuffs) Regulations, 2010 (S.I. No. 117 of 2010) as amended.

The Sea-Fisheries Protection Authority (SFPA) enforces food law, enacted by the European Communities (Food and Feed Hygiene) Regulations, 2009 (S.I. No. 432 of 2009) as amended, in food businesses handling and processing fish and fishery products, including shellfish.

The Department of Agriculture, Food and the Marine (DAFM) and the local authority veterinary service enforce food law, enacted by the same S.I., in most food businesses engaged in the handling and processing of meat and meat products. DAFM also enforces the same food law in food businesses engaged in the handling and processing of dairy products and eggs.

The food legislation section on the FSAI website provides a reference and guide to legislation made at national and EU level. This is available at: http://www.fsai.ie/legislation/food_legislation.html

The European Commission provides access to all European law through EUR LEX. This is available at: http://eur-lex.europa.eu/en/index.htm

CREATING A FOOD TRACEABILITY SYSTEM

All food business operators must have systems capable of identifying the traceability information required in the General Food Law and applicable Irish food law. These systems must be able to provide information to the competent authorities on demand.

LEGAL REQUIREMENTS

The minimum legal requirements for traceability are set out in Article 18 of Regulation (EC) No 178/2002. In light of experience, two Commission Implementing Regulations were introduced to strengthen the requirements for traceability for specific foods. Commission Implementing Regulation (EU) No 931/2011 sets out the specific traceability requirements for food of animal origin while Commission Implementing Regulation (EU) No 208/2013 sets out the specific traceability requirements for sprouts and seeds intended for the production of sprouts.

Commission Implementing Regulation (EU) No 931/2011 applies from 1st July 2012. For food businesses subject to S.I. No. 747 of 2007, i.e. supervised by the Health Service Executive, this was transposed into national law by the European Communities (General Food Law) (Amendment) Regulations 2012 (S.I. No. 473 of 2012). For food businesses subject to S.I. No. 432 of 2009, i.e. supervised by the Sea-Fisheries Protection Authority, the local authorities veterinary services or the Department of Agriculture, Food and the Marine, this was transposed into national law by the European Communities (Food and Feed) (Amendment) Regulations, 2012 (S.I. No. 164 of 2012).

Commission Implementing Regulation (EU) No 208/2013 applies from 1st July 2013. This had not been transposed into Irish law prior to the revision of this guidance note. However, producers of sprouts and seeds intended for the production of sprouts should monitor the legislation section of the FSAI website (www.fsai.ie) for updates.

This legislation is outlined and explained in the following sections. There is a summary of the European and corresponding national legislation in Appendix 7.

General legal requirement: ***Article 18(2) of Regulation of the General Food Law requires that a FBO "shall be able to identify any person from whom they have been supplied with a food….or any substance intended to be, or expected to be, incorporated into a food…" and, "to this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand".***

Article 18(3) states that FBOs "shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand."

Article 18(4) states that "food…which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions"

In addition to the general legal requirement: ***FBOs subject to S.I. No. 747 of 2007 must document their traceability systems.***

The more specific requirements for products of animal origin, sprouts and seeds intended for the production of sprouts are addressed in the following sections.

KEY STEPS IN DEVELOPING FOOD TRACEABILITY SYSTEMS

Step 1. Define the scope of the traceability system

Step 2. Decide on the optimal batch size

Step 3. Identify the traceability information needed, including:

- Information that must accompany food ingredients used by the food business operator
- Internal process information that is needed to maintain traceability through food processing or preparation where applicable
- Information that must accompany distribution of the food produced by the food business operator

Step 4. Establish a system of record keeping and retrieval

Step 5. Establish procedures for review and testing of the traceability system

Step 6. Document the traceability system

STEP 1. SCOPE OF A TRACEABILITY SYSTEM

Food business operators should define the scope of their traceability system before developing it. Traceability systems are composed of one or more of the following three elements, depending on the nature of the food business:

a) **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***

b) **Process traceability:** traceability of food and packaging through the operations within the food business operator's establishment whether or not new products are produced. (Note: this is not a legal requirement but is best practice)

c) **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.

Process traceability is not a legal requirement for any food business but is best practice. It is recognised 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.

STEP 2. 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. Although there is no legal obligation to establish batches of food, it is essential for good traceability. 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. The bigger the batch size, the greater the financial risk and the bigger the exposure of the business to reputation damage and possible litigation.

STEP 3. TRACEABILITY INFORMATION

Food business operators should identify the traceability information that is necessary for the effective functioning of their traceability system. The traceability information required will depend on the scope of the traceability system. Certain traceability information is required by law 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.

Supplier traceability information

By law, 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 on.

Food businesses supervised by the HSE under S.I. No. 747 of 2007 as amended:

In the case of food business operators supervised by the HSE and subject to S.I. No. 747 of 2007, i.e. most retail and catering, the legislation prescribes four pieces of supplier traceability information for food of non-animal origin, including food containing both products of plant origin and processed products of animal origin (composite products) that must be kept as a bare minimum.

These are:

- ***The name of the supplier***
- ***The address of supplier***
- ***Nature of products supplied***
- ***The date of each transaction/delivery***

This information may be contained on the invoices, receipts or dockets they receive from the supplier.

In addition, these food business operators must also comply, where appropriate, with the more stringent supplier traceability information for food of animal origin, including both processed and unprocessed products, set out in S.I. No. 473 of 2012. Food of animal origin includes unprocessed products such as raw meat, fish and eggs and processed products such as pasteurised milk, salami and cheese but excludes food containing both products of plant origin and processed products of animal origin such as pepperoni pizza or ham and spinach quiche. As a rule of thumb, food of animal origin supplied to a food business operator with an oval mark (EU plant approval number, e.g. IE 1234 EU) on it requires the additional information. The supplier traceability information required is:

Schedule 3 of S.I. No. 747 of 2007 as amended by S.I. No. 473 of 2012 requires that:

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 from which the food has been dispatched***
- ***the name and address of the consignor (owner), if different from the food business operator, from which the food has been 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, the following information is relevant:

Commission Implementing Regulation (EU) No 208/2013 requires that:

The food business shall, as a minimum, keep the following information:

- ***an accurate description of the seeds or sprouts, including the taxonomic name of the plant***
- ***the volume or quantity of the seeds or sprouts supplied***
- ***where the seeds or sprouts had been dispatched from another food business operator, the name and address of:***
    - ***(i) the food business operator from which the seeds or sprouts have been dispatched, and***
    - ***(ii) the consignor (owner) if different from the food business operator from which the seeds or sprouts have been dispatched***
- ***a reference identifying the batch as appropriate, and***
- ***the date of dispatch***

The food business operator shall ensure the information above is transmitted to any food business operator to whom he or she supplies the seeds or sprouts.

NOTE: This additional information is not required for sprouts after they have undergone a treatment which eliminates microbiological hazards, compatible with European Union legislation.

Food businesses supervised by the SFPA, DAFM, the local authority veterinary service and the HSE under S.I. No. 432 of 2009 as amended:

In the case of food business operators supervised by the SFPA, DAFM, the local authority veterinary service and a small number of businesses supervised by the HSE and subject to S.I. No. 432 of 2009 as amended by S.I. No. 164 of 2012, specific supplier traceability information is now prescribed for products of animal origin in Regulation (EU) No 931/2011 in addition to the general requirements of Article 18 of Regulation (EC) No 178/2002. The supplier traceability information required is:

Article 3 of Regulation (EU) No 931/2011:

Food business operators shall ensure that the following information concerning consignments of food of animal origin is made available to the food business operator to whom the food is supplied and, upon request, to the competent authority:

- ***an accurate description of the food***
- ***the volume or quantity of the food***

- ***the name and address of the food business operator from which the food has been dispatched***
- ***the name and address of the consignor (owner) if different from the food business operator from which the food has been dispatched***
- ***a reference identifying the lot, batch or consignment, as appropriate, and***
- ***the date of dispatch***

If any food business operators supervised by DAFM and subject to S.I. No. 432 of 2009 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. The supplier traceability information required is:

Commission Implementing Regulation (EU) No 208/2013 Food business operators at all stages of production, processing and distribution, shall ensure that the following information concerning the batches of seeds intended for the production of sprouts, or the batches of sprouts is kept on record. The food business operator shall also ensure that the information needed to comply with these provisions is transmitted to the food business operator to whom the seeds or sprouts are supplied:

- ***an accurate description of the seeds or sprouts, including the taxonomic name of the plant***
- ***the volume or quantity of the seeds or sprouts supplied***
- ***where the seeds or sprouts had been dispatched from another food business operator, the name and address of:***
    - ***(i) the food business operator from which the seeds or sprouts have been dispatched, and***
    - ***(ii) the consignor (owner) if different from the food business operator from which the seeds or sprouts have been dispatched***
- ***a reference identifying the batch as appropriate***
- ***the date of dispatch***

However, to develop a good supplier traceability system, it is recommended that all other food business operators maintain the following information which also includes the information required by the legislation:

- 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 (often the local authority) and any associated quality records generated by the food business operator should be maintained.

Process traceability information

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
    - 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

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.

Customer traceability[1] information

By law, 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.

Food businesses supervised by the HSE under S.I. No. 747 of 2007 as amended:

In the case of food business operators supervised by the HSE and subject to S.I. No. 747 of 2007, the legislation prescribes four pieces of customer traceability information for food of non-animal origin, including food containing both products of plant origin and processed products of animal origin (composite products) that must be kept as a bare minimum. These are:.

- ***Name of the customer***
- ***Address of the customer***
- ***Nature of products supplied***
- ***Date of transaction/delivery***

This information may be contained on the invoices, receipts or dockets supplied to the customer.

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, set out in S.I. No. 473 of 2012 (see Supplier Traceability Information section on page 12 for further explanation). As a rule of thumb, a food business operator

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

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.

Schedule 3 of S.I. No. 747 of 2007 as amended by S.I. No. 473 of 2012 requires that:

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***.

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

- ***an accurate description of the seeds or sprouts, including the taxonomic name of the plant***
- ***the volume or quantity of the seeds or sprouts supplied***
- ***the name and address of the food business operator to whom the seeds or sprouts are dispatched***
- ***the name and address of the consignee (owner), if different from the food business operator to whom the seeds or sprouts are dispatched***
- ***a reference identifying the batch as appropriate, and***
- ***the date of dispatch***

The food business operator must ensure the information above is transmitted to any food business operator to whom he or she supplies the seeds or sprouts.

NOTE: This additional information is not required for sprouts after they have undergone a treatment which eliminates microbiological hazards, compatible with European Union legislation.

Food businesses supervised by the SFPA, DAFM, the local authority veterinary service and the HSE under S.I. No. 432 of 2009 as amended:

In the case of food business operators supervised by the SFPA, DAFM, the local authority veterinary service and a small number of businesses supervised by the HSE and subject to S.I. No. 432 of 2009 as amended by S.I. No. 164 of 2012, specific customer traceability information is now prescribed for products of animal origin in Regulation (EU) No 931/2011 in addition to the general requirements of Article 18 of (EC) No 178/2002. The customer traceability information required is:

Article 3 of Regulation (EU) No 931/2011:

Food business operators shall ensure that the following information concerning consignments of food of animal origin is made available to the food business operator to whom the food is supplied and, upon request, to the competent authority:

- ***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 has been dispatched***
- ***the name and address of the consignee (owner) if different from the food business operator to whom the food are dispatched***
- ***a reference identifying the lot, batch or consignment, as appropriate, and***
- ***the date of dispatch***

If any food business operators supervised by DAFM and subject to S.I. No. 432 of 2009 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. The customer traceability information required is:

Article 3 of Commission Implementing Regulation (EU) No 208/2013:

Food business operators at all stages of production, processing and distribution, shall ensure that the following information concerning the batches of seeds intended for the production of sprouts, or the batches of sprouts is kept on record. The food business operator shall also ensure that the information needed to comply with these provisions is transmitted to the food business operator to whom the seeds or sprouts are supplied:

- ***an accurate description of the seeds or sprouts, including the taxonomic name of the plant***
- ***the volume or quantity of the seeds or sprouts supplied***

- ***the name and address of the food business operator to whom the seeds or sprouts have been dispatched***
- ***the consignee (owner) if different from the food business operator to whom the seeds or sprouts are dispatched***
- ***a reference identifying the batch as appropriate***
- ***the date of dispatch***

However, to develop a good customer traceability system, it is still recommended that food business operators subject to S.I. No. 747, as well as all other food business operators, maintain the information listed below which also includes the information required by the legislation:

- Records of the dispatch of food from the food business operator and their destination:
  - The name, address and contact details of the immediate customer
  - The name, address and contact details of the transport firm (where applicable)
  - Container code (where applicable)
  - Date of delivery or transaction
- A comprehensive inventory of the products being delivered:
  - Product name, nature and description
  - Product batch codes
  - Number of cases
  - Number of packs per case
  - Supplier details where necessary (for wholesale, import and retail businesses only)

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.

STEP 4. RECORD KEEPING AND RETRIEVAL

By law, food business operators must keep all relevant traceability records for the period of time specified by the food law.

The periods of time that traceability records must be maintained by the food business are laid down in food law as follows:

- ***Food business operators subject to S.I. No. 747 of 2007 as amended, 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. For sprouts and seeds intended for the production of sprouts the food business must also update the records and transmit the relevant information on a daily basis***
- ***Food business operators registered or approved under S.I. No. 432 of 2009 (generally processors, manufacturers and cold stores handing foods of animal origin including seafood), must maintain records for three years in all cases***

The type of records subject to these timescales that need to be maintained either by law or as part of best practice were discussed in the previous section on traceability information.

By law, food business operators are required to make information on the traceability of suppliers and customers available to the competent authorities on demand.

General Food Law 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 competent authorities demand them. Competent authorities 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.

By law, information on traceability for food of animal origin, sprouts and seeds intended for the production of sprouts must be made available to the competent authority without undue delay.

STEP 5. 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.

On the basis of 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.

STEP 6. DOCUMENTING FOOD TRACEABILITY SYSTEMS

By law, food business operators subject to S.I. No. 747 of 2007 must document their traceability system.

However, it is recommended that all food business operators should document the traceability system and include details of all of the 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.

PART 2. FOOD RECALL AND WITHDRAWAL

INTRODUCTION

This section of the guidance note deals with the recall or withdrawal of an unsafe food within the meaning of the General Food Law. Article 19 of the Regulation (EC) No.178/2002 on the general principles of food law, specifies the requirements of food business operators regarding the withdrawal and recall of unsafe foods[2].

This section also outlines the roles of the competent authorities and the food business operator. It helps food business operators identify unsafe and other non-compliant foods and the appropriate actions a food business operator should take. Information is provided on the development of a food recall/withdrawal plan and the management of a food recall/withdrawal. The general guidance is supported by templates for food recall/withdrawal system documentation, guidelines and templates for food recall/withdrawal notices as well as guidelines for media communication.

Whenever a food is identified as unsafe and it has left the immediate control of the food business operator, it must be removed from the market. If the affected food has not reached the consumer but is still in the distribution chain, it must be withdrawn and this requires food business operators to notify the competent authorities and trade customers. However, if an unsafe food may have reached consumers, in addition to removing the affected food from the distribution chain and notifying competent authorities and trade customers, food business operators must notify consumers and if necessary, the food has to be recalled from them unless another appropriate action can be initiated to protect public health. Food business operators should be clear that it is the fact that unsafe food may have been distributed to consumers that triggers the need to inform consumers rather than the requirement to remove the food from the consumer. Therefore, for example, it is possible in certain circumstances, e.g. gross spoilage, that a food could be removed from the distribution chain but not from consumers. However, in such an event, consumers would still have to be notified in an appropriate manner that the affected food may have been distributed to them.

Any food safety incident that requires consumers to be notified will be referred to as a food recall whether or not food is actually removed from consumers.

Successful removal of food from the market relies on the clear assignment of responsibilities within the food business and the competent execution of a verified food recall/withdrawal plan. A fully functional traceability system is the only effective way of identifying the location of unsafe and other non-compliant food.

[2] Foods that are not unsafe as defined in the General Food Law but are otherwise non-compliant with other provisions of food law, e.g. a food marginally exceeding a maximum residue limit for a pesticide, may be subject to a range of appropriate control actions which may include a food recall or withdrawal (see Appendix 6).

OBJECTIVE OF A FOOD RECALL/WITHDRAWAL

The objective of food recall/withdrawal is to protect public health and interests by: facilitating the efficient, rapid identification and removal of unsafe food from the market and where necessary, consumers and; to inform the competent authorities, other food businesses and the consumer, as appropriate.

DEFINITIONS

For the purposes of this document, unsafe food should be removed from the market in one of two ways:

Withdrawal: The removal of an unsafe food from the market before it has reached the consumer

Recall: The removal of an unsafe food from the market when it may have reached the consumer and the notification of the consumer

THE RESPONSIBILITY OF FOOD BUSINESS OPERATORS IN FOOD RECALL/WITHDRAWAL

GENERAL LEGAL REQUIREMENT

Article 19(1) of the General Food Law states "If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection"

Article 19(2) of the General Food Law states that "A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities."

Article 19(3) of the General Food Law states that "A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

Article 19(4) of the General Food Law states: "Food business operator shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied."

The food business operator has the primary responsibility to remove unsafe food from the market when it has left their immediate control. Where food has reached the consumer, food business operators must inform consumers of the reason for the removal of the food from the market and if necessary, recall the food from consumers when other measures are not sufficient to achieve a high level of health protection. Food business operators are legally required to notify and cooperate with the competent authorities regarding recall/withdrawal of unsafe food. Food business operators must also notify other food business operators who are affected and cooperate to facilitate effective and efficient food recall/withdrawal. The food business operator should prioritise the use of available resources to the efficient and effective removal of affected food from the market.

THE ROLE OF THE COMPETENT AUTHORITIES

The main role of the competent authorities is to protect the health of consumers. Consequently, they have a role in providing food business operators with advice on risk assessment and appropriate control measures as well as assistance in the event of a food recall/withdrawal. Food business operators should always consult their competent authority when they become aware that a food they have placed on the market is not in compliance with food law.

Notwithstanding the obligations on food business operators to remove unsafe food from the market and communicate the food recall/withdrawal appropriately with customers and consumers, the competent authorities have a role to make sure that the process is being managed effectively. Ultimately, if food business operators fail in their obligations, the competent authorities can order the withdrawal or recall of a food and its destruction if necessary. This role is supported in food law as follows:

Article 54 of Regulation (EC) No. 882/2004 on official controls specifies the actions that competent authorities may take in the case of non-compliance with food law. Article 54 (2)(c) specifically states that one action available is "monitoring and ,if necessary, ordering the recall, withdrawal and or destruction of …food"

Regulation (EC) No 882/2004 is transposed into national law by the European Communities (official Control of Foodstuffs) Regulations, 2009 (S.I. No. 117 of 2010) as amended for most businesses supervised by the HSE and by the European Communities (Food and Feed Hygiene) Regulations, 2009 (S.I. No. 432 of 2009) as amended for food businesses supervised by the SFPA, DAFM, the local authority veterinary service and a small number of HSE food businesses.

Generally, the FSAI has a role in coordinating national and international food recalls/withdrawals and some local food recalls/withdrawals where the level of public health risk is high. Otherwise, the official agencies coordinate food recalls/withdrawals which are more local in scale.

In addition, the FSAI coordinates the national activities associated with the EU Rapid Alert System for Food and Feed (RASFF). The FSAI is obliged to report food incidents involving serious risks to public health to the European Commission in cases where unsafe foods have been exported from the Republic of Ireland. Also, the FSAI receives information about unsafe food/serious risk to food safety from the RASFF system and food business operators are obliged to take appropriate action when notified by the competent authorities. Where necessary, the FSAI publishes food alerts for action or information and food allergen alerts depending on the nature of the incident. Details of these roles are specified in the FSAI's 'Code of Practice No. 5, Food Incidents and Food Alerts' which is available on www.fsai.ie.

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:

1. **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
2. **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

PROCESS 1. 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 all the documentation necessary 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.

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.

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 competent authorities. 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 (see Part 2: Food Recall and Withdrawal, pages 24 and 25)
- 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 (see Part 1)
- 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

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. An example of such a table is shown in Figure 1 of Appendix 4. Each food business operator should develop its own 'role and responsibility' table to suit its own organisational 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
- Competent authorities

The lists should also contain references to any files (electronic or otherwise) where further details are kept. Food business operators should refer to the example contact list shown in Figure 2 of Appendix 4 when constructing their own contact lists.

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 competent authority, e.g. the FSAI can be contacted on a 24 hour, seven days a week basis via the emergency number: 01 685 6555.

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. Appendix 1 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.

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 summarised as follows:

- Unsafe food has not reached consumers (Withdrawal):
  - Competent authorities
  - Affected food businesses as applicable:
    - Suppliers
    - Distributors
    - Wholesalers
    - Retailers
    - Caterers
- Unsafe food has reached consumers (Recall):
  - Competent authorities
  - Affected food businesses as applicable:
    - Suppliers
    - Distributors
    - Wholesalers
    - Retailers
    - Caterers
  - Consumers

Further detailed information on notifications via different channels including the media can be found in Appendix 5. Food business operators should use this information in addition to the general information below.

Notification of the competent authorities

By law, food business operators must notify the competent authorities 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[4].

The food recall/withdrawal plan should contain procedures to facilitate early consultation with the competent authorities. 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 food law or due to inaccurate risk assessment.

Food recall/withdrawal plans should outline the typical information which is required by the competent authorities, 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? Note: food distributed in Northern Ireland is classed as 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

In the case of notifications made to the FSAI, food business operators should have links to the FSAI food incident notification form in their food recall/withdrawal plan and a hard copy for reference. The form is available on the FSAI web site at the following address:

http://www.fsai.ie/notification_food_incident.html

The food recall/withdrawal plan should specify that the competent authorities must be notified without delay and that in all circumstances notification of the competent authority 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 competent authorities throughout the incident management process. Procedures are also necessary to formally close the food recall/withdrawal to the satisfaction of the competent authorities.

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 Appendix 5 Figure 3 for a template of a trade notification.

Notification of consumers

By law, when food has been identified as unsafe within the meaning of the General Food Law (see Appendix 2) 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. See Appendix 5, Figures 4 and 5 for templates of consumer information notices and an example of a press release.

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

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.

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.

PROCESS 2. 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 food law. This in turn, triggers the legal obligations of food recall/withdrawal governed by the General Food Law.

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

STEP 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
  - Competent authorities
  - 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 competent authority as appropriate.

STEP 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 Appendix 1). This requires the food business operator to take initial precautionary measures and to identify the legal status of the affected food (see Appendix 2) by conducting a risk assessment (see Appendix 3).

General legal requirement: ***Article 14 of the General Food Law sets out the food safety requirements for food business operators. Specifically, Article 14 (1) states that food business operators "shall not place food on the market if it is unsafe". Unsafe food is defined in Article 14(2) as food that is injurious to health and/or unfit for human consumption.***

The General Food Law also notes that food that conforms to the Community provisions regarding food safety, is considered safe insofar as these provisions apply. However, food can be safe within the meaning of the General Food Law but still not in compliance with other provisions of food law, e.g. a food that has used a non-permitted additive that has no food safety consequences. Different control actions may be required in each case.

It is essential that food business operators are able to identify when a food is unsafe and when it is safe but non-compliant with other provisions of food law. Food business operators should familiarise themselves with the information in Appendix 2 and follow the identification scheme at the end of Appendix 2. This will also require the food business operator to conduct a risk assessment as in Appendix 3.

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 competent authority as appropriate. However, advice from the competent authority 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 seek to have the competent authority make the decision on whether to withdraw or recall the unsafe food. However, if the competent authority 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 food law.

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 act 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.

STEP 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

STEP 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 competent authorities, 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 competent authorities must be notified without delay. In all circumstances, notification of the competent authority 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 Appendix 5).

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 communications 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 to 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.

STEP 5. 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 competent authorities when a food incident is closed.

STEP 6. 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 competent authority, where legally required. Food business operators should consult the competent authority regarding disposal of unsafe food.

STEP 7. 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 competent authorities?
- 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 competent authorities happy with the actions taken?

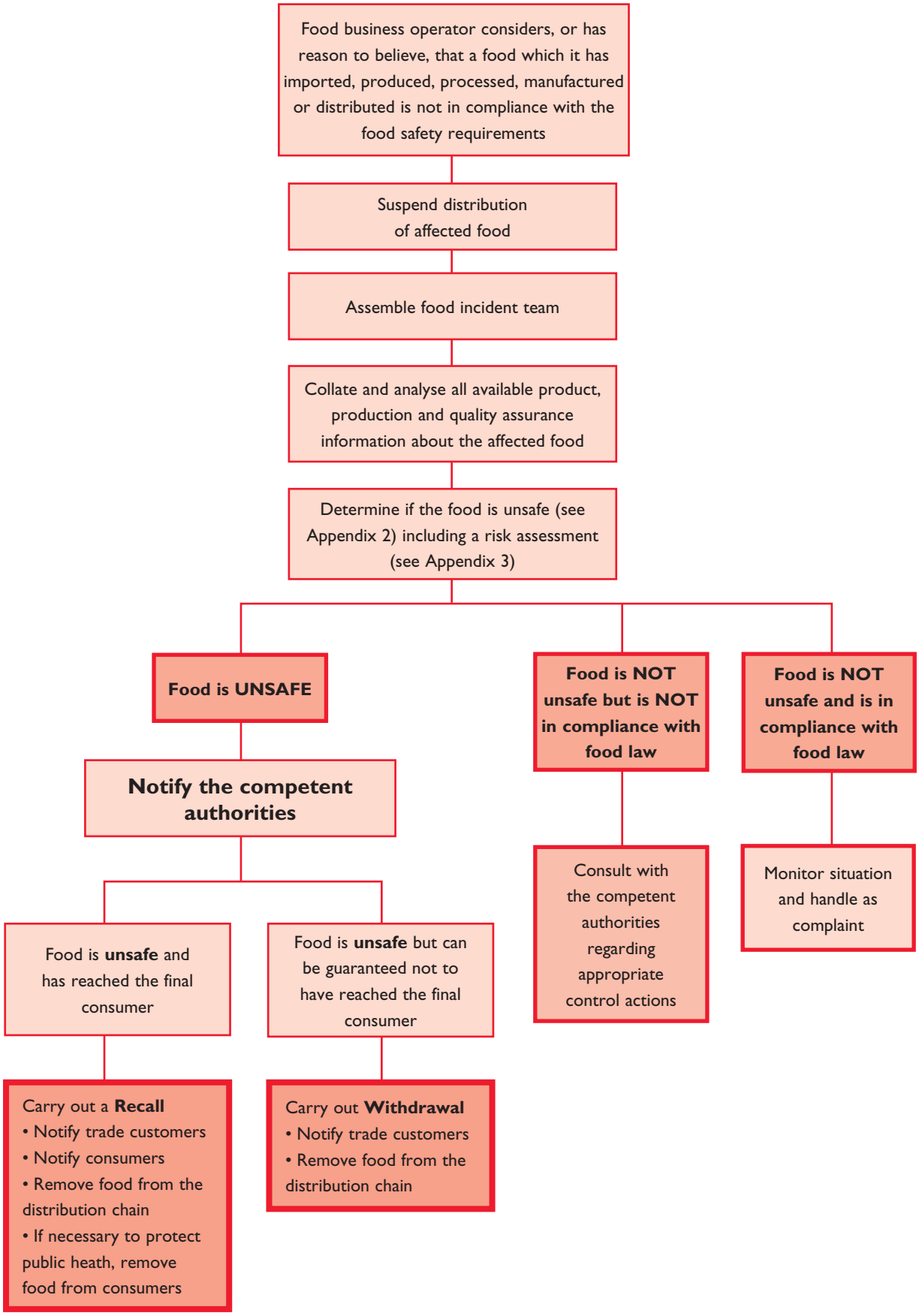
Food business operators should produce a final report of the food recall/withdrawal review to draw all information together in one place and act as a resource for future training and continuing professional development. Such reports may also be useful for the food business operator in the event of litigation.

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.

APPENDIX 1. FOOD RECALL DECISION TREE



APPENDIX 2. 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 law, 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:

1) Does the food pose a public health risk? **Conduct a risk assessment before answering this question (see Appendix 3)**

   (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).

   1. If **yes** go to **3**
   2. If **no** go to **question 2**

2) Is the condition of the food unacceptable for human consumption for reasons of contamination, e.g. extraneous matter, chemical residues, bacterial or other microbiological agents, or through putrefaction, deterioration or decay?

   1. If **yes** go to **3**
   2. If **no** go to **question 5**

3) Is the risk to public health or the unacceptability of the food eliminated by the normal conditions of use of the food either by the consumer or by another food businesses, e.g. cooking a raw food, or is the information on the label, or otherwise generally available, sufficient for the consumer to avoid a particular health effect, e.g. labelling of allergens?

   1. If **yes** go to **question 5**
   2. If **no** go to **4**

4) The food is UNSAFE as defined in the general food law

5) Is the food in compliance with all Community and national provisions of food law, e.g. maximum limits for microbiological and chemical contaminants, maximum limits on additives, labelling requirements etc.?

   1. If **yes**, the food is not unsafe and is in compliance with all the Community and national provisions of food law
   2. If **no**, the food is not unsafe but does not comply with all the Community and national provisions of food law

Return to the Decision Tree in Appendix 1 to determine the appropriate risk management action.

APPENDIX 3. PERFORMING A RISK ASSESSMENT

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

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.

An Example of a Food Incident, a Risk Assessment and Subsequent Risk Management Actions:

The Problem: External testing by a third party has found that the pH of an acid preserved food is 5.2. A check of the internal quality assurance records shows that critical limits for cooking of the food were achieved in the factory and the pH checks were correct. However, calibration records show that a few days after product dispatch, the pH probe used in the QA process was calibrated and found to be inaccurate. The product does not look or smell spoiled and there were no problems with the packaging process or packaging QA checks. 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 cooking process removes all vegetative pathogens but does not kill all bacterial spores. The only pathogenic bacteria with spores capable of surviving the cooking process, is *Clostridium botulinum*. The spores of *Cl. botulinum* can germinate and bacteria can grow at ambient temperatures and an environmental pH above 4.6. *Cl. botulinum* produces a potent neurotoxin during its growth that causes botulism in animals and humans. The botulinum toxin is relatively heat stable and is not degraded by normal pasteurisation temperatures.

Exposure Assessment: The product pH and storage conditions and remaining shelf-life are favourable for *Cl. botulinum* to grow and produce toxin. There is no re-heating to temperatures that would degrade the toxin. The consumer is likely to have bought the product and stored it at home for at least its shelf-life. It is also possible that because the product has a 'best-before' date and not a 'use-by' date, some consumers would store the product for longer than its shelf-life. The chances of the consumer being exposed to *Cl. botulinum* toxin are high.

Hazard Characterisation: Botulism is a condition where a person who eats food containing the toxin produced by *Cl. botulinum* can suffer paralysis, asphyxiation and death. The public health literature cites many cases of botulism caused by acid preserved food reported in the literature and these often relate to failure of cooking processes, failure of pH control and failure of hermetically sealed packs. The scientific literature suggests that botulinum toxin is one of the most potent toxins known and that minute amounts can cause severe health effects. All members of the population are vulnerable.

Risk Characterisation: The chances of exposure are high and the consequences of exposure are severe. An adverse public health effect is likely to be experienced by any consumer. It is not possible to quantify the risk or the uncertainties associated with the risk. The food poses a public health risk.

Return to the Identification Scheme in Appendix 2 to determine the appropriate legal classification of the affected food.

APPENDIX 4. EXAMPLES OF FOOD RECALL/ WITHDRAWAL PLAN DOCUMENTATION

Figure 1: Example of a Recall/Withdrawal Plan – Roles and Responsibility Chart

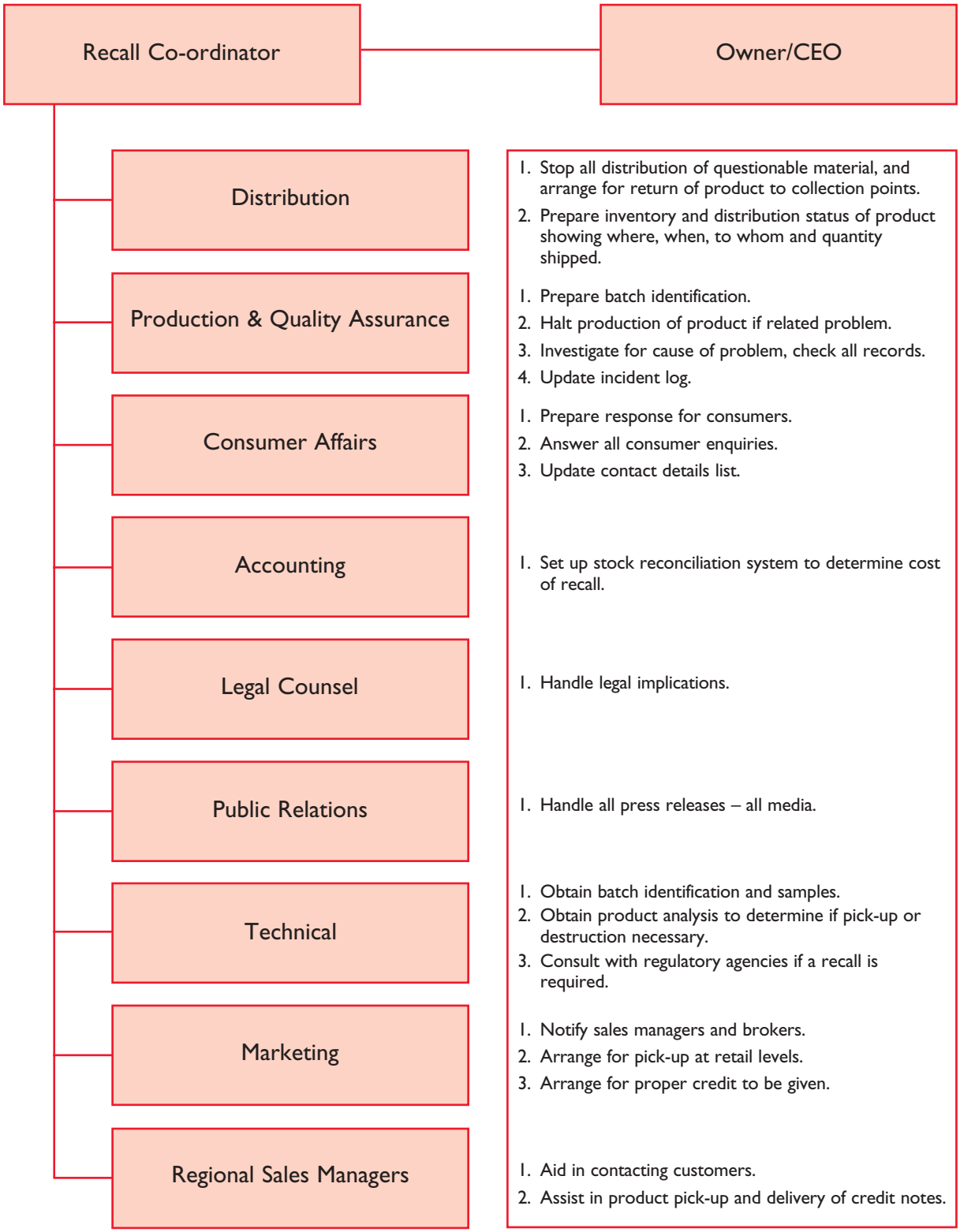


Figure 2: Recall Plan Contacts List Example

Company Contacts List

CEO/Owner	Mr. A	Tel: Home Tel: Mobile Tel:	Email: Fax:
Recall coordinator	Ms B	Tel: Home Tel: Mobile Tel:	Email: Fax:
Recall coordinator alternative	Ms Q	Tel: Home Tel: Mobile Tel:	Email: Fax:

Supplier List

Packs 'R' Us Main Contact	Mr. A	Tel: Home Tel: Mobile Tel:	Email: Fax:
Packs 'R' Us Alternative contact	Ms B	Tel: Home Tel: Mobile Tel:	Email: Fax:
Raw products Inc. Main Contact	Ms C	Tel: Home Tel: Mobile Tel:	Email: Fax:

Customer/Distributor List

I Buy Ltd **Main Contact**	Mr. A	Tel: Home Tel: Mobile Tel:	 Email: Fax:
I Buy Ltd **Alternative contact**	Ms B	Tel: Home Tel: Mobile Tel:	 Email: Fax:
We distribute Inc. **Main Contact**	Ms C	Tel: Home Tel: Mobile Tel:	 Email: Fax:

Competent Authority List

FSAI **Main Contact**	Food Incidents	Tel: Home Tel: Mobile Tel:	 Email: Fax:
DAFF **Main contact**	Ms B	Tel: Home Tel: Mobile Tel:	 Email: Fax:
HSE-EHS **Main Contact**	Ms C	Tel: Home Tel: Mobile Tel:	 Email: Fax:

APPENDIX 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. Figure 3 shows an example of a trade notification notice.

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:

1. Start the notice with a clear indication of what the notice is about, e.g. 'Warning: Food Recall' or 'Warning: Important Safety Notice'
2. Say what the product is (name, brand, description)
3. 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
4. Avoid 'downplaying' the incident
5. 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 time-span during which the food may have been purchased
   - List of batch codes of the food affected
   - Dates of minimum durability ('use-by', 'best-before')

6. Include a photograph or illustration of the food indicating where the identification information can be found
7. 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
8. If the health risk is serious, 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

Figure 4 shows an example of a consumer information notice.

In-store Notifications

In-store notifications are displayed by retail stores in a visible and appropriate manner. ***By law, 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 requirements of the food law. 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 organisations, e.g. Irish Anaphylaxis Campaign, might be appropriate.

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 following newspapers:

- Product solely distributed and sold in the Republic of Ireland:
    - Irish Independent
    - Irish Times
    - Irish Examiner
    - Irish Daily Mail
    - Irish Daily Star
    - Irish Daily Mirror
    - Irish Sun
    - Sunday Independent and/or Sunday World (if recalling at the weekend)
    - Local newspapers or appropriate niche publications where necessary
- Product distributed and sold outside the Republic of Ireland:
    - Consult the competent authorities and the appropriate national authority in the country where the product is sold

Note: Newspapers have deadlines for press adverts which differ from newspaper to newspaper. 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

Figure 5 shows a sample press release.

It is highly recommended that food business operators consult with the FSAI concerning press releases. In some cases, a press release by the FSAI on behalf of the food business operator, or a joint press release, may be a more effective means of communication.

Figure 3: Example of a Trade Notification Form

URGENT

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 _____

Figure 4: Example of an In-store Notification or Paid Newspaper Advertisement

WARNING

Food Recall

Company name

Food name/description

Pack size

Batch identification

Food photograph or illustration

Details of what is wrong with the product

Actions the consumer should take

We apologise for any inconvenience

Company address and contact details

Figure 5: Sample Press Release

PRESS RELEASE - FOR IMMEDIATE RELEASE

04 June 2007
Food Recall

Ham-It-Up Cooked Ham Produced by B Ltd, Co. Dublin

B Ltd is recalling all cooked ham products under the brand name Ham-It-Up. This product has been implicated in a number of cases of Salmonellosis in the South West region of the country. Although testing of the ham has yet to identify *Salmonella*, B Ltd is taking this public health measure in conjunction with the Food Safety Authority of Ireland (FSAI). The FSAI has also advised anybody showing symptoms such as fever, diarrhoea and/or vomiting to seek medical advice.

All Ham-It-Up brand ham is affected irrespective of its 'use-by' date. Consumers should not consume the product. Consumers are also advised to dispose of the product, however, the label should be sent to the following address for a full refund along with the name and address of the consumer.

B Ltd.
Unit B, Street C
Co. Dublin

Mr Meat, CEO of B Ltd said "We apologise to our customers for any inconvenience this recall has caused. However, I stress that this is a public health measure and that no *Salmonella* has yet been found in the implicated food". Dr. Safe, FSAI said "B Ltd has cooperated fully with the FSAI investigation and have acted responsibly to protect public health. Anybody who has consumed this product and is showing symptoms such as fever, diarrhoea and/or vomiting should seek medical advice"

Consumers should contact the following number for further information:

01 -112211223

APPENDIX 6. APPROPRIATE CONTROL ACTIONS FOR FOOD THAT IS NOT UNSAFE BUT IS NEVERTHELESS NON-COMPLIANT WITH THE PROVISIONS OF FOOD LAW

The following control measures are based on enforcement measures for competent authorities 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 law, 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 General Food Law but is nevertheless non-compliant with applicable provisions of other food law. 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 is in compliance, 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 non-compliant, 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 food law

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

APPENDIX 7. LEGISLATION ON TRACEABILITY OF FOOD DETAILED IN THIS GUIDANCE

EU Legislation	National Legislation	Official Agency	Scope
Article 18 of Regulation (EC) No 178/2002	European Communities (General Food Law) Regulations, 2007 as amended (S.I. No. 747 of 2007 as amended)	Health Service Executive Environmental Health Officers Service	General requirements for one step forward and one step back traceability with minimum information requirements set for food of non-animal origin and composite products
	European Communities (Food and Feed Hygiene) Regulations, 2009 as amended (S.I. No. 432 of 2009 as amended)	Department of Agriculture, Food and the Marine, Sea Fisheries Protection Authority, Local Authority Veterinary Service and the Health Service Executive	General requirements for one step forward and one step back traceability
Commission Implementing Regulation (EU) No 931/2011	European Communities (General Food Law) (Amendment) Regulations, 2012 (S.I. No. 473 of 2012)	Health Service Executive Environmental Health Officers Service	Additional traceability requirements for products of animal origin
	European Communities (Food and Feed Hygiene) (Amendment) Regulations 2012 (S.I. No. 164 of 2012)	Department of Agriculture, Food and the Marine, Sea Fisheries Protection Authority, Local Authorities Veterinary Service and the Health Service Executive	
Commission Implementing Regulation (EU) No 208/2013	To be transposed	Health Service Executive Environmental Health Officers Service	Additional traceability requirements for sprouts and seeds intended for the production of sprouts
	To be transposed	Department of Agriculture, Food and the Marine, Sea Fisheries Protection Authority, Local Authorities Veterinary Service and the Health Service Executive	

NOTES

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