GUIDELINES FOR PREVENTING AND RESPONDING TO FOOD INCIDENTS
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Objectives

An incident is defined as any event where, based on the information available, there are concerns about actual or suspected threats to the safety or quality of food or feed, or where food or feed does not meet legal requirements, that could require intervention to protect consumers’ interests.

These guidelines are primarily intended to address those incidents where there is a failure to meet food or feed safety requirements as defined by EC General Food Law Regulation 178/2002.

LEGISLATION

General Food Law Regulation 178/2002

EC Regulation 178/2002, laying down the general principles and requirements of food law, came into force on 21 February 2002, with the main legal requirements such as traceability and product recall applicable from 1 January 2005. This Regulation establishes the basic principle that the primary responsibility for ensuring compliance with food law, and in particular the safety of the food, rests with food businesses. This principle also applies to feed businesses.

Article 3 sets out the following definitions:
Food business means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities relating to any stage of production, processing and distribution of food.
Feed business means any undertaking, whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution or storage for feeding to animals on his own holding.
Food business operator means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.
Feed business operator means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

Key obligations of food and feed business operators

<table>
<thead>
<tr>
<th>Safety</th>
<th>Operators shall not place on the market unsafe food and feed</th>
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<tbody>
<tr>
<td>Responsibility</td>
<td>Operators are responsible for the safety of the food and feed which they produce, transport, store or sell</td>
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<tr>
<td>Traceability</td>
<td>Operators shall be able to rapidly identify any supplier or consignee</td>
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<tr>
<td>Transparency</td>
<td>Operators shall inform the competent authorities if they have reason to believe that their food or feed is not safe. In the UK, the competent authorities are FSA and the relevant enforcement authority ie the local authority or the port health authority.</td>
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<tr>
<td>Emergency</td>
<td>Operators shall immediately withdraw food or feed from the market if they have reason to believe that it is not safe</td>
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<tr>
<td>Prevention</td>
<td>Operators shall identify and regularly review the critical points in their processes and ensure that controls are applied at these points</td>
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<tr>
<td>Co-operation</td>
<td>Operators shall co-operate with the competent authorities in actions taken to reduce risks</td>
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The principle provisions and requirements under the General Food Law Regulation are set out in Article 11 (import of food and feed), Article 12 (export of food and feed), Article 17 (responsibilities), Article 18 (traceability), Article 19 (withdrawal, recall and notification by food business operators) and Article 20 (withdrawal, recall and notification by feed business operators).

**Food Hygiene Regulation 852/2004**

EC Regulation 852/2004 on the hygiene of foodstuffs came into force on 1 January 2006. It lays down general hygiene requirements for food businesses at all stages of the food chain including a requirement in Article 5 for operators (except primary producers) to put in place, implement and maintain procedures based on the HACCP principles.

The EC has provided guidance on certain provisions of the Food Hygiene Regulation along with guidance on implementation of procedures based on the HACCP principles. Annex II of the HACCP guidance sets out how the HACCP principles can be applied in a flexible and simplified way in certain food businesses. FSA has also developed a food safety management pack Safer Food Better Business to help small catering businesses and small retail businesses comply with the new legislation. FSA Scotland has developed a HACCP-based system called Cook Safe and FSA Northern Ireland has developed Safe Catering.

The Food Hygiene (England) Regulations 2006 and equivalent regulations in Scotland, Wales and Northern Ireland provide enforcement powers and penalties.

**Microbiological Criteria Regulation 2073/2005**

EC Regulation 2073/2005 on the microbiological criteria for foodstuffs came into force on 11 January 2006. It lays down food safety criteria for certain important foodborne bacteria, their toxins and metabolites, such as *Salmonella*, *Listeria monocytogenes*, *E.coli (VTEC) 0157*, *Enterobacter sakazakii* and *Staphylococcal enterotoxins* in specific foodstuffs and histamine in fish to indicate the acceptability of a product to be placed on the market. It also lays down certain process hygiene criteria to indicate the correct functioning of the production process. Microbiological criteria should be used to validate and verify food safety management procedures based on HACCP principles and GHP/GMP. It does not introduce a requirement for routine end product testing or positive release but does set specific sampling requirements for certain meat products.

**Food Safety Act 1990**

The Food Safety Act came into force on 1 January 1991. It introduces, in section 21, the concept of a due diligence defence, whereby: *it shall be a defence for the person charged if he can prove that he took all reasonable precautions and exercised all due diligence to avoid the offence by himself or by a person under his control.*

The Act was amended in 2004 to align domestic legislation with the general principles and requirements of the EC General Food Law Regulation and to introduce new enforcement powers and penalties.
Other Related Legislation

Food business operators need to ensure that they are aware of the requirements under other food and feed legislation relating issues such as food contact materials, food improvement agents, food labelling, contaminants, pesticides, veterinary residues, etc.

In addition, the UK General Product Safety Regulations 2005, implementing Directive 2001/95/EC, place a general duty on producers to ensure that products placed on the market are safe in normal or reasonable foreseeable use. This legislation could be relevant in cases such as an over-pressurised bottle of sparkling wine. Product-specific legislation continues to take precedence in areas where it has provisions with similar objectives to those of the GPS Regulations.

FURTHER INFORMATION

Further information on legislative requirements can be obtained from the EC website or the FSA website.
MODULE 1: INCIDENT PREVENTION

INTRODUCTION

This section is intended to assist food and feed businesses to identify and control potential hazards in order to ensure the safety of food and minimise the number of food safety incidents.

FOOD SAFETY MANAGEMENT SYSTEMS

All food businesses should have a full understanding of the products they produce, manufacture, sell and/or distribute; and should have systems in place to identify and control hazards which are significant to the safety of food. This can be achieved by implementation of prerequisite requirements, by applying HACCP principles and by using guides to good hygiene practice and assurance schemes. These are applicable to all types of food business and at all stages of the food chain but allow for flexibility depending on the nature of the products involved and the size and complexity of the business.

Food safety management systems should be documented and updated as necessary. Written records should be kept for inspection by the local authorities.

Prerequisite requirements

Prerequisite requirements are the basic environmental and operating conditions in a food operation that are necessary for the production of safe food. They control generic hazards and form part of GHP/GMP.

The following list gives examples of the types of prerequisite requirements covering three key areas: product, premises and personnel. Not all of these are relevant to all types of food business, but they provide a checklist of the types of controls that operators should consider depending on the size and complexity of their business.

Examples of pre-requisite requirements

Product
- Monitoring supplier competence
- Supplier auditing
- Raw material specifications (including packaging)
- Product specifications
- Production specifications
- Production and process control (including temperature control)
- Allergen control
- Foreign body control
- Product or ingredient sampling and testing, as appropriate, using recognised test methods and competent laboratories
- Batch identification and ‘one up one down’ traceability
- Quarantine procedures
- Monitoring and acting upon customer complaints
- Product Incident Management Plan, including corrective actions
- Product withdrawal and recall procedures
Premises
- Good hygiene design
- Cleaning schedules
- Maintenance schedules
- Chemical control programme
- Pest control programme
- Water supply and quality
- Waste management procedures

Personnel
- Documented procedures for personal hygiene
- Appropriate medical screening of food handlers
- Appropriate training of personnel

A prerequisite programme must be in place before a HACCP system is developed. This will enable the HACCP system to focus on the significant product and process food safety hazards that require specific control to assure food safety. Prerequisite programmes should be documented and records maintained.

Food businesses should keep up to date with legislative changes/best practice and to be aware of potential new food safety issues through, for example:
- Monitoring RASSF notifications and FSA food alerts
- Reviewing scientific literature
- Contact with and advice from research associations and trade associations

HACCP

HACCP is a tool to help food business operators identify, evaluate and control hazards related to a specific product/process line. It has been adopted by the Codex Alimentarius Commission as the international standard for managing food safety based on seven principles. These principles can be implemented with sufficient flexibility to provide a proportionate, risk-based approach which is applicable to any type of food business. HACCP for manufacturers, retailers and the food service industry is not necessarily the same. In a number of cases, particularly in food businesses which do not manufacture foods, hazards can be controlled through the implementation of prerequisite programmes without the need for HACCP, although a hazard analysis should be undertaken to determine if there are any CCPs.

Primary production is exempt from the HACCP requirements under the Food Hygiene Regulation 852/2004.

HACCP principles

<table>
<thead>
<tr>
<th>Principle</th>
<th>Description</th>
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<tr>
<td>Principle 1</td>
<td>Conduct a hazard analysis</td>
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<tr>
<td>Principle 2</td>
<td>Determine the CCPs</td>
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<td>Principle 3</td>
<td>Establish critical limits</td>
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<td>Principle 4</td>
<td>Establish a system to monitor control of the CCP</td>
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<td>Principle 5</td>
<td>Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control</td>
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<tr>
<td>Principle 6</td>
<td>Establish procedures for verification to confirm that the HACCP is working effectively</td>
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<tr>
<td>Principle 7</td>
<td>Establish documentation concerning all procedures and records appropriate to these principles and their application</td>
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Application of the seven principles

Stage 1: Define the scope of the HACCP study

A HACCP study should be carried out on a specific product/process line or a specific range of activities.

Stage 2: Establish a HACCP Team

The size of the HACCP Team will depend on the size and type of food business, but should include a range of expertise appropriate to the product under consideration, its production (manufacture, storage and distribution), its consumption and the associated potential hazards: it should also involve the higher management levels as much as possible. The team leader should be experienced in applying HACCP principles and team members should be HACCP trained. Other relevant specialists may be co-opted as necessary. The membership of the team should be documented.

External expertise is available from guides to good hygiene practice, consultants and directly from FSA to help develop and review the HACCP plan, but the day to day management of the plan is the responsibility of the food business.

Stage 3: Describe the product

The HACCP Team should draw up a full description of the product including, but not limited to:

- Composition (eg raw materials and ingredients, recipe etc)
- Chemical and physical structure (eg Aw, pH, etc)
- Processing (eg heating, freezing, drying, salting, smoking, etc)
- Packaging system (eg vacuum, modified atmosphere, etc)
- Storage and distribution conditions (eg frozen, chilled, etc)
- Required shelf life under prescribed conditions (eg use by or best before date)
- Instructions for product use (eg storage, handling and cooking instructions)

Stage 4: Identify intended use

The HACCP Team should identify the intended use of the product by the customer and define the consumer target groups including the suitability of the product for vulnerable groups of the population (eg infants or the elderly, allergy sufferers, etc).

Stage 5: Construct a flow diagram

The HACCP Team should draw up a flow chart setting out all aspects of the food operation from raw materials selection through to the processing, storage, distribution and retail/consumer handling. Each step of the process (including process delays and recycle/rework loops) should be clearly outlined in the correct sequence together with sufficient technical data. Types of data may include, but are not limited to:

- Specifications for raw materials/ingredients and packaging
- Floor plans, equipment and services layout
• Equipment design features
• Flow of products
• Production parameters, in particular time/temperature for raw materials and intermediate and finished products, including potential for delay
• Routes of potential cross-contamination
• High/low risk area segregation
• Product storage and distribution conditions
• Cleaning and disinfection procedures
• Waste disposal procedures
• Personnel routes and personal hygiene practices
• Consumer use instructions

Stage 6: On-site confirmation of flow diagram

The HACCP Team should confirm each step of the flow diagram on site during operating hours. The flow diagram should be amended to take account of any deviations found from the original diagram.

Stage 7: List all potential hazards associated with each process step, conduct a hazard analysis and consider any measures to control the identified hazards

The HACCP Team should list all the potential hazards that may reasonably be expected to occur at each step in the production process. This should include all hazards which may be present in the raw materials, hazards that may be introduced during the process and hazards that survive the process step.

The team should then conduct a hazard analysis to identify which hazards need to be eliminated or reduced to acceptable levels. The following should be considered:

• The likely occurrence of the hazard (eg previous company/industry experience)
• The severity of the hazard (eg life-threatening/mild, chronic/acute)
• Numbers of consumers potentially exposed to the hazard (eg distribution)
• Age/vulnerability of those exposed (eg young/old, allergy sufferers)
• Survival or multiplication of pathogenic micro-organisms
• Production or persistence of toxins, chemicals or physical agents
• Contamination of raw materials, intermediate products and/or final products

The hazard analysis should be documented.

The team should then consider what control measures, if any, exist which can be used to prevent, eliminate or reduce hazards to an acceptable level. More than one control measure might be required to control a specific hazard that occurs at different parts of the production process and more than one hazard might be controlled by one control measure. Control measures need to be underpinned by the prerequisite programmes.

Hazard analysis is needed to determine if there are CCPs but, in the event that no CCPs are identified, a formalised HACCP system is not required. This may include marqueses, market stalls and mobiles sales vehicles; establishments mainly serving beverages (bars, coffee shops etc); small retail shops (such as grocery shops); and the storage and transport of pre-packed food or non-perishable food.
Stage 8: Determine the CCPs

The HACCP Team should identify all CCPs in the product/process. This requires professional judgement and may be facilitated by the application of a decision tree. A number of decision trees have been developed: an example is given in Figure 1.

**Figure 1: Example of a decision tree to identify CCPs.**

*Answer each question in sequence at each process step for each identified hazard*

When using a decision tree, each step identified in the flow diagram must be considered in sequence. At each step, the decision tree must be applied to each of the identified hazards. If a hazard has been identified at a step where control is necessary for safety and no control measure exists at that step, or at any other, the product or process should be modified at that step or at an earlier or later stage, to include a control measure. The decision tree should not be used if the hazard is managed by the prerequisite programmes. The use of the decision tree should be documented. Training in the application of a decision tree is recommended.
Stage 9: Establish critical limits for each CCP

The HACCP Team should identify critical limits for the control measure(s) at each CCP. The critical limits separate acceptability from unacceptability. They are set for observable and/or measurable parameters which can demonstrate that the critical point is under control. Those that can be observed or measured relatively quickly are to be preferred, for example temperature, time, pH, moisture content, preservative or other ingredient level, or sensory parameters such as visual appearance or texture.

Some critical limits are defined in legislation or guides to good hygiene practice, while others may need experimental data to be collected or advice from specialists with appropriate expert knowledge. In some cases, it may be necessary to specify more stringent levels to reduce the risk of exceeding a critical limit due to process variation. Details of the establishment of the critical limits should be documented.

Stage 10: Establish a monitoring system for each CCP

The HACCP Team should establish a monitoring system for each CCP to ensure compliance with specified critical limits. The monitoring system must be able to detect loss of control at CCPs and ideally should provide information in time for corrective action to be taken.

Monitoring systems may either be on-line (eg time/temperature measurements) or off-line (eg measurement of salt, pH or $A_w$). Off-line systems require monitoring to be carried out away from the production line and occasionally may result in a very long time period elapsing before results are available and action can be taken. This may not be appropriate for all food products eg chilled foods with short shelf-lives.

Monitoring systems may also be continuous (eg recording process temperatures on a thermograph) or discontinuous (eg sample collection and analysis). Discontinuous systems must ensure that the sample monitored is representative of the bulk product.

Whichever monitoring system is chosen, the team must ensure that the results obtained are directly relevant to the CPP and that any limitations are fully understood.

The team must also decide who is to perform monitoring and checking; when monitoring and checking is to be performed; and how monitoring and checking is to be performed and recorded. Records associated with monitoring CCPs must be signed by the person(s) doing the monitoring and verified by a responsible reviewing official in the company.

Stage 11: Establish a corrective action plan

The HACCP Team should specify the corrective action(s) to be taken when monitoring results indicate a failure to meet a critical limit or when monitoring results indicate a trend towards loss of control. This must include action to be taken with regard to products that have been manufactured during the period when the process was out of control. The corrective actions should be documented.
Stage 12: Verification including validation

The HACCP Team should validate the HACCP plan prior to implementation to ensure that all significant hazards have been identified and that the selected controls are adequate to assure food safety. Validation should include formal sign-off of the HACCP plan by the person(s) responsible for food safety management.

The team should then put in place procedures to be used to determine compliance with the validated HACCP plan. There are two main aspects of verification; firstly, demonstrating conformance; and secondly, gathering information that the HACCP system and the pre-requisite requirements are effective. This may include a review of the HACCP plan and its records; random sampling; testing at selected CCPs; testing intermediate or finished products; and analysis of customer complaints.

The frequency of verification depends on the type of food business, the hazards involved and the number of deviations detected over time. Independent verification of the HACCP system can be carried out by an accredited third party auditor.

Stage 13: Review the HACCP system

The HACCP Team must have a mechanism in place that will automatically trigger a review of the HACCP system prior to any changes which may affect overall product safety. Examples of change include:

- Change in raw material/supplier (including change of origin)
- Change in ingredients/recipe
- Change in processing conditions
- Change in packaging, storage and/or distribution conditions
- Change in staff levels/responsibilities
- Change in consumer use
- New information on hazards associated with the product

At least annually, the HACCP Team should also perform a periodic review of the HACCP system.

Any changes arising from the review must be incorporated into the HACCP plan. Data arising from the review must also be documented.

Stage 14: Establish documentation and record keeping

Documentation and record keeping should be appropriate to the size and type of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained.

Documentation includes:

- HACCP plan
- Hazard analysis
- CCP determination
- Critical limit determination and
- Modifications to the HACCP system
Record keeping includes:
  - CCP monitoring activities
  - Deviations and associated corrective actions and
  - Verification activities

Documents and records should be kept for a sufficient time to allow the competent authority to audit the HACCP system.

Good Practice Guides

National Guides to Good Hygiene Practice are being developed by individual food sectors to support the effective application of the new EC Food Hygiene Regulation. Good Practice Guides are voluntary but where a food business is following the guidance in a recognised guide, the enforcement authority must take this into account when assessing compliance with the legislation. Several new guides are being developed and are expected to become available during 2006. Existing guides are also being revised in line with the new requirements. FSA assesses national guides developed in accordance with their guidelines and recognises those that it considers are practicable guides to compliance with the legislation. A full list of Good Practice Guides and their status is available on its website.

FURTHER INFORMATION

Further information on HACCP and guides to good hygiene practice can be obtained from the EC website or the FSA website.

Information on HACCP training can be obtained from the Sector Skills Councils:

Improve (food and drink manufacturing)

People 1st (hospitality)

Skillsmart (retail)
MODULE 2: INDUSTRY INCIDENT RESPONSE

INTRODUCTION

This section is intended to assist food and feed businesses to put in place an Incident Management Plan and product withdrawal/recall procedures to ensure that, when a problem does occur, consumer safety is not compromised. This includes the risk assessment process to determine the actions required in the event of an incident.

INCIDENT MANAGEMENT

Operator Responsibilities under the EC General Food Law Regulation 178/2002

Articles 19 and 20 of EC Regulation 178/2002 lay down the requirements for food business operators to withdraw or recall unsafe food and feed from the market and to inform the competent authorities where, in the case of food, there is reason to believe that the food is not in compliance with food safety requirements and, in the case of feed, if the feed does not satisfy specified feed safety requirements. In cases where the product may have reached the final consumer, food business operators should inform the competent authorities of action taken to prevent risks to consumers, including consumer notification, and are required to collaborate with the competent authorities on action to avoid or reduce risks posed by a food or feed which they have supplied.

It is important for food business operators to have systems and procedures in place, in the form of an effective Incident Management Plan and product withdrawal/recall procedures, in order to meet their legal obligations and to fulfil their responsibility to consumers.

Under the EC General Food Law Regulation 178/2002, the brand owner is regarded as the food business operator. Food manufacturers and suppliers should therefore report incidents to the brand owner who will take appropriate action.

Incident Management Plan

The risk of unsafe food reaching consumers can be minimised through the implementation of an Incident Management Plan. An effective plan will ensure compliance with legal requirements; provide a systematic assessment of incidents; manage and control serious incidents; and protect company assets, which includes brand reputation.

The key components of an Incident Management Plan are:

1. Product Incident Policy
2. Incident Management Team
3. Procedures and supporting documentation
4. Supporting Systems
5. Resources
6. Training

1. Product Incident Policy

A policy on the handling of food safety incidents should be agreed at a senior level within the company and should be available to anyone within the business who may be involved with
incident management. The policy should set out the objectives of the Incident Management Plan and the requirement to provide adequate resources in the event that a product withdrawal/recall becomes necessary.

2. Incident Management Team

An Incident Management Team should be in place to make decisions in the event of a food safety incident. The team should ideally comprise a group of Directors and/or Senior Managers responsible for, or with a detailed knowledge of, the following functions:

- Technical/Safety/Quality
- Sales
- Marketing/Public Relations
- Buying
- Production
- Distribution/Logistics
- Regulatory Affairs/Legal
- Consumer services

Any or all of the above functions can be included in the team, but consideration should be given to the need for a fast response; the larger the team, the slower decisions will be taken. Team members should have clear roles and responsibilities, and it is important that actions can be delegated to other support staff that have been trained in incident management. A single co-ordinator should be nominated to lead the Incident Management Team and manage any withdrawal/recall of products. A record should be kept of, for example, actions taken/telephone calls made by members of the team during the incident.

As in-house expertise may not be available to small and medium size businesses, it is important that careful consideration is given in the Incident Management Plan as to how this expertise can be obtained and put into place at very short notice.

3. Procedures and supporting documentation

An Incident Management Plan should include detailed procedures and supporting documentation covering, as appropriate, the following:

- Objective
- Incident investigative procedures
- Incident management procedures
- List of Incident Management Team members and deputies
- Specified responsibilities and tasks of the members of the Incident Management Team
- Operational procedures for the Incident Management Team
- Operational procedures for specific tasks
- Product withdrawal/recall procedures
- Incident status register
- Checklists for tasks
- Internal company contact list
- Customer contact list
- Supplier contact list
- Enforcement Agency contact list (including police)
4. **Supporting Systems**

Integrating the required information from the Incident Management Plan into computer systems and networks will be beneficial and allow ease of access and updating. It is important to consider integrating such information as traceability records, stock inventory, process and quality control records to enable these to be accessed remotely; easily and readily interrogated when time constraints are demanding and easily transferred to external experts and/or to customers.

If such systems are not in place, access to all supporting documentation should be readily available by other means to key staff to enable the incident investigation to be carried out as thoroughly and as quickly as possible.

5. **Resources**

The Incident Management Team should have appropriate resources and support at all times and this requirement should be carefully considered during the development of the Incident Management Plan. For example: the number of staff required to carry out the operational tasks within the product withdrawal/recall process in specified time scales; the provision of appropriate heat, light, food and drink to continue to work for a significant period of time; and the ability of hardware and software to cope with a high level of incoming and outgoing messages/calls.

6. **Training**

Training to deal effectively with an incident, particularly if this leads to a product withdrawal/recall, is essential to achieving a successful outcome. It is important that the Incident Management Team reviews the skills base of the team and support staff. If any shortcomings are identified, these should be addressed by appropriate training and/or by bringing in skills from outside the business.

Incident management scenarios to test and review the Incident Management Plan are highly recommended.

**Incident Management Process**

Although there are key steps relating to the management of any incident, each incident will be unique and should be handled accordingly. Therefore whilst the process to investigate and manage an incident can be defined as key steps, the outcome of the process cannot be standardised.

The key steps within the incident management process are:

1. **Risk assessment**
   - **Hazard identification**
- Hazard characterisation
- Exposure assessment
- Risk characterisation

2. Risk management
3. Implementation of management decisions
4. Risk communication

A **hazard** is defined as a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

A **risk** is defined as the probability or likelihood of an adverse health effect occurring, and severity of that effect, as a consequence of a hazard.

**Risk Assessment** is defined as the scientific evaluation of known/potential adverse health effects resulting from human exposure to food borne hazards.

**Risk Management** is defined as the process of evaluating and weighing policy options to accept or minimise or reduce an assessed risk and, if required, to select and implement appropriate action.

**Risk Communication** is defined as the interactive process of exchange of information/opinion on hazards, risk, risk-related factors and risk perceptions among all interested parties. This includes the explanation of risk assessment findings and the basis of the risk management decisions.

**Undertaking Risk Assessment**

There are four steps within the risk assessment process:

- Hazard identification - identification of a hazard
- Hazard characterisation - identification of the nature of the hazard’s effects
- Exposure assessment - assessment of exposure to the consumer
- Risk Characterisation - comparison of exposure assessment against known data sources

**Hazard Identification**

Food businesses may be made aware of a potential food safety problem from a number of sources such as consumers, customers or enforcement authorities. Whatever the source of the information, there should be a mechanism in place to alert and inform an appropriately competent person within the company who can assess the significance of the information.

Information should be collected in order to understand fully the hazard, the nature of the complaint/issue and its significance.

**Hazard Characterisation**

Based on the information collected, an assessment and judgement should be made of the possible effect of the hazard, particularly if there is any possible health risk to consumers. It is important to consider not only short-term effects, but also possible long term or cumulative effects, associated with the hazard.
Exposure Assessment

Based on the information collected, collated and assessed within the hazard identification and characterisation processes, it is essential that an accurate assessment be made of the likely or actual exposure to consumers. Much of the information required to make this assessment will be in the possession of the company or available from its customers.

Risk Characterisation

Through the risk characterisation process, the information on exposure assessment and known safety data is directly compared and assessed. This may require third party expertise and consideration of a broader perspective if an issue is widespread across the food chain.

In carrying out these four inter-related processes, the company should obtain as much detailed information as possible and have company records at hand in order to understand fully the hazard and risk. A good method of collating and assessing this information is to have a series of questions, which are required to be answered, allowing an accurate, logical and scientifically based judgement to be made during the risk management process.

It is important to understand that each incident should be managed on a case-by-case basis and even though standardised questions or checklists may be used, the circumstances will be unique to the actual incident.

Wherever possible, judgements and decisions should be based on scientific evidence and fact. However there will be occasions where uncertainty exists; this must be acknowledged and decision-making must still take place. The company should ensure that it can demonstrate that it has taken all reasonable and appropriate steps to protect consumers and has fulfilled its legal obligations eg through appropriate documentation.

Undertaking Risk Management

This is the process whereby the company considers alternative courses of action to accept or reduce the risk and, if required, to implement appropriate action. As part of this process, the company may decide to consult other interested parties, whilst considering the risk assessment and other factors. Typically action arising from the risk management process would be:

- Review, update and monitor food safety management procedures including, as appropriate, quality assurance procedures, raw materials specification, product labelling etc.
- Carry out a product withdrawal
- Carry out a product recall

Product Withdrawal is defined as the process by which a product is removed from the supply chain, except that in the possession of consumers.

Product Recall is defined as the process by which a product is removed from the supply chain, including that in the possession of consumers, when other measures are not sufficient to achieve a high level of health protection.
Implementing Management Decisions

In the event of a product withdrawal/recall, the procedures laid down within the Incident Management Plan should be followed.

The Incident Management Team should manage the product withdrawal/recall and ensure the actions taken are in compliance with the Incident Management Policy.

Undertaking Risk Communication

Food business operators have a legal obligation to inform other interested parties and consumers when a product recall is undertaken. This may be done by a number of methods eg newspaper advertisements, notices at point of sale, websites and carelines. It is, however, important for food business operators to ensure that their trade customers are fully aware of the details concerning the product recall and that consumers are aware of the action they are required to take.

There are three important principles relating to effective risk communication:

- Communication interface
- Accuracy of communication
- Speed of communication

If any one of these principles is absent, in the event of an incident, a company, its customers and consumers are placed at risk.

During a product recall, contacting the right people without delay is essential. Within an Incident Management Plan there should be specific contact lists, however, the number of organisations involved in a recall may be significant and contacts may have to be prioritised. Advanced planning and maintenance of accurate and up-to-date contact lists is essential; access to emergency contact lists should be available at all times, allowing communication at any time of day or night.

There are a number of organisations which are critical contacts with respect to incident management and product recall. In such cases, it is beneficial for companies to establish good working relationships and gain an in-depth understanding of each other’s requirements. This is particularly beneficial for local government enforcement agencies i.e. Trading Standards, Environmental Health and, particularly in the event of evidence of, or threat of, malicious contamination, the Police.

Incident Notification

Articles 19 and 20 of EC Regulation 178/2002 require food business operators to inform the competent authorities immediately where, in the case of food, there is reason to believe that the food may be injurious to human health, and in the case of feed, if the feed does not satisfy specified feed safety requirements.

It is advisable for a company to undertake an initial risk assessment and consider appropriate risk management options prior to formal notification as this will greatly assist with the understanding and communication of the incident but an early call could be made to the relevant local authority and/or FSA for advice.
FSA has an online form which food businesses may use to notify incidents where there is a need to withdraw or recall products from the market. Businesses should also notify the relevant local authority or, in the case of imports, the relevant port health authority.

**Dealing with Large and Complex Incidents**

When a food safety incident is deemed by FSA to be large and complex, because it could affect a large number of food products, FSA will convene a Scoping Group comprising Agency officials and representatives from industry, including implicated companies and relevant trade associations, the enforcement authorities and consumer organisations. The Scoping Group will establish the nature and scale of the issue, map out the part of the supply chain involved, contribute to risk assessment and risk management options, and develop an action plan and communication plan.

**Trade Association Responsibilities**

The role of trade associations is to work closely with its members, other trade bodies in the supply chain, FSA and local authorities in the effective and efficient handling of food safety incidents. This might include having systems and procedures in place such as:

- 24/7 contact details for member companies
- Principal points of contact for members, FSA and media (including out of hours)
- An internal incident management team

The extent to which trade associations are involved in a food incident will depend on its nature, scale and complexity. In general, the action taken by trade associations might include:

- Reminding members of their legal obligation to notify FSA and their local authority about affected products
- Obtaining expert advice from FSA on the potential risk to consumers
- Communicating information/action to members in a timely manner
- Seeking additional information or clarification on aspects that are unclear
- Liaising with other trade associations at a UK, EU and international level
- Collecting and collating information from members for submission to FSA where this is necessary over and above companies legal requirements
- Collating issues/concerns from members for submission to FSA
- Organising meetings with members and others as appropriate
- Preparing position statements and Q and As
- Handling generic (non-company specific) media enquiries on behalf of members
- Assisting FSA and members with risk communication activities
- Contributing to the post-incident review and lessons learnt

Trade associations represent the interests of their membership and will seek to promote cooperation with interested parties in the event of an incident.

Those companies who are not affiliated to a trade association should take steps to ensure that they are fully aware of how advice and support can be gained to assist them in dealing with an incident. Direct dialogue with local government agencies, and where necessary with the police, should be undertaken to ensure their legal obligations are met and that any risk to the consumer is minimised.

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1 Trade associations are not in a position to collect information from their members that is legally required to be provided by them to FSA and their local authority.