FOOD STANDARDS AGENCY

PRINCIPLES FOR PREVENTING AND RESPONDING TO FOOD INCIDENTS

A GUIDANCE DOCUMENT PRODUCED BY

THE FOOD STANDARDS AGENCY'S TASKFORCE ON INCIDENTS

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This has been produced by the Taskforce on Incidents which was chaired by the **Food Standards Agency** and with members drawn from the following organisations

British Hospitality Association (BHA)
British Retail Consortium (BRC)
Chartered Institute of Environmental Health (CIEH)
Trading Standards Institute (TSI)
Association of British Insurers (ABI)
Food and Drink Federation (FDF)
Local Authorities Co-ordinators of Regulatory Services (LACORS)
Small Business Council
National Consumer Council
National Farmers Union (NFU)
Which?

Plus 2 independent members

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PREFACE

WHY ARE THESE DOCUMENTS IMPORTANT?

This guide has been developed by the Taskforce on Incidents, to aid industry and others prevent or deal efficiently with food incidents if they occur.

Food incidents can have an impact on human health, undermine consumer confidence in the quality and safety of food and are costly to the UK economy.

The contents are voluntary in nature and do not replace legal obligations set out in EC General Food Law Regulation 178/2002, but aim to summarise current best practice in incident management. They draw on lessons learnt by all key stakeholders in the prevention and management of food incidents and updates will be added as approaches are refined and improved.

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 that could require intervention to protect consumers' interests.

Food and feed (where it impacts on food safety or quality) which does not meet legal requirements that could require intervention to protect consumer's interests are included in the definition of incidents and are included within the scope of this document.

TASKFORCE ON INCIDENTS

The Taskforce on incidents was set up by the Food Standards Agency (The Agency) to strengthen existing controls in the food chain in order to reduce the possibility of future contamination incidents occurring, such as those involving Para Red and Sudan I Also to improve the management of such incidents where they do occur.

The Agency facilitated the Taskforce, which included representatives from the food industry, enforcement authorities, consumer organisations and independent members.

AIM AND SCOPE

The aim of the documents is to outline the roles and responsibilities of all key players in preventing and responding to food and feed incidents. It outlines the main elements of incident prevention and also a coherent process of incident response from notification, through risk assessment, risk communication and risk management, to post-incident actions. The document provides guidance for those who have a role in incident prevention or response in the food industry, enforcement community or competent authority (The Agency). These guidelines are primarily intended to address those incidents that require action in accordance with EC General Food Law Regulation 178/2002. As far as possible the document has been arranged so that individual modules (Incident Prevention, Incident Response by Industry, FSA or Enforcement Authorities) can be used independently.

FOOD AND FEED LEGISLATION

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. The key obligations on food and feed business operators are:

Key obligations of food and feed business operators	
Safety	Operators shall not place on the market unsafe food and feed
Responsibility	Operators are responsible for the safety of the food and feed which they produce, transport, store or sell
Traceability	Operators shall be able to rapidly identify any supplier or consignee
Transparency	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 the Agency and the relevant enforcement authority i.e. the local authority or the Port Health Authority. In relation to Northern Ireland, the relevant District Council or Department of Agriculture and Rural Development (DARD) regarding feed. See also annex A.
Emergency	Operators shall immediately withdraw food or feed from the market if they have reason to believe that it is not safe
Prevention	Operators shall identify and regularly review the critical points in their processes and ensure that controls are applied at these points
Co-operation	Operators shall co-operate with the competent authorities in actions taken to reduce risks

Further details on this and other relevant food legislation can be found in Annex A. Draft UK guidance on Regulation 178/2002 can be found in Annex B. Food business operators need to ensure that they are aware of the requirements of food and feed legislation relevant to their operations.

MODULE 1: INCIDENT PREVENTION

1.1   INTRODUCTION

This section is intended to assist food and feed businesses to identify and control potential hazards in order to ensure the safe production of food and minimise the number of food incidents. This module does not introduce any new obligations on businesses.

1.2   FOOD SAFETY MANAGEMENT SYSTEMS

All food businesses should have a full understanding of the products they produce, manufacture, sell and/or distribute; and shall 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 Hazard Analysis Critical Control Point (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. All companies operating in the food industry, irrespective of size, should have access to appropriate expertise. This expertise may be available in-house or through a consultancy arrangement.

1.3   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 good manufacturing and hygiene practices (GMP, GHP).

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.

1.3.1   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 and supervision of personnel

The prerequisite requirements need to 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 may wish to keep up to date with legislative changes/best practice and to be aware of potential new food safety issues through, for example:
- Monitoring Rapid Alert System for Food and Feed (RASFF) notifications and Food Standards Agency food alerts
- Reviewing scientific literature
- Contact with and advice from research associations and trade associations

1.4   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 the prerequisite requirements without the need for HACCP, although businesses should undertake a hazard analysis to determine if there are any Critical Control Points (CCPs).

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

1.4.1   HACCP principles

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

1.4.2 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 should 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 to be HACCP trained or understand the principles of HACCP. 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 from information provided by the Agency, 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 (e.g. raw materials and ingredients, recipe etc)
- Chemical and physical structure (e.g. A_w, pH, etc)
- Processing (e.g. heating, freezing, drying, salting, smoking, etc)
- Packaging system (e.g. vacuum, modified atmosphere, etc)
- Storage and distribution conditions (e.g. frozen, chilled, etc)
- Required shelf life under prescribed conditions (e.g. use by or best before date)
- Instructions for product use (e.g. 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 (e.g. 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 (e.g. previous company/industry experience)
- The severity of the hazard (e.g. life-threatening/mild, chronic/acute)
- Numbers of consumers potentially exposed to the hazard (e.g. distribution)
- Age/vulnerability of those exposed (e.g. 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 requirements.

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 marquees, 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

| Q.1 | Do control preventative measure(s) exist? |

- Yes
- No
- Modify step, process or product

Is control at this step necessary for safety?
- Yes

- No → Not a CCP → **Stop (*)**

| Q.2 | Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level? (**) | Yes |

- No

| Q.3 | Could contamination with identified hazard(s) occur in excess of acceptable levels(s) or could these increase to an unacceptable level? (**) |

- Yes
- No → Not a CCP → **Stop (*)**

| Q.4 | Will a subsequent step, prior to consuming the food, eliminate the identified hazard(s) or reduce the likely occurrence to an acceptable level? (**) |

- Yes
- No → **Critical Control Point**

Not a CCP → **Stop (*)**

(*) Proceed to the next identified hazard in the described process
(**) Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCP's of HACCP plan.

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. It would be sensible to record how the decision tree was used. 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 (e.g. time/temperature measurements) or off-line (e.g. 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 e.g. chilled foods with short shelf-lives.

Monitoring systems may also be continuous (e.g. recording process temperatures on a thermograph) or discontinuous (e.g. 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 should 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 should 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.

1.5   GOOD PRACTICE GUIDES

National Guides to Good Hygiene Practice are being developed by individual food sectors to support the effective application of the food hygiene legislation. 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. . Existing guides are also being revised in line with the new requirements. The Agency assesses national guides developed in accordance with their guidelines, and recognises those that it considers are practicable guides to compliance with the legislation. Details of the Good Practice Guides and their status is available on www.food.gov.uk.

1.6   FURTHER INFORMATION

Further information on HACCP and guides to good hygiene practice can be obtained from the [ECs 'Europa' website](#) or [The Agency's 'food' website](#). Information on HACCP training can be obtained from the Sector Skills Councils:

- [Improve](#) (food and drink manufacturing)
- [People 1st](#) (hospitality)
- [Skillsmart](#) (retail)

1.7   TRACEABILITY

Legal traceability requirements for all EU food and feed businesses took effect on 1 January 2005. Further details of these requirements can be found at Annex B and in detail at the following web address:

http://www.food.gov.uk/multimedia/pdfs/fsa1782002guidance.pdf

These legal requirements do not require internal traceability, that is, a system which would allow linkages to be made between the sale of finished products and the source of materials used to produce them. Nevertheless, businesses may want to consider the benefits to be gained from such systems, specifically:

- improved consumer protection through better targeted, and more rapid recalls and/or withdrawals;
- greater efficiency within businesses, with more information to assist in process control and management;
- provision of reliable information to consumers to support authenticity claims about products;
- deterrence of fraud; and
- increased consumer confidence.

It is for businesses to decide whether to adopt internal traceability on the basis of costs and benefits. In addition to meeting regulatory demands, traceability systems:

- provide information within food businesses to assist in process control and management e.g. stock control, efficiency of material usage and quality control; and
- assist businesses when problems arise supporting effective withdrawal or recall of products, allowing detection of the cause of a problem so that targeted action can be taken to prevent recurrence.

Accurate and timely information and continued confidence in the information provided can be brought about by improved traceability records and regular testing of the robustness of their traceability and recall procedures**.**

Some questions that food businesses should ask themselves are:

- how reliable are your traceability records?
- have you tested the robustness of your traceability and recall procedures? and
- are they subject to regular review?
- how far can you be sure that traceability extends?
- what steps have you taken to verify the reliability of the traceability systems of your suppliers?
- in the event of an incident, would you be able to narrow down the problem to the affected batch or batches?

MODULE 2: INDUSTRY INCIDENT RESPONSE

2.1   INTRODUCTION

This section has been written by the food industry to represent best practice. It 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. This module does not introduce any new obligations on businesses.

2.2   INCIDENT MANAGEMENT

2.2.1 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. They 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.

2.2.2 Incident Management Plan

It is important for food business operators to have systems and procedures in place which minimise the risk of unsafe or unfit food being placed on the market, in order to meet their legal obligations and to fulfil their responsibility to consumers. The risk of unsafe food reaching consumers can be minimised through the development and implementation of an effective Incident Management Plan and product withdrawal/recall procedures.

> 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 should take appropriate action

An effective plan will help ensure compliance with legal requirements; provide a systematic assessment of incidents; manage and control serious incidents; and protect company assets, which include 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 be made 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 would ideally comprise a group of 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 more slowly 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 trained in incident management.

A single co-ordinator may wish to be nominated to lead the Incident Management Team and manage any withdrawal/recall of products. A record should be kept of actions taken, for example telephone calls made by members of the team during the incident and details relating to these telephone calls.

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)
- Service providers/ consultants contact list
- Key document samples or templates
- Training procedure
- Testing procedure
- Plan review procedure

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 may 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 is to 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. 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 out going 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, they could 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.

2.2.3 Incident management process

Although there are key steps relating to the management of any incident, each incident will be unique and 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
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 two way 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*

1. Undertaking Risk Assessment

There are four steps within the risk assessment process:
- Hazard identification
- 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

a. 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.

b. 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.

c. 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.

d. 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 attempt to 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. These will allow an accurate, logical and scientifically based judgement to be made during the risk management process.

It is important to understand that each incident is to 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 are to 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 e.g. through appropriate documentation.

2.   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
- Provide information and advice to consumers

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

Product recall means the process by which a product is removed from the supply chain and where consumers are advised to take appropriate action for example, to return or destroy food.

It is advisable to keep a record of initial risk assessment and the reasons why the decision was made to follow a course of action.

3.   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 incident management policy.

4.   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 e.g. 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 could 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.

2.2.4   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 collate all appropriate data and undertake an initial risk assessment prior to formal notification; if in doubt an early call could be made to the relevant local food authority and/or the Agency (Tel 020 7276 8448) for advice. Collating data and having accurate information in place , will greatly assist with the understanding of the incident by local authorities and/or the Agency.

The Agency 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.
http://www.food.gov.uk/foodindustry/regulation/foodfeedform

Businesses should also notify the relevant local authority or, in the case of imports, the relevant port health authority. In relation to feed in Northern Ireland, the Department of Agriculture and Rural Development (DARD) should be informed.

2.2.5 Dealing with Large and Complex Incidents

When a food safety incident is deemed by The Agency, industry or other stakeholders to be large and complex, because it could affect a large number of food products, the Agency will, at the suggestion of any stakeholder, convene a Scoping Group. More detailed information on the workings of any Scoping Group can be found in Module 3.

2.2.6 Trade Association Responsibilities

The role of trade associations is to work closely with its members, other trade bodies in the supply chain, the Agency and local authorities in the effective and efficient handling of food safety incidents. This may include having systems and procedures in place such as:
- 24/7 contact details for member companies
- Principal points of contact for members, the Agency 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 may include:

- Reminding members of their legal obligation to notify the Agency and their local authority about affected products
- Obtaining expert advice from the Agency 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, where possible, from members for submission to the Agency where this is necessary over and above companies legal requirements
- Collating issues/concerns from members for submission to the Agency
- 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 the Agency 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 co-operation 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.

Module 3: THE FOOD STANDARDS AGENCY INCIDENT RESPONSE

3.1   CORE PROCESS

An <u>incident</u> 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 that could require intervention to protect consumers' interests.

For all incidents the key steps are the same:

- Incident notification
- Information gathering for risk assessment
- Risk assessment
- Risk management options and decision Making
- Risk communications (aligned from the outset)
- Follow up, review and lessons learned
- Post incident actions (if required)

Within the Agency, consistency, including an audit trail for decision-making, is achieved by managing all incidents according to an agreed incident protocol. The Protocol is risk-based and can be tailored to the size and complexity of the incident. At the core of the Agency's response is an incident team who manage the backbone of incident response and management – log all notifications, ensure protocol is followed, organise and support appropriate meetings, maintain the audit trail, help gather information from stakeholders.

In accordance with the Incident Protocol, a core principle is to convene an ad hoc incident group, chaired by the Head of Division in the relevant policy area (e.g. Food Protection Division, Microbiological Safety Division), which manages the process from risk assessment to outcome. It is important to note, that from the outset, membership of the ad hoc team must include representatives from the incident team, lead policy division, Legal Division, Communications Division, and other relevant policy areas such as Local Authority Liaision Division, as required. The Group will meet daily, if required, in the early days of an incident. The chair of the ad hoc group is accountable to Directors for the outcome of the incident.

3.2 MAJOR FOOD CONTAMINATION ISSUES

When there is a food contamination issue involving a serious and/or widespread outbreak of illness the Agency will work with other government agencies, notably the HPA, to understand, manage and communicate the risk and, where appropriate, provide advice to people who may have eaten the

affected products and may be concerned. To do this an Outbreak Control Team (OCT) is usually set up which will be chaired by the HPA. Where the incident is serious or widespread it is normal practice for the FSA and the relevant Local Authorities to be part of the OCT as well as the HPA. When the Agency is a member of the OCT the Agency will follow the same guidelines outlined in this document when working with companies, Local Authorities etc

In the case of large and complex incidents it may also be appropriate to convene a Scoping Group, comprising of: Agency officials, representatives from industry, including implicated companies and relevant trade associations, the enforcement authorities and consumer organisations. The Scoping Group can be convened at the suggestion of any stakeholder

The Scoping Group will:-

- Establish the nature and scale of the issue and to map out the part of the supply chain involved;

- The Trade Association representatives will facilitate collection of information from their membership and/or sector and pass to the Agency;

- Lacors, Home Authority and relevant local food authority representatives will raise issues relevant to local authorities and co-ordinate input as appropriate;

- Contribute to any risk assessment;

- Contribute to any risk management decisions;

- To develop an action plan and identify the roles and responsibilities of each stakeholder;

- To agree a co-ordinated communication plan for stakeholders; (including consideration on how best to reach small businesses and those companies not represented by a Trade Association)

.

The need for the Group and the frequency of its meetings will be determined by the Agency according to the potential size and complexity of the incident. It will comprise Agency officials and representatives from industry, including implicated companies and relevant trade associations, the enforcement authorities and consumer organisations. It is likely to meet either before or just after the ad hoc group, depending on how events unfold. The Agency will consider wherever possible, the harmonisation of a large incident with EC

Member States and will take advise from its EU and International strategy branch. Further information of what can be found at :

http://www.europa.eu.int/comm/food/committees/regulatory/scfcah/toxic/summary19_en.pdf and http://www.food.gov.uk/multimedia/pdfs/itf0528.pdf

3.3   INCIDENT NOTIFICATION

Best practice indicates that stakeholders alert the Agency immediately of a potential problem using the definition of an incident above, and that all relevant information be shared by those notifying in an open and timely manner.

EXAMPLES OF SOURCES & TYPES OF INFORMATION NOTIFIED. Notifications under EC General Food Law Regulation 178/2002 by the food industry. Surveys (conducted by the Agency/others).

- Uncontrolled/accidental release to the environment, reported by e.g. Environment Agencies.

- On farm incidents.

- Reports from Local Food Authority enforcement officers.

- Reports from ports of entry.

- Significant cases/outbreaks of food poisoning/suspected food poisoning from public health bodies.

- Pesticides Safety Directorate, Veterinary Medicines Directorate reports.

- Information from other EU Member States via the RASFF system.

- Food or feed that contains a substance at a concentration above the legal limit, or one prohibited in food and feed.

Food with incorrect allergy labelling.

If in any doubt, call the Agency (Tel 020 7276 8448).

▶ You can also inform the Agency online, using the incident notification report form.

http://www.food.gov.uk/foodindustry/regulation/foodfeedform

▶ **Operators must also notify their Local Food Authority**. In relation to feed in Northern Ireland, the Department of agriculture and Rural Development (DARD).

3.3.1 The Agency initial actions post-notification (Please refer to diagram on page 3-10)

- The Agency Incident Team logs report on incident database
- Move swiftly to determine additional information required, via ad hoc group
- In the case of significant outbreaks the Agency makes early contact with the Outbreak Control Team.
- Assess likely severity and complexity of the emerging issue
- For severe/complex incidents the Agency provides early warning to key stakeholders both internally and externally, explaining that updates will follow as information becomes available.
- For severe/complex incidents convene Scoping Group, if required.

The severity of an incident will be assessed on the public health risk, including impact on special groups. Incident complexity will be based on size and scale (local/national/international, number of cases or number of products affected and number of organisations likely to be involved e.g. manufacturers, retailers, Government bodies, other Agencies).

3.4 INFORMATION GATHERING FOR RISK ASSESSMENT

The extent of the initial information available will vary from one incident to another. In addition, the key questions may vary according to the class of hazard and the cause of the incident. Detailed lists are provided at Annexes C-F to act as a guide.

- Broadly, the aim is to establish the detailed nature of the hazard, where and when the incident occurred, who is likely to be affected, size and complexity (UK, overseas), potential for wider implications (e.g. other parts of the food industry) and if food products are affected, their quantities, distribution and availability to consumers.
- In the Agency, the incident ad hoc group will review the information gathered and use it to underpin a risk assessment.
- In large food incidents there may be many hundreds of products affected. This will require coordinated action through the **Scoping Group. See 3.2**

3.5   RISK ASSESSMENT

Following notification, the ad hoc incident group will undertake a risk assessment. In some instances, assessment of the issue may be relatively straightforward and consist of comparison of information received with pre-existing limits, guidelines or standards.

In most cases, however, assessment of the issue will require informed scientific judgement to assess from the information received, the potential consumer exposure to any hazard and the size and acceptability of any resultant risk. In many situations, the Agency will seek expert advice on risk assessment from its standing scientific advisory committees, or, where necessary, from other independent experts.

Ongoing discussion of a communications strategy, with timescales, must occur during this phase. The Agency has developed a communication protocol for handling incidents(Please refer to Annex G.

3.6   RISK MANAGEMENT

In managing the implications of incidents, the primary objective of the Agency is to protect consumers. In most cases, this means protecting consumers against public health risks that, on the basis of a risk assessment, we judge to be unacceptable. In carrying out its functions the Agency also has a statutory duty in protecting other interests of consumers and we may therefore also take action where for example – as a result of work on food authenticity or labelling – we believe there is the potential for consumers to be misled. It also aims to protect consumers against activities which are illegal.

In selecting or advising on a risk management option, the Agency has a statutory duty under section 23 of the Food Standards Act 1999 to be proportionate, taking into account not only the nature and magnitude of the risks that have been assessed, but also the likely costs and benefits of any action. In reaching a decision the Agency takes into account factors such as any uncertainties in the information, size and complexity of the response required, considerations of illegality and any actions already taken. Consumer expectations may also be an important factor.

Communications are critical at this stage, especially for serious and/or complex incidents and they would follow on from the early warning provided at the outset. Accuracy and speed are essential. Effective two-way channels of communication will be established with contacts in other Government Departments and major stakeholders, including Trade Associations, Consumer Groups, LACORS, CIEH, TSI and Local Food Authorities. The Agency Board and Ministers will be informed of the risk management and communications strategy.   That includes Ministers in those devolved administrations where affected food producers are in Scotland, Wales or Northern   Ireland.

- Other EU Member States will be alerted through the RASFF system (by the Incidents Branch) where affected products have been distributed outside the UK.

- In the case of severe/complex incidents, the Agency will establish a dedicated information cell, with the purpose of providing timely, regular and accurate updates to key stakeholders and establishing effective two way communications.

- Members of the incident Scoping Group may assist with routes of communication through the affected part of the supply chain, to help prevent duplication and confusion. The Group will also consider how best to reach small businesses and those companies not represented by a Trade Association.

3.6.1 Examples of risk management & communication options include

- Informing stakeholders that no action is required
- Providing information and advice to consumers, perhaps tailored for special groups
- Use of voluntary restrictions
- Withdrawing affected food products or batches
- Recalling affected food products or batches
- Imposition of an emergency control order under the Food Safety Act
- Imposition of a FEPA order (Food and Environment Protection Act 1985)

Food Alerts Where action has led to withdrawal or recall of product(s), the Agency will alert Local Food Authorities. The most appropriate way of communicating with Local Authority officers is through use of a Food Alert, either for Information or for Action. Food Alerts are issued electronically to local authorities and have attached any parallel Agency press release, which may be used as the basis for a local press release in accordance with the code of practice. The incident team will always endeavour to issue Food Alerts in a timely fashion, consistent with progress on the incident as a whole.

Food Alerts are also e-mailed or faxed to other key stakeholders for the incident and may be published on the Agency's website http://www.food.gov.uk/enforcement/alerts/

It is the Agency's usual practice to publish details of those products affected by an incident and the options for doing so will be discussed as early as possible in the incident handling timetable. Besides the use of the Agency's website, these also include trade association websites and/or notifications in the press by the companies concerned and/or trade associations where consumers need to take action themselves

As required by 178/2002, if the product(s) may have reached consumers, food business operators are legally obliged to inform consumers of the action they have taken. This may be done by a number of methods e.g. newspaper advertisements, notices at point of sale, websites and carelines.

Quality Assurance and Testing It may be appropriate, depending on the nature of the contaminant, for the Agency and industry stakeholders to agree as early as possible which testing methodologies are considered to be reliable, and what limits of detection should be applied.

3.7 RISK COMMUNICATION

The communication of risks and advice to consumers and with other stakeholders is not simply an activity to be added to the end of the process, once risk management decisions have been taken. Food business operators have a legal obligation to inform consumers of the action they have taken, if the product(s) may have reached consumers, including, for example, point of sale notices. In the Agency, a communications strategy must be discussed within the incident ad hoc group from the outset. Communications could also form part of any ongoing discussion of risk management options.

The Agency presumes in favour of publishing all relevant information from incidents, and advising consumers and other stakeholders on the implications for them and any actions they could take. The tools used will vary depending on circumstances and audiences.

Agency guidelines on risk communication are provided at Annex G.

3.8   FOLLOW UP, REVIEW & LESSONS LEARNED

All incidents are subject to review by the Agency's Incident Team once complete. Lessons learned are then reflected in a revision of the incident protocol.

For selected incidents and all major and/or complex incidents a review may also take place with all key players, including external stakeholders. Lessons from such reviews are also likely to be reflected in an update of this document.
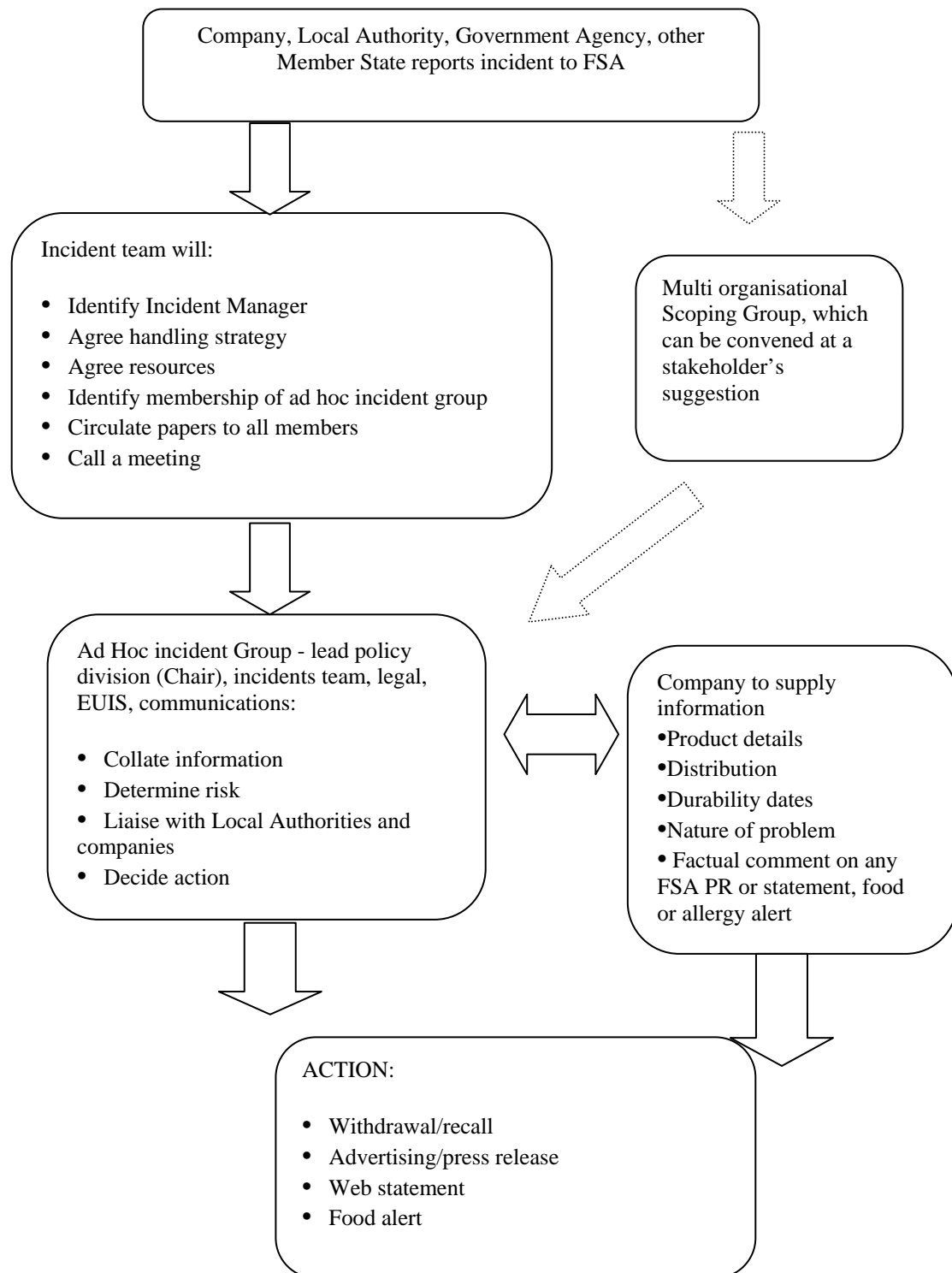
3.9   POST INCIDENT ACTIONS

The follow up to any incident should (having regard to the Openness Policy) include feedback from brand owners, Local Food Authorities and other stakeholders as appropriate. This will ensure that actions (such as withdrawal of foods from the market) have been completed effectively. Communication with consumers and other stakeholders could be reviewed if the situation changes. A number of specific post incident actions may also be required, either by the Agency or by stakeholders. These will depend on the nature of the incident.

Disposal of affected products may be required and advice should be provided by manufacturers/retailers to consumers on how affected products should be collected and/or disposed of. A secure area should be provided for the storage of affected products until they can be disposed of properly.

Detailed disposal guidance provided by the Trading Standards Institute is available at Annex H.

Formal enforcement action may also be required.

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┌─────────────────────────────────────────────────┐
│  Company, Local Authority, Government Agency, other │
│  Member State reports incident to FSA              │
└─────────────────────────────────────────────────┘
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Incident team will:

- Identify Incident Manager
- Agree handling strategy
- Agree resources
- Identify membership of ad hoc incident group
- Circulate papers to all members
- Call a meeting

Multi organisational Scoping Group, which can be convened at a stakeholder's suggestion

Ad Hoc incident Group - lead policy division (Chair), incidents team, legal, EUIS, communications:

- Collate information
- Determine risk
- Liaise with Local Authorities and companies
- Decide action

Company to supply information

- Product details
- Distribution
- Durability dates
- Nature of problem
- Factual comment on any FSA PR or statement, food or allergy alert

ACTION:

- Withdrawal/recall
- Advertising/press release
- Web statement
- Food alert

MODULE 4: ENFORCEMENT AUTHORITIES INCIDENT RESPONSE

4.1 INTRODUCTION

Food authorities are directed on their actions relating to food incidents through the statutory Food Law Code of Practice made under Section 40 of the Food Safety Act 1990. Food Authorities are required to have regard to the Code when discharging their duties. The following information is based upon the Code.

4.2 FOOD INCIDENT DEFINITION

An <u>incident</u> 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 that could require intervention to protect consumers' interests.

From an enforcement authority perspective, a food incident begins when a Food Authority or the Food Standards Agency (FSA) becomes aware that food or its labelling (e.g. in relation to the presence of undeclared allergens) fails or appears to fail to meet food law requirements. A food incident can be a relatively minor matter or a major food hazard.

4.3 FOOD HAZARD DEFINITION

A 'food hazard' is a food incident involving a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse effect on the health or safety of consumers.

Incident identification and classification

Food authorities can become aware of a food hazard in a number of different ways. This may be through;
- Inspection of premises
- Complaints from the public
- Investigation of food poisoning outbreaks
- Notification from industry/business
- Notification from the Food Standards Agency

Authorities will classify the hazard into one of the following categories.

A localised food hazard – one in which food is not distributed beyond the boundaries of the Food Authority and is NOT deemed to be a serious localised food hazard**;**

A serious localised food hazard – one in which food is not distributed beyond the boundaries of the Food Authority but which involves *E. coli* 0157, other VTEC, *C. botulinum,* Salmonella Typhi *or* Salmonella Paratyphi*,* Listeria monocytogenes or other chemical contamination or physical hazards, which the Food Authority considers significant because of, for example, the vulnerability of the population likely to be affected, the numbers involved or any deaths associated with the incident;

A non-localised food hazard – one in which food is distributed beyond the boundaries of the Food Authority and can be serious or non-serious.

4.4 ASSESSMENT BY FOOD AUTHORITIES

Once a food hazard has been identified, the Food Authority will immediately carry out an assessment to determine the likely scale, extent and severity of the risk to public health or safety, involving other agencies as appropriate. These other agencies may include home, originating and neighbouring authorities, medical specialists, food examiners, public analysts and microbiologists, toxicologists and risk assessors.

Food Authorities will have procedures in place to call the appropriate agencies together at short notice. And to implement urgent control measures whenever they are required and will identify a lead authority if necessary.

The assessment will include the following:

• The nature of the hazard
• The toxicity of the contaminant, the allergenicity of an undeclared ingredient/constituent, or the virulence and pathogenicity of the organism
• The type of injury which might be caused by a physical contaminant
• The population likely to be affected and its vulnerability
• The likely quantity and distribution of the food in the food chain up to the point of consumption
• The ability and willingness of the producer or distributor to implement an effective withdrawal of the product;
• The ability to identify accurately the affected batch(es) or lot(s)
• The accuracy and extent of records held by the producer or distributor
• The likely effectiveness of any trade withdrawal or product recall at all stages of the food chain, including how long affected product has been on the market and anticipated use
• The stage(s) at which the fault is likely to have occurred (for example in processing, packaging, handling, storage or distribution) and its likely significance to the problem
• Whether other products produced in the same establishment may have been affected
• Whether the food has been imported
• Whether any of the food has been exported
• Whether there are wider implications for others in the same industry or for establishments using similar processes in other food industries

• The possibility that the complaint or problem has been caused by a malicious act
• The actual cause(s) of the hazard
• Whether there have been any reports of illness that may be associated with the problem.

4.5   ACTION BY FOOD AUTHORITIES

The Code sets out in detail the actions to be taken by authorities. It is expected that when a Food Authority becomes aware of a food hazard, it will take action to protect public health and safety at the earliest opportunity. Food authorities will consult the Code for Crown Prosecutors, their own enforcement policy, and the enforcement concordat to ensure that their response is proportionate to the nature and seriousness of the incident.
This could include;

- Agreement to a voluntary recall of all affected products
- Agreement on a change of process or procedure
- Detention or seizure of the food concerned,
- Instigation of prosecution,
- Or the use of any other relevant powers, as appropriate.

4.6 COMMUNICATION WITH THE FOOD STANDARDS AGENCY

In order to ensure effective action the code specifically requires food authorities to communicate with the Agency in the following circumstances:

- When the incident involves a serious localised food hazard or a non-localised food hazard.
- When the Food Authority becomes aware that a food business operator within their area has withdrawn food from the market

4.7 RESPONSES TO FOOD ALERTS: "FOR ACTION" FROM THE FOOD STANDARDS AGENCY

Food authorities maintain facilities to receive food alerts and updates from the Agency, including those received outside normal hours.

Food authorities will normally ensure that any action specified by the FSA in a food alert is undertaken promptly and in accordance with any risk assessment carried out by the FSA. Where food authorities propose to take alternative action, this should be agreed with the FSA before implementation.

Annex A - LEGISLATION

General Food Law Regulation 178/2002

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

Safety	Operators shall not place on the market unsafe food and feed
Responsibility	Operators are responsible for the safety of the food and feed which they produce, transport, store or sell
Traceability	Operators shall be able to rapidly identify any supplier or consignee
Transparency	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 the Agency and the relevant enforcement authority i.e. the local authority or the port health authority or in NI the relevant District Council.
Emergency	Operators shall immediately withdraw food or feed from the market if they have reason to believe that it is not safe
Prevention	Operators shall identify and regularly review the critical points in their processes and ensure that controls are applied at these points
Co-operation	Operators shall co-operate with the competent authorities in actions taken to reduce risks

The principal 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. The Agency 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. The Agency (Scotland) has developed a HACCP-based system called Cook Safe and the Agency (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. For example, *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.

<u>Other Related Legislation</u>

Food business operators need to ensure that they are aware of the requirements under other food and feed legislation relating to 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 Agency's website. Food Business operators can obtain further advice on relevant food legislation from their home authority.

ANNEX B   -   AGENCY GUIDANCE ON 178/2002

Guidance Notes on Articles 14-16 and 18-20 of the General Food Law Regulation (EC) 178/2002

Regulation (EC) No. 178/2002 lays down general principles and requirements of food law and food safety procedures, and established the European Food Safety Authority.

The regulation provides a framework for food and feed law in the EC and imposes both on Member States and on food and feed business operators. It applies to all stages of production, processing and distribution of food and feed, but does not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption. The principal aim of the regulation is to protect public health and consumers' interests in relation to food.

New Food Standards Agency (FSA) Guidance Notes on compliance with Articles 14, 16, 18 and 19 of the General Food Law Regulation (EC) 178/2002 have been developed, covering food safety, traceability and the need to notify, withdraw and/or recall products not conforming with the food safety requirements applying under the regulation. Separate guidance is also being produced on the provisions in the regulation on animal feed.

This guidance has been produced with the aim of providing informal non-statutory advice. It should be read in conjunction with the regulation itself and the British legislation which followed – the Food Safety Act 1990 (Amendment) Regulations 2004 (No. 2990) and the General Food Regulations 2004 (No. 3279).

The EC guidance on the regulation was issued on 20 January 2005. Agency guidance taking account of the EC Guidance was issued on 10 March 2005.

The Agency consulted in July 2005 on how well the EC guidance had been working, to inform a review of the guidance by the European Commission.

The reaction from business was that following the EC guidance was resulting in disproportionate costs to the food industry. The EC guidance classifies

traceability information in two categories, the first to meet the legal requirements and the second to be followed as best practice. Responses from food businesses to the consultation exercise indicated that following such best practice guidance could result in additional costs. The new FSA guidance notes have been developed to address this.

Compared with the EC guidance, these FSA guidance notes:

- give a greater discretion to food businesses over time requirements for keeping traceability records
- change the need for immediate production of traceability records in certain cases to a need to produce these within 'a short timescale'
- concentrate on the requirements of the legislation and providing minimal advice on good practice

The Agency view is that the FSA guidance notes are more appropriate for food businesses in the UK. This approach has been agreed with the European Commission.

The Full text of the guidance is available at the following web address:

http://www.food.gov.uk/multimedia/pdfs/fsa1782002guidance.pdf

ANNEX C - CHEMICAL HAZARDS

1.   The pathway from primary production to the consumer may often be complex with many routes by which various potentially toxic chemicals may enter food;

- Raw materials may contain unacceptable levels of natural toxins produced by food crops (such as lectins in red kidney beans) or by moulds or other pests growing on them (such as mycotoxins). They may also contain excessive levels of chemicals derived from the environment in which they were produced (such as dioxins or heavy metals).

- Food processing may induce chemical changes in the food (such as the formation of ethyl carbamate or chloropropanols).

- Storage and distribution may lead to chemical deterioration or to the migration of chemicals through or from food packaging materials into food.

Collecting information for risk assessment

2.   The information initially available to inform a risk assessment of chemical hazards will vary from one survey or incident to another. For surveys conducted by the Food Standards Agency, there will be direct access to information on the nature and identity of the foods that are contaminated, on the levels of contaminant found and associated measurement uncertainty and, in most cases, on the likely extent of any problem. Past experience shows that information is likely to be more limited for many environmental and on-farm incidents, particularly when these are first notified. In such cases, further information should be sought to inform the risk assessment. This should include as much of the following as possible:

- What is the nature of the hazard, and is it clear which chemical(s) are involved?

- What is the amount or concentration of the chemical(s), or other indication of the size of the incident?

- What is the duration of the incident so far, and is it likely to continue?

- At what stage has any fault occurred or is likely to have occurred – on-farm, in processing, or downstream - and how has it led to the reported problem?

- What is the location of the incident and the nature of the production or processing environment that is or may be affected (e.g. farm-land, types of crops, watercourses, food ingredients or products implicated)?

- Are there other affected or potentially affected products or commodities produced or stored on the same premises or within the affected area?

- Are there wider implications for others in the same industry or for premises using similar processes in other food industries?

- What are the possible points of entry into the food and feed chains for the contaminant and food products or commodities that may be affected?

- What are the likely quantities and distribution of the particular food in the food chain up to the point of consumption, including any supply outside the UK?

- Can the affected and/or implicated batch(es) be accurately identified and traced?

- Are downstream processes, such as cooking, likely to affect the risk?

- If identifiable food product(s) are affected, are they still within their recommended shelf life and likely to be available either at the retail level or after frozen or other storage by the consumer?

- What group of the population is likely to be affected and to what extent if this product is consumed; are they particularly vulnerable?

- Is any action being taken by other organisations?

- What uncertainties exist in any of the above information and what are the implications of this uncertainty?

The risk assessment process

3.   The Chemical Safety Division (CSD) of the Agency should be consulted for toxicological advice on chemical issues. Experts within CSD will conduct a preliminary risk assessment, consisting of hazard identification, hazard characterisation, exposure assessment and risk characterisation.

- Hazard identification and characterisation involves identification of the nature of the toxic effects associated with a substance, information on the dose response, and consideration of whether any established safety guideline values are applicable.

- Exposure assessment typically consists of an estimation of dietary exposure – by the general population and any relevant affected subgroups - from any specific foods implicated by the survey or incident, together with an assessment of the contribution from the rest of the diet to total dietary exposure. It may also be necessary to consider the importance of dietary exposure in the context of other sources of exposure.

- Risk characterisation involves comparison of the exposure assessment with the relevant safety guideline values, or with the dose response information if no relevant guideline values are available.

- If the preliminary risk assessment indicates that exposure is at or above the safety guideline, and the uncertainty associated with the estimate is likely to be significant, there is a need to try to refine the exposure assessment as quickly as possible. Wherever feasible, the uncertainty in the exposure assessment should be expressed as a lower bound to upper bound range.

4.   The preliminary CSD risk assessment will help identify whether independent expert advice is required, taking into account as appropriate factors such as:

- The nature of the chemical toxicant.

- The likely variation in concentrations of the toxicant in the matrix in which it has been detected.

- The possible exposure of members of the public.

- The nature of the health effects of concern.

- The likelihood of there being immediate or long-term effects on health.

- The existence of sub-groups of the population with particular sensitivity to the material/toxicant (e.g. allergy). and

- The distribution of the product, i.e. potential size of exposed population.

- Potential exceedance of a statutory limit, taking into account any uncertainties associated with the analytical methodology, whether the sample containing the non-compliant level was representative of the relevant production run, batch, lot or container, whether the incident of non-compliance is indicative of a wider problem.

5.   If no Tolerable Daily Intake or Acceptable Daily Intake is available, or it is likely to be exceeded, independent expert advice is likely to be required.

This should be sought from the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT). The COT Secretariat is responsible for communications with the COT chairman or members, and will be able to advise on whether and how to consult the committee.

6.   For incidents, or other cases, such as surveillance results, where the preliminary risk assessment indicates a potential for immediate and serious risk to consumer health, urgent advice may be requested from an ad hoc group of the COT or from the COT Chairman. The advice of the COT is published with relevant supporting papers on the COT website. Any urgent advice received from the COT is the subject of an information paper presented to the full Committee at its subsequent meeting and is then published.

Risk management options

Public health considerations

7.   Where levels of a chemical contaminant in a food have the potential to cause serious adverse health effects or immediate harm, the affected batch(es) of product should be withdrawn from sale immediately and recalled from consumers' homes as quickly as possible. Consumers and other stakeholders must be informed about the situation and what it means for them.

8.   Where levels of a chemical contaminant in a food have the potential to cause harm following repeated or chronic exposure, the affected batch(es) of product should be withdrawn from sale. Consumers and other stakeholders must also be provided with appropriate advice about products that they have already bought or consumed.

9.   Where levels of a chemical contaminant in a food have the potential to cause harm only if consumed by a particularly affected population, advice must be issued to that population and the need for further action considered on a case-by-case basis.

ANNEX D   -   RADIOLOGICAL HAZARDS

The source of radioactivity in food

1.   Naturally occurring radioactivity is found in most foods, and accounts for the majority of the dose received from this source by most consumers. Man-made radionuclides can enter the environment, and hence food, in a number of ways. The most likely route is by authorised discharges from licensed nuclear sites. These discharges can be made to the atmosphere or to water, and the Food Standards Agency, the Scottish Environment Protection Agency in Scotland and the Environment and Heritage Service of the Department of The Environment in Northern Ireland undertake routine monitoring around UK sites , checking that authorised discharges do not give rise to unacceptable levels in foods.

2.   Radionuclides can also be found in foods as a result of past weapons testing, accidents at nuclear sites (such as the Chernobyl disaster of 1986), transport incidents, satellite re-entry or accidents involving radioactive sources.

The basis for risk assessment

3.   Acceptable levels for radioactivity in food may be expressed either in terms of the annual dose a person receives from all sources of radioactivity, including the contribution from food, measured in milliSieverts (mSv), or the amount of a particular radionuclide in a particular foodstuff, measured in Becquerels per kilogram of food (Bq/kg).

4.   For all practices that add to the background radiation exposure of the public, the International Commission on Radiological Protection (ICRP) recommends a system of radiological protection based on justification, optimisation and limitation. For a member of the public, the annual statutory dose limit is 1mSv from all sources excluding medical and natural radiation. This compares with the overall dose received by a member of the public from such background radiation of about 2.6mSv.

5.   Specific EU legislation sets limits for radioactivity in foodstuffs in certain situations:

- Council Regulation (Euratom) No 3954/87 lays down the maximum permitted levels of radioactive contamination of food and of animal feed following a nuclear accident or any other radiological emergency.

- Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products originating in third countries, following the accident at the Chernobyl nuclear power station sets limits for certain foodstuffs.

6.   In the UK, restrictions on the movement and slaughter of sheep grazing in certain areas were made under the provisions of the Food and Environment Protection Act 1985 (FEPA) after the accident at Chernobyl in 1986. These Orders have since been amended by partial revocations to reduce the area covered. Farmers may be granted a consent to move sheep out of the restricted area if the sheep are monitored and the level of caesium-137 in the meat is below the UK limit of 1000Bq/kg.

Collecting information for risk assessment

7.   Where food is found to contain, or suspected of containing, elevated levels of radioactivity, an immediate risk assessment must be conducted. This will be led by experts in Emergency Planning, Radiation and Incidents Division (EPRID) in the Agency. Information on the type, level, and source of contamination must be ascertained.

8.   For problems highlighted by surveys carried out by the Agency, there will be direct access to much of the information required. For other incidents, there will be a need to gather much of the information needed to inform the risk assessment. This should include as much of the following as possible:

- What is the nature of the hazard, and is it clear which radionuclide(s) are involved and what form they are in?

- What is the amount or concentration of the radionuclide(s), or other indication of the size of the incident?

- What is the nature of the incident, and what pathways are affected?

- What is the duration of the incident so far, and is it likely to continue?

- What is the location of the incident and the nature of the production or processing environment that is or may be affected (e.g. farm-land, types of crops, watercourses, food ingredients or products implicated)?

- Are there other affected or potentially affected products or commodities produced or stored on the same premises or within the affected area?

- Are there wider implications for others in the same industry?

- What is the duration of the incident so far, and is it likely to continue?

- Is any action being taken by other organisations?

- What uncertainties exist in any of the above information and what are the implications of this uncertainty?

The risk assessment process

Statutory limits

9.   If the contamination is the result of a nuclear emergency such as an accident at a nuclear reactor, the level of the radioactivity in the food should be compared with the levels specified in Regulation No 3954/87. In the initial stages, if samples are not readily available, the levels of radioactivity should be calculated using computer models available to EPRID. The main model used is R91STAR, which can estimate ground level air concentration or deposition values from an atmospheric dispersion model and thereby inform risk management and communication. Samples shall be collected as soon as possible from the area that may be contaminated, and sent to an accredited laboratory for determination of the actual levels of radionuclides present in exposed foodstuffs.

10.   For food imported from outside the EU, the country of origin and the level of radioactivity should be compared with the specifications in EU Regulation No 737/90. If the level is above these limits, Port Health Authorities/local authorities have powers under the Imported Food Regulations 1997 to issue a notice requiring the removal of the consignment from EU territory,

Exposure assessment

11.   For elevated results when the situation is not classified an emergency, technical experts in EPRID should estimate the dose that consumers would receive from the food at typical and high levels of consumption. To calculate the dose, the level of the radioactivity from the particular radionuclide in a foodstuff is multiplied by the dose per unit intake factor for that radionuclide, carried out in accordance with ICRP-60[7] methodology. The consumption rates of the foodstuff from habit surveys or the Total Diet Study are then taken into account to calculate the total effective dose of radiation caused by the radionuclide over a set timescale. This dose is compared both with the dose limit and also the natural background dose that consumers would receive. The levels of contamination should also be compared with World Health Organisation guidelines where appropriate, such as levels of radioactivity in drinking water, as well as to those given in Regulation 3954/87.

12.   If the radiological contamination results from a terrorist attack, the levels in Regulation 3954/87 are the most appropriate for comparison.

Risk management options

13.   If either the level of contamination or the annual dose received were considered to be unacceptable, immediate measures must be taken to restrict

the access of consumers to affected food. Consumers and other stakeholders must be informed about the situation and any action they should take.

14. If elevated levels are found, but the dose limit is unlikely to be breached, the need for precautionary public advice to protect affected groups such as infants consuming milk should be considered on a case-by-case basis.

15.   A rolling monitoring strategy should be developed for foods produced within or in areas adjoining the affected area designated in any FEPA Order, or of foods containing ingredients which showed elevated levels. Such monitoring would help confirm the extent of any contamination and allow evaluation of the risk over time. Again, consumers and other stakeholders should be informed of the action taken by the Food Standards Agency, the reason for this action, and any action that they themselves should undertake.

ANNEX E   -   MICROBIOLOGICAL HAZARDS

The nature of microbiological hazards

1.   There is a diverse range of potential microbiological hazards which may include:

- Reported cases or outbreaks of food poisoning or of suspected   or alleged food poisoning.

- Food incidents associated with clinical illness or potential illness, including:

    - microbial contamination;
    - bacterial toxins;
    - marine algal toxins;
    - processing or packaging defects (e.g. undercooking, defective seals in canning);
    - incorrect instructions (e.g. risk of undercooking; unsafe recipes);

- Microbiological hazards reported through the RASFF system.

- Adverse results from the marine algal toxin monitoring programme.

- On farm incidents with implications for the food chain, such as outbreaks of botulism in cattle, untreated sewage contamination of agricultural land.

Collecting information for risk assessment

2.   Gathering of detailed information for a risk assessment must include as much of the following as possible:

- What is the nature of the hazard and are pathogens involved?

- What group of the population is likely to be affected and to what extent if this product is consumed; are they particularly vulnerable?

- What are the likely quantities and distribution of the particular food in the food chain up to the point of consumption, including any supply outside the UK?

- If identifiable food product(s) are affected, are they still within their recommended shelf life and likely to be available either at the retail level or after frozen or other storage by the consumer?

- At what stage has the fault occurred or is likely to have occurred - processing, packaging, distribution, storage, handling - and what is its likely relevance to the problem?

- Are there other affected or potentially affected products produced on the same premises?

- Can the affected and/or implicated batch(es) be accurately identified and traced?

- Are there wider implications for others in the same industry or for premises using similar processes in other food industries?

- What uncertainties exist in any of the above information and what are the implications of this uncertainty?

3.   This information can largely be obtained from the notifying local authority. other local authorities, such as the home and/or originating authorities for the implicated manufacturer/retailer/supplier/importer, should also be contacted to gather additional information.

4.   When an outbreak has occurred, information on the epidemiological and microbiological investigation will generally be obtained from Divisions of the HPA in England, the National Public Health Service (NPHS) in Wales and the equivalent bodies in Scotland and Northern Ireland. The lead in outbreak, investigation, and control rests with the local public health officials who form the Outbreak Control Team (OCT). The lead in investigation of national outbreaks in England rests with the HPA, in Wales with the NPHS and in Northern Ireland with CDSC(NI). The National Health Service Board and local authorities share the responsibility for the control of communicable disease in Scotland. In Northern Ireland, communicable disease control is the responsibility of the area health and social services boards which are supported in this function by the Environmental Health Service. If the investigation suggests an association with a nationally or regionally distributed food, the Food Standards Agency is responsible for advising local authorities and food companies on the action that should be taken. In this type of incident, it is important that roles and responsibilities of the OCT and the Agency are clearly established.

The risk assessment process

5.   An assessment of the risk will be carried out by experts in the Microbiological Safety Division of the Agency.

Risk management options

Public health considerations

6.   Risk management and communication options will vary depending on the nature of the hazard. These could include:

- No further action.

- Further testing to be carried out.

- Product withdrawal by food business operators from warehouses, the distribution chain, retailers, caterers and/or

- Product recall by food business operators

7. Where a microbiological hazard has the potential to cause serious adverse health effects or immediate harm, the affected batch(es) of product should be withdrawn from sale immediately and where necessary recalled from consumers' homes as quickly as possible. Consumers and other stakeholders must be informed about the situation and what it means for them.

8. Where a microbiological contamination of food has the potential to cause harm only if consumed by a particularly population, advice must be issued to that section of the population.

Microbiological standards and guidelines

9. In the case of microbiological contamination, statutory limits, if they apply, generally do so at the point of production, rather than at the point of sale. In general, products containing micoorganisms in excess of statutory limits should be withdrawn from sale, irrespective of any risk to health. The decision will take into account:

- Whether the sample(s) was representative of the relevant production run, batch, lot or container;

- Whether there is potential for multiplication of the microorganism(s) within the shelf-life of the product;

- Whether there are any steps that will reduce or remove the microoganism(s) of concern;

- Whether the incident of non-compliance is indicative of a wider problem.

ANNEX F   -   PHYSICAL HAZARDS

The nature of physical hazards

1. In any food production process there is the potential for physical contaminants to be introduced into food. The risk of such contamination occurring can be minimised by the use of adequate and appropriate controls. Examples of physical contaminants and how they may be introduced into food include:

- Raw materials may contain foreign bodies such as insects that have been living on food crops, or remnants of packaging materials.

- During food processing or preparation potential physical contaminants can enter food (such as plastic, glass, wood or metal) due to poor maintenance of equipment.

- Poor design or maintenance of food premises may lead to physical contaminants entering the food (such as flying insects through unscreened vents).

- Poor storage and handling may lead to physical contamination.

- Miscellaneous cases of malicious contamination of foods.

Collecting information for risk assessment

2. The information initially available to inform a risk assessment of any physical hazard will vary from one incident to another.

3. In some instances initial information may be limited. In such cases, further information should be sought and include as much of the following as possible:

- What is the nature of the hazard?

- At what stage of food production or processing has any fault occurred or is likely to have occurred – and how has it led to the reported problem?

- What is the location of the incident and the nature of the production or processing environment that is or may be affected?

- Are there other affected or potentially affected products or commodities produced or stored on the same premises?

- Are there wider implications for others in the same industry or for

premises using similar products or processes in other food industries?

- What are the likely quantities and distribution of the particular food in the food chain up to the point of consumption, including any supply outside the UK?

- Can the affected and/or implicated batch(es) be accurately identified and traced?

- If identifiable food product(s) are affected, are they still within their recommended shelf life and likely to be available either at the retail level or after frozen or other storage by the consumer?

- What group of the population is likely to be affected and to what extent if this product is consumed; are they particularly vulnerable?

- Is any action being taken by other organisations?

- What uncertainties exist in any of the above information and what are the implications of this uncertainty?

The risk assessment process

4. Advice on the potential public health risks associated with foreign bodies in food should be sought from Emergency Planning Radiation and Incidents Division within the Agency, which might in turn seek advice from external experts.

Risk management options

5 Where a physical contaminant in a food has the potential to cause serious adverse health effects or immediate harm, the affected batch(es) of product must be withdrawn from sale immediately and steps taken to recall them from consumers' homes as quickly as possible. Consumers and other stakeholders must be informed about the situation and what it means for them.

Annex G
COMMUNICATING DURING AN INCIDENT – A DRAFT PROTOCOL

INTRODUCTION

The Agency's core purpose is to put the consumer first and to be open and transparent in its dealings with all its stakeholders: the public, industry, NGOs, local authorities and the media. Part of this commitment is to inform the public where foods that are or have been on sale are unsafe. The Agency may also inform the public about foods that are illegal but do not necessarily pose a food safety risk. The Agency is committed to giving people the facts about any particular food incident as quickly as possible while at the same time ensuring that it meets its obligations to consult manufacturers, retailers, importers and other organisations involved in the production and retailing of the affected product before putting information into the public domain. The Agency is well aware of the need to be proportionate and measured in the way it communicates incidents.

There have been more than 5,000 food and feed related incidents since the Agency was set up in 2000. The vast majority of these have been resolved satisfactorily because of the work done by the Agency, local authorities and industry working together. It is through this co-operation that incidents are resolved swiftly and public health best protected.

But it is important that all parties to a food incident: industry, the Agency, local authorities and European authorities know what to expect from the Agency's external communications:

- Why is the Agency acting?
- What will it be saying?
- When will organisations involved see what it is saying?
- Can they comment?
- Will the comments be considered?
- How long will organisations have before it goes public?

This protocol aims to answer these questions and lays out the obligations for those involved in a food incident.

The protocol will replace Annex G (*Guidelines for Risk Communication*) of the Principles for Preventing and Responding to Food Incidents. The words and phrases used in this Annex have the same meaning as in the main document, e.g. recall and withdrawal.

FSA COMMITMENT

The Agency is committed to being fair and straightforward in its dealings with external stakeholders. It is part of the Agency's statutory remit to inform and advise the public about any potential risk to health. For each incident the Agency will decide upon a communications strategy which will outline the most appropriate communication methods to be employed, including whether to advise the public about products which may be illegal but do not pose a risk to health. The Agency views its website and the media (print, broadcast and web) as the quickest and most effective methods of alerting the greatest number of people.

Communication methods used by the Agency during a food or environmental contamination incident may include:

- a food (or feed) alert for information or action and/or
- an allergy alert
- a web statement (information published on FSA website)
- a press release (proactively sent to the media)

When the incident is complex and multi-layered then all of these means of communication may be used and as the situation evolves additional material may be made public.

- The Agency will inform any investigating body that is looking into the company or the alleged incident about the action it intends to take and will share with investigators the contents of any food alert, allergy alert, web statement or press release.

- It is particularly important during serious incidents that bodies whose work complements and supports the Agency's activities are informed and involved in the management of an incident from an early stage. This is especially true in the case of local authorities who may have an enforcement role to play.

- The Agency, in its press releases/web statements, etc. will be open and factual about the potential risk, the products affected and what our advice is. The Agency will state what the company (ies) involved have done (e.g. to remove the product from sale) and what advice has been given to consumers if they have the affected product or if they have consumed it.

- Whenever possible the Agency will let the producer, retailer or importer see the information it intends to make public before it does so.

- When a food incident is particularly widespread and/or poses an immediate risk to people's health then the Agency will consider taking on the role of communications co-ordinator. This will involve being the focal point for advice to the public, industry, NGOs and local authorities, using the web, press releases and Agency spokespeople to inform the public. This role would only be taken on following a discussion meeting ("scoping meeting") with companies involved,

relevant trade associations, the enforcement authorities and consumer organisations and with the agreement and support of all the parties involved. The Agency's role would not extend to compiling or assembling lists of affected products but the Agency would consider publishing any lists provided on its website.

- Best practice indicates that stakeholders alert the Agency to any potential food incidents as soon as they become aware of them. We recognise that it is advisable for a company to collate all appropriate data and undertake an initial risk assessment before formal notification. However, experience shows that early engagement with the Agency helps in this process. The Agency uses this information to assess the potential risk to people and to formulate a suggested course of action for the company involved. It is a legal obligation under EC Regulation 178/2002 for the FBO to inform the competent authorities if they have placed food on the market that does not meet food safety requirements and as such they should have undertaken a risk assessment. The Agency will also carry out a risk assessment and use this information to advise the public.

- The Agency will sometimes receive from local authorities or other enforcement bodies information relating to possible investigation and/or prosecution action, which is provided to it on the basis that it is not disclosed to third parties. The Agency will not publish such information, where it is satisfied that it has no legal obligation to do so.

FOOD ALERTS

- Food alerts are the main means used by the Agency to communicate information about incidents to local authorities. They are issued to inform authorities of actions taken by a company in response to identified risks (food alert for information) or to inform local authorities where action is required by them to protect consumers (food alert for action). The Agency is at present reviewing how food alerts are described and used to ensure they provide the most appropriate, relevant and useful information to local authorities and others. The work is likely to be ready for consultation with stakeholders in the summer of 2008. This protocol will be updated when any changes take place.

- The food alert will accurately state to consumers the risk (as known at the time), the products involved (including brand names, durability dates, batch codes, etc.) and the actions taken by the relevant company (ies) or action required by local authorities, including the legal basis (on food alerts for action) for that action.

- Draft food alerts are circulated to the relevant companies/local authorities for comments on factual accuracy prior to release.

- However, late notifications to the Agency may severely limit the time available for consultation as the need to mitigate risks to consumers will be paramount.

- As well as being sent to all local authorities in the UK, food alerts are placed on the Agency website, and are, therefore, visible to the public. This is done as part of our commitment to openness and on the basis that the public has a right to know about food incidents

- Where products have been exported to other Member States, the Agency will produce a rapid alert notification for transmission to the European Commission and Member States. The notification is transmitted via a closed and confidential system, and the information contained within the notification is only available to the competent authorities within the Member States.

DECISION ON WHEN TO ISSUE A PRESS RELEASE/ISSUE A FOOD ALERT/PUBLISH A WEB STATEMENT

The Agency's approach is based upon openness and letting consumers have the facts. We will therefore make a judgement as to whether to issue a press release/web statement once we have enough facts to put into the public domain. Each incident is different and should be treated on its merits but the sort of issues the Agency would consider when deciding what it might issue are:

- Potential levels of risk to consumers

- Distribution of product (i.e. national or local) and to what sort of businesses (catering, retail, etc.)

- Shelf life of product

- The sort of action the company is taking (e.g. advertising, press releases, etc.)

WEB STATEMENTS/PRESS RELEASES

- The Agency expects that the company and the Agency would have been working closely together before the production of a press release and therefore the sign-off process should be reasonably straightforward.

- The Agency will seek to show statements/press releases, etc. to relevant companies in advance of publication. In normal circumstances the *minimum* time the Agency will share statement/press release information will be at least 2 hours before publication.
- In major incidents the Agency will also inform the relevant local authority (and LACORS) what the Agency is going to be saying so it can prepare for and respond to media enquiries.
- There will be circumstances where this time frame may need to be shortened. When this happens the Agency will explain why.
- The Agency has systems in place which mean that statements and press releases can be published out of normal working hours. When working out of hours the Agency will endeavour to give extra time for companies to comment.
- The reason for the deadline will always be explained to the company at the time the material is sent through.
- All information sent to companies before going into the public domain is supplied for factual comment. The Agency will be prepared to consider new information or additional comments if they are relevant.
- The Agency will answer follow up questions about the facts, including the potential risk, from journalists, but will not answer questions that should properly be answered by the company involved.
- The Agency will share its media distribution lists with relevant organisations when asked to do so.
- The Agency will correct any errors it makes on its website or in printed material when managing an incident. This can be done both during and out of office hours.

LANGUAGE

The Agency will always strive to match language to risk. We will explain in straightforward terms what the risk is, what we know about the affected product(s) and whether there are gaps in our knowledge. We will be restrained and proportionate in what we say and attempt through our use of language to avoid causing needless concern or worry; this will particularly be the case where the contamination may appear to be distasteful or unpleasant to the public but not pose a threat to health. The Agency will also strive to be proportionate when giving detailed information about the substance responsible for the incident and will be conscious of the need to avoid giving unnecessary or irrelevant facts about its effects in other contexts.

FSA CONSISTENCY ACROSS THE NATIONS

The Agency applies the same approach to risk assessment and risk management across the UK and will manage its communication in the same proportionate and considered manner. FSA communications will be talking directly to the communication managers in the Scotland, Wales and Northern Ireland to ensure there is uniformity of approach to risk management and communication.

WORKING WITH EUROPE

The European Food Safety Authority (EFSA) is the European risk assessment body whose opinions on scientific issues drive decision-making at EU level. EFSA is looking to improve the speed at which it responds to requests for urgent advice in emergency situations. The European Commission has powers to introduce emergency measures and the aim is to avoid inconsistent decisions being taken within the EU. However, there may still be occasions where it is necessary, pending an EFSA opinion, for national bodies such as the FSA to make quicker risk assessments in order to inform the public and industry about risk.

AGENCY LINKING TO COMPANY WEBSITES

FSA web statements, food and allergy alerts related to withdrawals and recalls will, wherever possible, link to the website(s) of the affected companies or relevant action groups. This will be in addition to linking to any press notices issued by the company. Doing this will convey to FSA website visitors that the Agency has been working with retailers/manufacturers on publicising a particular incident, and company websites will often contain additional information of interest to consumers, local authorities and other interested parties.

In addition the FSA homepage web statement linking to the alert should explain the difference between recalls and withdrawals. This is in addition to the existing text that explains about the food and allergy alerts, and how to subscribe to them via email and SMS.

SHARING OF Q&As

The Agency produces questions and answers (Q&As) for most incidents that are likely to receive press coverage. On occasion, when an incident is complex and high profile, we put Q&As on our website for additional information. However Q&As are usually produced for internal use. These cover issues such as: when we first found out about the incident, who informed us, quantity of product involved, our risk assessment, threat to health, further actions to be taken. During major incidents internal (and external) Q&As change and numerous versions can be produced. The Agency will share its internal Q&As with companies, local authorities and other relevant bodies involved in an incident.

NAMING

The Agency is committed to being open and transparent. This means that when there has been a food incident the Agency will normally name those companies involved, even those who have sold products on in good faith or were unwitting receivers of affected goods. The reason the Agency does this is to give people as much information as possible so that they can know who produced the product and where it may have been purchased.

INFORMATION FOR LOCAL AUTHORITIES

It is often the case that a local authority (LA) will have informed the Agency about a possible food safety incident. It may also be the LA who will consider any possible legal action.

LAs are already informed by the Agency about the majority of food incidents through the food alert system. However on some occasions (e.g. when food has already been consumed and/or the incident is relevant to only one shop or small area) the LA may not be involved. The Agency is committed to ensuring relevant LAs are aware of what action the Agency is proposing. This is especially important when legal proceedings may be possible against any of the organisations involved in the incident. The Agency will:

- inform LAs who have responsibility for the home premises of the company about what action it is planning to take, for example, a web statement or press release;
- share in advance (as above) what information it is intending to make public;
- correct factual errors and consider other comments;
- Explain if the Agency may not be able to give much time to consider comments on the release/web story before publication.

Annex A

CONTACTS AT THE FSA

The FSA can be contacted 24 hours a day. The main press office contacts are:

Terrence Collis – Director of Communications – 020 7276 8880

Justin Everard – Head of Media Relations 020 7276 8847

Bradley Smythe – Senior Press Officer 020 276 8831

Out of Hours:

07623 978 344

ANNEX H - GUIDANCE FOR LOCAL AUTHORITIES ON STORAGE OF GOODS DURING TESTING AND RECYCLING OR DISPOSAL OF REJECTED MATERIAL

Storage

Food should be stored in such as way as to keep the food from deterioration, yet not in a way that might inhibit future analysis. For example all perishable food and all frozen foods should be kept frozen and other items e.g. ambient shelf stable, canned and dried samples at temperatures not exceeding 40°C.

For legal continuity purposes the food should be kept in a secure place, sealed to ensure the integrity of the food and clearly identified. Food must be kept in suitable containers, which prevents leakage or spills, deterioration of the food and contamination to and by other foods.

Recycling or disposal of rejected matter

Third portions of food samples or other food stored can be disposed of in the following ways
1. Recycled as animal feed or as biofuel
2. Disposal into landfill
3. Incinerated, rendered, composted or disposed of by other approved
   methods specified in the regulations

Recycling

Only food which is not from an animal origin, that is within its minimum durability date, and has been stored in accordance with its storage instructions, should be recycled as animal feed.   Oil can still go to landfill, however, the recommended route for disposal is to bio-diesel production or for burning as fuel. Store used cooking oil in covered leak-proof containers and check that your collector transports it separately from other waste.

Landfill

All other food, which is not of animal origin should be disposed into landfill. Each container must be labelled 'Not for Human Consumption'.

Incineration, rendered, composted or disposed of by other approved methods specified in the regulations

Any 'foods of animal origin' or 'former foodstuffs of animal origin' must be disposed of by methods that do not lead to contamination of other foods, or to water supplies (including those provided for livestock). Although there are some derogations agreed for the trade, we strongly recommend that disposal of such foods to landfill is no longer an option for local authorities. The food must be incinerated, rendered, composted or disposed of by other approved methods specified in the regulations. 'Former foodstuffs of animal origin' includes cooked meat and fish, salami, pate, ready meals, pies, pasties, smoked salmon, sushi and cooked prawns.

ANNEX I – GLOSSARY AND ABBREVIATIONS

CCP	Critical Control Points (CCP's) are points in the food supply chain which have been identified as areas where potential hazards may reasonably be expected to occur. This could include contamination of the raw materials, during processing, storage or transport.
EC General Food Law Regulation 178/2002	Lays down the principles and requirements of European food law, including procedures in matters for food safety and procedures for food safety
FEPA	Food and Environment Protection Act Orders (FEPA). Ministers have powers under FEPA to make emergency Orders to stop the sale of contaminated food. These are generally used for major industrial accidents, radioactive contamination or similar events. An Order usually designates the area to be controlled and can restrict the movement, sale or supply of foods or agricultural products.
Food Safety Act 1990	A wide-ranging law on food safety and consumer protection in the food sector throughout Great Britain. A separate but similar law applies in Northern Ireland.
Food Standards Act 1999	Established the Food Standards Agency It sets out the Agency's main objective of protecting public health in relation to food and gives the Agency the powers necessary to enable it to act in the consumer's interest at any stage in the food production and supply chain.
Home authority	The home authority principle is a scheme developed by local authorities to help businesses by providing contact points for advice and guidance. For a business with multiple branches, your home authority will be the LA where your head office is located.
RASFF	Rapid Alert System for Food and Feed (RASFF) Is a European Commission mechanism which enables Member States to exchange information on measures taken to ensure food safety

APHA	Association of Port Health Authorities
BHA	British Hospitality Association
BRC	British Retail Consortium
CDSC(NI)	Communicable Disease Surveillance Centre (Northern Ireland)
CIEH	Chartered Institute of Environmental Health
DARD(NI)	Department of Agriculture and Rural Development
DHI	Dairy Hygiene Inspectorate
DWI	Drinking Water Inspectorate
EA	Environment Agency
EC	European Commission
EFSA	European Food Safety Authority
EMI	Egg Marketing Inspectorate
FDF	Food & Drink Federation
HMI	Horticultural Marketing Inspectorate
HPA	Health Protection Agency
GCNI	General Consumer Council for Northern Ireland
LACORS	Local Authorities Coordination of Regulatory Services
MHS	Meat Hygiene Service
NCC	National Consumer Council
NFU	National Farmers Union
PSD	Pesticides Safety Directorate
SEPA	Scottish Environmental Protection Agency
SBC	Small Business Council
SCC	Scottish Consumer Council
TSI	Trading Standards Institute
VMD	Veterinary Medicines Directorate
WCC	Welsh Consumer Council
Which?	Which?
WSB	Wine Standards Board

ANNEX J - Organisations represented on the Taskforce

Food Standards Agency (The Agency) - http://www.food.gov.uk/
The Food Standards Agency is an independent Government department set up by an Act of Parliament in 2000 to protect the public's health and consumer interests in relation to food.

British Hospitality Association (BHA) - http://www.bha-online.org.uk/aboutus.asp
The British Hospitality Association represents all sections of the hotel, restaurant and catering industry.

The Association exists to ensure that the views of the British hospitality industry are represented in a forceful, coherent and co-ordinated way to government and policy makers in the UK and internationally.

British Retail Consortium (BRC) - http://www.brc.org.uk/mission04.asp
The British Retail Consortium is the lead trade association representing the whole range of retailers, from the large multiples and department stores through to independents.

The BRC exists to campaign to promote and protect retailers' interests; advise retailers on threats to and opportunities for their businesses; offer a range of competitive, professional services; and improve the general perception of the retail industry in the UK.

Chartered Institute of Environmental Health (CIEH) -
http://www.cieh.org/about/
Founded in 1883, the Chartered Institute of Environmental Health (CIEH) is a professional and educational body, dedicated to the promotion of environmental health and to encouraging the highest possible standards in the training and the work of environmental health professionals.

Trading Standards Institute (TSI) - http://www.tsi.org.uk/institute/
The Trading Standards Institute is a professional association which represents Trading Standards professionals in the UK and overseas - in local authorities, the business and consumer sectors and in central government.

Association of British Insurers (ABI) - http://www.abi.org.uk/
The ABI provides leadership on issues bearing on the industry's collective strength and image and to shape and influence decisions made by the Government, regulator and other public authorities, within and outside the UK, in order to benefit the industry collectively.

Food and Drink Federation (FDF) - http://www.fdf.org.uk/about_fdf.aspx
The Food and Drink Federation (FDF) represents the UK food and drink manufacturing industry, the largest manufacturing sector in the UK.

The FDF help food and drink manufacturers operate in an appropriately regulated marketplace and communicate their values and concerns to a range of audiences in the UK and abroad. The FDF also works in partnership with other main players in the food chain to help ensure that members food is safe and that consumers can have confidence in it.

Local Authorities Co-ordinators of Regulatory Services (LACORS) -
http://www.lacors.gov.uk/pages/trade/whatislacors
LACORS provides advice and guidance to help support local authority regulatory and related services. It was set up in 1978 to co-ordinate the enforcement activities of trading standards.

Central to LACORS' work is the promotion of quality regulation, development of policy and dissemination of comprehensive advice, guidance and good practice, which is principally aimed at local authorities.

National Consumer Council - http://www.ncc.org.uk/
The National Consumer Council (NCC) makes a practical difference to the lives of consumers around the UK, using its insight into consumer needs to advocate change. We work with public service providers, businesses and regulators. Our relationship with the Department of Trade and Industry — our main funder — gives us a strong connection within government. We conduct rigorous research and policy analysis to investigate key consumer issues, and use this to influence organisations and people that make change happen.

National Farmers Union (NFU) - http://www.nfuonline.com/x203.xml
The National Farmers Union represents the farmers and growers of England and Wales. Its central objective is to promote successful and socially responsible agriculture and horticulture, while ensuring the long-term viability of rural communities.

The Small Business Council sbcsecretariat@sbs.gsi.gov.uk
The SBC is a non Department Independent Body comprising of 19 small business owner managers from all parts of the UK and representing different business sectors. The Council works closely with Ministers and policy makers inside Whitehall. The Council meets regularly with small businesses across the UK to hear their views.

Which? - http://www.which.co.uk/

Which? exists to tackle the issues that matter to all consumers.

We're fiercely independent and don't take funding from government or companies. Our magazines and website help people make the right choice when buying products and services, tell consumers their rights and expose company wrongdoing.

Which? also campaigns to stop businesses ripping off or endangering customers.

ANNEX K - CONTACTS

The Food Standards Agency's Incident Team

Tel: 020 7276 8448

Alternative 'Out of Hours' contact No: 020 7270 8960

The Agency's online incident report form is available from

http://www.food.gov.uk/foodindustry/regulation/foodfeedform