Food Standards Scotland

For safe food and healthy eating

SHPN

SCOTTISH HEALTH PROTECTION NETWORK

Promoting and Supporting Good Practice

Guidance on the management of outbreaks of foodborne illness in Scotland

A supplementary guide to the management of public health incidents: Guidance on the roles and responsibilities of NHS led incident management teams.

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Comments for consideration in future iterations of this guidance should be sent to the SHPN Guidance Team by emailing phs.shpn-admin@phs.scot.

Food Standards Scotland (FSS) is Scotland's national food body for protecting consumers from food safety risks and promoting healthy eating. FSS is also designated as a competent authority and enforcement authority under food and animal feed law in Scotland.

Public Health Scotland (PHS) is Scotland's national agency for improving and protecting the health and wellbeing of Scotland's people.

The Scottish Health Protection Network (SHPN) is an obligate network of existing professional organisations and networks that aims to promote, sustain, and coordinate good practice in the health protection community across Scotland.

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Abbreviations

AA	Agricultural Analyst
A&E	Accident & Emergency
APHA	Animal and Plant Health Agency
CPH/CPHM	Consultant in Public Health/Consultant in Public Health Medicine
ECDC	European Centre for Disease Prevention and Control
EH	Environmental Health
EPIS	Epidemic Intelligence Information System
EU	European Union
FBE	Food Business Establishment
FBO	Food Business Operator
FA	Food Authority
FE	Food Examiner
FSA	Food Standards Agency
FSMS	Food Safety Management System
FSS	Food Standards Scotland
GDG	Guidance Development Group
GI	Gastrointestinal
GP	General Practitioner
HACCP	Hazard Analysis and Critical Control Point
HEPN	Hygiene Emergency Prohibition Notice
HPNS	Health Protection Nurse Specialist
HPT	Health Protection Team
IMF	Incident Management Framework
IMT	Incident Management Team
LA	Local Authority
MLST	Multilocus Sequence Typing

MLVA	Multiple Locus Variable-number tandem repeat Analysis
MPHI	Management of Public Health Incidents
NHS	National Health Service
NPIS	National Poisons Information Service
OCL/OLs	Official Control Laboratories/Official Laboratories
PA	Public Analyst
PAG	Problem Assessment Group
PFGE	Pulse Field Gel Electrophoresis
PHS	Public Health Scotland
PRIN	Product Recall Information Notice
RAN	Remedial Action Notice
SBAR	Situation Background Assessment Recommendations
SFCIU	Scottish Food Crime and Incidents Unit
SFELC	Scottish Food Enforcement Liaison Committee
SGAHWD	Scottish Government Animal Health and Welfare Division
SHPIR	Scottish Health Protection Information Resource
SHPN	Scottish Health Protection Network
SHPN-GIZ	Scottish Health Protection Network – Gastrointestinal and Zoonoses
SMO	Senior Medical Officer
SRUC	Scotland’s Rural College
STEC	Shiga Toxin-producing Escherichia coli
UKAS	United Kingdom Accreditation Service
UKHSA	United Kingdom Health Security Agency
WGS	Whole Genome Sequencing

1. Introduction

1.1 Purpose of the guidance

This guidance provides details of specific multi-agency arrangements and actions relating to the management of outbreaks of foodborne illness (foodborne outbreaks) in Scotland. For the purposes of this guidance food includes all food and drink products including bottled water. It may also cover certain animal feeding stuffs (e.g. pet food) which has caused human illness through consumption or handling.

This guidance supports: Management of Public Health Incidents: Guidance on the Roles and Responsibilities of NHS led Incident Management Teams. Scottish Guidance No 12.1 (2020 edition); referred hereafter as the MPHI guidance. It highlights the key additional functions of Food Standards Scotland (FSS) and the Local Authority teams with responsibility for the enforcement of food law (referred to as LAs throughout this document) during the management of foodborne outbreaks. It also provides information on specific pathogens as well as chemicals and toxins which can be associated with foodborne incidents, that can be referred to during outbreak investigations (See Sections 5 and 6).

1.2 Background

This guidance replaces the previous 'Food Standards Agency (FSA)/Scottish Executive Health Department Guidance on the Investigation and Control of Outbreaks of Foodborne Disease in Scotland', published in 2002 (and updated in 2006) by a working group chaired by Professor Cairns Smith.

The legal basis for this guidance is defined in Part 1, Section 30 of The Food (Scotland) Act 2015, which provides powers to FSS to issue guidance to Scottish ministers and public bodies on 'the exercise, generally, of their functions in relation to matters connected with the management of outbreaks (or suspected outbreaks) of foodborne diseases'.

1.3 Who this guidance is for

All those involved in the investigation and control of foodborne outbreaks in Scotland should follow this guidance or refer to it when developing their own plans for managing such incidents. LAs and other relevant authorities should refer to this document in conjunction with the Food Law Code of Practice (Scotland) and associated guidance during the management of any incident in which an outbreak of human illness may be attributed to the consumption of a contaminated food.

Separate arrangements are in place for the management of food safety incidents not involving human illness. These investigations are led at a local level by LA Environmental Health (EH) professionals, and co-ordinated nationally by FSS when the incident is defined as serious or extends beyond the boundaries of a single LA. FSS's Incident Management Framework (IMF) should be referred to for details of the management of such food safety incidents.

1.4 How to use this guidance

Regular training and exercising of this guidance are important to ensure expertise is developed and that procedures for establishing team and cross agency working arrangements are fully understood by all involved in the management of foodborne outbreaks. NHS Boards and LAs should take account of this guidance in any reviews of their local plans, ensuring roles and responsibilities are fully recognised, and that they have a fully co-ordinated approach for the investigation and management of foodborne outbreaks which are of public health significance. Effective collaboration and co-ordination are particularly important in ensuring a cohesive response to foodborne outbreaks which extend beyond a single NHS Board or LA area.

2. Scope

2.1 What this guidance covers

The Food (Scotland) Act 2015 defines ‘foodborne diseases’ as ‘diseases of humans capable of being caused by the consumption of infected or otherwise contaminated food’.

The terms ‘foodborne disease’, ‘foodborne illness’ and ‘food poisoning’ are often used interchangeably, and the nature of public health risks covered by these definitions can be unclear. This guidance will use the terms 'foodborne illness' and 'foodborne outbreaks' when referring to illness and outbreaks attributed to the contamination of food by microbiological or chemical agents or toxins.

This guidance provides a framework for all public health professionals which will assist them in the management of outbreaks of illness potentially linked to contamination of a food product or products with:

- infective microbiological agents (bacteria, viruses, fungi, parasites or protozoa)
- harmful chemical agents/toxic substances including biotoxins produced by bacteria, plants, and fungi

This guidance focuses on the management of foodborne outbreaks associated with infective agents, as these are more frequently linked to human illness. Whilst foodborne outbreaks caused by harmful chemical agents are less common, the process for managing these incidents is broadly similar. LAs and NHS Boards should consider the need to consult other specialist organisations throughout the management of incidents involving chemical agents, depending on the circumstances surrounding the outbreak and the nature of the contaminant implicated. Further details on the management of foodborne outbreaks attributed to chemical contaminants can be found at Section 6.2.

This guidance does not cover the following:

- Outbreaks associated with the consumption of drinking water from public and private drinking water supplies or those which have been attributed to direct contact with animals or environments contaminated by animal faeces.

- Procedures for the response and recovery from emergencies which may result from the radiological contamination of food. Advice on such incidents can be obtained from Food Standards Scotland and the Scottish Environmental Protection Agency (SEPA), with further information on emergency response available from Preparing Scotland.

This document is considered to be 'Good Practice Guidance' and has been developed by an expert Guidance Development Group (GDG) (see Appendix 2 for GDG membership information) formed under the auspices of the Scottish Health Protection Network (SHPN). The GDG developed recommendations based on existing policy and guidance (referenced in this document), supplemented by expert opinion. Key stakeholders were consulted prior to publication (see Appendix 3). This guidance will be reviewed regularly (3-year minimum review period).

Information pertaining to foodborne pathogens and chemical contaminants (section 6.2) was derived from an extensive search of relevant guidance and peer reviewed published literature. Further details can be found in Appendix 4 around the methods used.

3. Statutory responsibilities and legislation which apply to the management of foodborne outbreaks

3.1 Responsibilities of NHS Boards and PHS

One of PHS's key functions is to work in partnership with LAs and NHS Boards to ensure effective preparation and response to outbreaks and incidents. A number of other statutory agencies are also involved in planning for and managing public health incidents, each having its own statutory duties to fulfil with regard to the protection of public health, and taking responsibility for the actions it takes. NHS Boards, as the lead agency for protecting health, are responsible for the overall integrity of the arrangements for planning for public health incidents, and for the effectiveness of the incident response.

The responsibilities of NHS Boards and PHS, and related legislation, in particular the Public Health etc. (Scotland) Act 2008, are set out in detail in the MPHI guidance).

This document should be used in conjunction with the MPHI guidance during the management of foodborne outbreaks.

3.2 Responsibilities of FSS and Local Food Authorities (LAs)

During a foodborne outbreak, LAs and FSS are responsible for food chain investigations (including inspections of food production environments) and the traceability (trace forward/trace back) of food stuffs which are suspected to be the source or vehicle. They are also responsible for any enforcement action against implicated Food Business Operators (FBOs). LAs also have responsibility for the enforcement of additional legislation, including, but not limited to, Health & Safety, Waste etc which may require action as a result of outbreak investigations.LA Environmental Health Officers (EHOs) designated as Competent Persons in terms of The Public Health etc. (Scotland) Act 2008 have powers and responsibilities under the Act to protect the people of Scotland from infectious diseases, contamination and other such hazards, and may take action in that regard.

The management of foodborne outbreaks is underpinned by the food law powers of the LA and FSS. The Food Safety Act 1990 and Regulation (EC) 178/2002 provide the framework of food law applicable in Scotland. This legislation firmly places the responsibility on FBOs to ensure that all food placed on the market is safe. FBOs are also legally required to inform the competent authorities (either the LA or FSS) immediately when they have reason to believe that food which they have imported, produced, processed, manufactured or distributed is not in compliance with food safety requirements, and/or when it may be injurious to human health.

LAs have responsibility for enforcing legal food safety requirements and verifying compliance with the regulations in most food businesses across Scotland. Food establishments which require veterinary supervision (i.e. abattoirs, cutting plants, and game handling establishments) are subject to enforcement by FSS.

Respective legal obligations, responsibilities and powers under current food law for acting in circumstances where there are reasonable grounds for suspecting food may present a risk for public health are detailed in Section 6.3.

3.3 Responsibilities of the Public Analyst/Food Examiner/Agricultural Analyst

In Scotland, scientific services for the official analysis and examination of food and animal feed are provided by four Public Analyst (PA) laboratories located in Aberdeen, Dundee, Edinburgh and Glasgow, which are designated as Official Laboratories (OLs) under Food Law (see below). During the investigation of a suspected foodborne outbreak, the PA laboratory (represented by a food microbiologist/food examiner; FE) or Public Analyst) may advise the LA on appropriate food, water and environmental sampling arrangements (including appropriate transportation and storage) and perform, or arrange for, relevant analyses to be undertaken. They are also responsible for reporting and interpreting the results of these analyses and advising the LA and/or FSS when initial results indicate the need for additional sampling. In circumstances where an outbreak of illness has been linked to the consumption or handling of animal feed, advice should be sought from a qualified Agricultural Analyst (AA); this expertise can also be accessed via the PA laboratory.

The legal basis for the PA and FE role is provided by the Food Safety Act (1990), which defines how food sampling should be undertaken for the purposes of the Act. This includes a requirement for such samples to be submitted for analysis by a PA/FE, and for results to be reported on a formal certificate of analysis or examination. The Food Safety (Sampling and Qualifications) (Scotland) Regulations 2013 made under the Act specify the qualifications necessary to be a PA/FE. They also specify the procedure to be followed when a sample has been procured, and the format for reporting results on certificates of analysis and examination. Similar legal requirements are defined in the Agriculture Act (1970) which apply to AAs who specialise in the sampling, analysis and interpretation of results pertaining to animal feed.

The PA/FE/AA is responsible for the analysis/examination of samples taken for the purpose of the execution and enforcement of specified food and feed law, where the relevant provisions of the Act are applied in the same way. This function is provided for in The Food Hygiene (Scotland) Regulations 2006 and The Official Food and Feed Controls (Scotland) Regulations (2009) for example.

Additional requirements for sampling, analysis and interpretation of results are prescribed in food safety legislation and nationally recognised guidelines (e.g. Health Protection Agency (HPA, now UK Health Security Agency; UKHSA) Guidelines for assessing the microbiological safety of ready to eat foods placed on the market).

Regulation (EU) 2017/625 requires Competent Food Authorities to designate OLs to carry out the analysis of food and feed samples taken for the purposes of official controls and other official activities. In Scotland, the four LA operated PA laboratories, Aberdeen Scientific Services (ASS), Tayside Scientific Services (TSS), Edinburgh Scientific Services (ESS) and Glasgow Scientific Services, have been designated as OLs. These laboratories provide the majority of PA/FE/AA services for FSS and the 32 LAs across Scotland. The OLs provide a broad range of scientific, analytical and examination services relating to public health and consumer protection. These services include the analytical testing of food and feed for a wide range of chemical contaminants, additives and nutritional analysis, and examination for hygiene indicator organisms and the key microbiological pathogens that are capable of causing foodborne illness. In some cases it may be necessary for OLs to sub-contract certain services to other OLs or specialised laboratories which are designated to undertake additional official control testing required by law. The Food Standards Scotland website maintains an up to date list of OLs which are designated to undertake official control testing across Great Britain. OLs must be accredited in accordance with the EN ISO/IEC 17025 standard and subject to an annual audit carried out by the United Kingdom Accreditation Service (UKAS), which is the national accreditation body. OLs are required to undergo rigorous training in the specific procedures used, and to demonstrate competence through external performance assessment schemes and on-going participation in collaborative trials co-ordinated by National Reference Laboratories (NRLs) for food and animal feed which are designated by FSS and FSA as specialist laboratories to provide advice to OLs on methods and provide assurance over official control testing of food and feed.

The PA/FE/AA will also liaise with the appropriate Clinical Reference Laboratories in Scotland or UKHSA, to arrange for the typing/sequencing of pathogens isolated from food and environmental samples taken during the investigation of a foodborne outbreak. The PA's formal test certificate will take full account of the interpretation made by the Reference Laboratory pertaining to the characterisation of the isolate when making their assessment of food safety.

4. Key functions of incident management during a foodborne outbreak

Section 7 of the MPHI guidance sets out the key functions of public health incident management. These functions are expanded upon here, with particular focus on foodborne outbreaks. Sections 6.1.3 and 6.2.2 of this document also contain additional supporting information in relation to some of the more common foodborne pathogens, toxins and chemical contaminants, which may be helpful in identifying the likely causative agent, food vehicle or source of a foodborne outbreak and guiding further investigations and management.

Decisions on appropriate leadership during foodborne outbreaks will be determined on a case by case basis, and will depend on the national significance, scale and complexity of the incident, but in most cases will be based on the following general principles.

In line with sections 4 and 6 of the MPHI guidance, when a foodborne outbreak is localised to a single NHS Board area or linked to a particular event or a single FBO within an NHS Board area, a local Consultant in Public Health or Consultant in Public Health Medicine (CPH/CPHM) usually leads the outbreak response, involving PHS and UKHSA in circumstances where a national or international supply chain is implicated.

The relevant LA Environmental Health (EH) Professional leads the investigation of the implicated Food Business Establishment (FBE) in line with local outbreak control plans and the Food Law Code of Practice (Scotland). When the outbreak involves cases across multiple NHS Boards or may be linked to a foodstuff which has been distributed to a number of LA areas throughout Scotland then the outbreak response leadership should be agreed between NHS boards and PHS. If other parts of the UK are affected then the lead organisation will be determined through discussion with PHS, UK Health Security Agency (UKHSA) and any other UK public agencies who are involved. FSS will coordinate and manage all food chain investigations required during a national outbreak in accordance with their IMF, working alongside FSA when it escalates to a UK wide incident. The general principles of a foodborne outbreak investigation are the same whether the outbreak is managed at a local level or across a number of LAs/NHS Boards.

During the early stages of an outbreak investigation it may not be apparent if the mode of transmission is foodborne, person-to-person, or via animal or environmental exposure. It may therefore be necessary to investigate a number of possible hypotheses initially.

The process for managing a foodborne outbreak will vary depending on the circumstances, however it can be broadly split into four key areas:

- **Identification** – Confirming the outbreak and initiating a response (by convening a problem assessment group (PAG) where required).
- **Investigation** – Convening an incident management team (IMT) to construct the case definition, develop hypotheses, collect appropriate evidence and assess the risks.
- **Intervention** – Identifying appropriate risk management procedures and implementing control measures that will prevent further cases.
- **Information** – While the incident is active this will involve communicating the findings of investigations, actions taken, and further control measures required. When the incident is closed it will involve preparing an IMT Report, and completing a summary report form to inform national surveillance.

The algorithm in Section 5.4 of this document (Supporting Tools) sets out how all of the activities at each stage contribute to the management of a foodborne outbreak. Some activities can take place concurrently, while others must await outcomes from earlier activities. Certain activities such as communications and control measures may take place repeatedly throughout the investigation. The outbreak risk assessment and hypothesis should also remain under review throughout the investigation.

4.1 Identification and initial response

4.1.1 Identification of an outbreak

NHS Boards and PHS analyse and interpret information collected through various reporting routes which may alert them to the possibility of a foodborne outbreak occurring.

- Routine surveillance and follow-up of infectious disease notifications or laboratory reports identifies a cluster of cases of a potentially foodborne infection, e.g. Salmonella or Shiga toxin-producing Escherichia coli (STEC), linked in time and/or place.
- Laboratory typing or whole genome sequencing of clinical isolates identifies a cluster of cases with the same microbiological profile which may indicate a common source of infection.
- Cases of illness associated with a particular foodstuff or FBO are reported to EH officers at the LA or to the NHS Board Health Protection Team (HPT). These reports may come from various sources including: food consumers and other members of the public, frontline healthcare professionals e.g. general practitioner or accident and emergency departments, and the media. Intelligence may also come from the food establishment itself in line with their legal obligations to inform the LA or FSS when they become aware that food they have placed on the market may have caused human illness.

Authorities may also be alerted to the potential risk of a foodborne outbreak in situations where a food incident, or sampling carried out by the LA or for the purposes of FSS's national surveillance programmes, identifies contamination in food which has been placed on the market. In the absence of reports of human illness, the appropriate LA would lead the incident response in close liaison with FSS, ensuring the relevant NHS Board CPH/CPHM and PHS is appropriately informed of potential risks to the public. If cases of human illness occur, the relevant NHS Board(s) or PHS would lead the incident response in line with this guidance.

When a LA or FSS undertakes a risk assessment which identifies that an incident could cause a significant public health risk, they will inform the relevant NHS Board CPH/CPHM and/or PHS who may convene a PAG and IMT. This can occur when there is notification of a single case of an infection that is potentially foodborne with significant public health implications (e.g. botulism) or even in the absence of any cases of human illness, if the potential risk is considered to warrant such a response.

4.1.2 Initial response

Having been alerted to a possible foodborne outbreak, the NHS Board CPH/CPHM should review all the available evidence, carry out an initial assessment and, if possible, develop working hypotheses in consultation with relevant partners e.g. the LA EH professional, the consultant clinical microbiologist and/or the relevant reference laboratory. Depending on the nature and scale of the incident, it may also be appropriate to consult FSS and/or PHS at this stage. If the initial assessment indicates that an outbreak is or may be occurring which is likely to present an on-going public health risk (or is considered to require further investigation for any other reason) then an IMT should be convened to oversee and coordinate any actions that may be required. In the first instance, the CPH/CPHM may convene a PAG to undertake an initial assessment and determine if an IMT is required (see section 6.4 of MPHI guidance).

Where initial information indicates that a specific FBO may be implicated in the outbreak, the LA EH Professional (and/or FSS where appropriate) should immediately lead an investigation of the FBE, guided by the Food Law Code of Practice (Scotland). The FBE should be visited at the earliest opportunity to assess their compliance with food law (including a review of the food safety management systems in place) and the need for sampling to be undertaken of foods produced by the business, and/or the production environment.

Depending on the initial assessment or outcome of a visit to an implicated FBE it may be necessary to implement immediate control measures prior to the first IMT. These could include voluntary actions by the FBO to mitigate risk, the use of enforcement notices to control food production, and/or the prohibition of operations or measures to remove suspected food products from the food chain such as recalls and the seizure/detention of implicated foodstuffs.

For localised outbreaks, LAs and NHS Board CPH/CPHMs should always consider the need to inform FSS (usually via PHS) of any outbreak of human illness that has been linked to food, taking account of the severity of the illness, evidence pointing to an association with unusual or unexpected hazards and/or types of food, and the potential for widespread exposure through commonly consumed products. This information may be important in enabling FSS to identify potential links to other food incidents reported elsewhere, and to assess the need for a food safety risk assessment and any further investigations in conjunction with LAs.

4.2 IMT arrangements

The IMT should be convened in line with section 6 of the MPHI guidance, which sets out the organisational arrangements for the management of public health incidents, including suggested membership of the IMT (section 6.5), the role of the IMT (section 6.6) and decision making by the IMT (section 6.8).

4.2.1 IMT membership

In addition to the suggested membership set out in section 6.5 of the MPHI guidance, the Chair of the IMT for foodborne outbreaks should consider representation from the following:

- FSS
- The Public Analyst Laboratory and/or other appropriate Food/Feed Reference Laboratories
- The relevant NHS reference or specialist clinical and/or microbiology laboratory
- Other agencies as required depending on the suspected source e.g., FSA, the Animal and Plant Health Agency (APHA), Marine Scotland and UKHSA
- Expert scientists as required e.g. a toxicologist from the National Poisons Information Service (NPIS) if a toxin/chemical hazard is suspected or confirmed

Where appropriate, member organisations should notify the Chair of any observers they wish to invite to IMT meetings in order that roles and responsibilities of attendees are understood.

When the IMT suspects criminal activity, it should consider involving Police Scotland and/or the Crown Office Procurator Fiscal Service, who may be invited to attend the IMT. The LA should also consider the need to involve officers from the Scottish Food Crime and Incidents Unit (SFCIU) of FSS, in line with the MOU between the Society of Chief Officers of Environmental Health in Scotland and FSS, to review any relevant information and/or intelligence which may point to fraudulent practice or the adulteration of food and may require criminal investigation.

For national outbreak investigations led by PHS, membership of the IMT will normally include representation from each of the affected NHS Board areas' health protection teams; usually a CPH/CPHM or Health Protection Nurse Specialist (HPNS). For such multi-NHS Board area foodborne outbreaks, FSS will be a member of the IMT along with the relevant LAs involved in the outbreak investigations. During national outbreaks, FSS will coordinate the food chain investigations with the relevant LA EH professionals and will be responsible for updating the IMT on the outcomes of these investigations.

If a foodborne outbreak involves cases of illness in more than one UK country, the overall investigation will usually be led by UKHSA (unless it is agreed that it would be more appropriate for it to be led by PHS). In outbreaks which are linked to products which have a UK wide distribution, the food chain investigations will usually be led by the Food Standards Agency (FSA), unless it is agreed that it would be more appropriate for FSS to lead (e.g. when the implicated FBO is located in Scotland). In all UK wide outbreak investigations, PHS and FSS would represent Scotland on the related UKHSA-chaired IMT, with support from relevant HPTs as appropriate. In these situations it may still be necessary for PHS to convene an IMT to coordinate any actions that need to be taken in Scotland. In the case of a multi-country outbreak which extends outwith the UK, FSS and PHS would provide input to the related food chain and epidemiological outbreak investigations via FSA and UKHSA.

4.2.2 IMT sub-groups

As per section 6.6 of the MPHI guidance, the IMT may require to set up subgroups to consider specific aspects of the incident investigation e.g. epidemiological investigations (including any analytical studies), clinical care, or communications. Where subgroups are formed, terms of reference should be drawn up to ensure that the remit of the subgroup and reporting arrangements to the main IMT are clear.

In foodborne outbreaks it may be appropriate to set up a specific food subgroup to allow more detailed discussions relating to the findings of premises inspections and food chain investigations which need to be handled out with the main IMT meetings. A sample terms of reference and agenda for the food subgroup are included in Section 5.1 of this document. Key topics for the food subgroup would include issues associated with the FBO's Food Safety Management System/Hazard Analysis and Critical Control Point (HACCP) plans, traceability of implicated food chains, environmental and food sampling strategies, and appropriate enforcement measures.

The IMT would determine the membership and chair of the food subgroup, which would normally be chaired by the appropriate Food Authority (the relevant LA EH Lead Officer or FSS) and include representation from the following:

- FSS,
- LA EH professionals involved in the investigations,
- A health protection specialist nominated by IMT chair,
- Public Analyst/Food Examiner and, where required, appropriate Reference Laboratory professionals.

As with all foodborne outbreaks, LAs should ensure that there is on-going communication with other relevant LAs and/or FSS on all technical and enforcement matters relating to the implicated FBE, and the food subgroup is not intended to replace this. Rather, it is a forum for reviewing the outcomes of food chain investigations in the context of the outbreak, and to provide a means of consolidating evidence required to support decision making by the IMT. It is the role of the subgroup to provide a written update in the form of a highlight report to each meeting of the IMT, summarising its investigations and key findings to date and highlighting any areas that require further discussion (see Section 5.2). This will ensure that the IMT is kept fully informed of the food chain investigations whilst ensuring that its discussions remain focussed on key issues pertinent to the overall management of the outbreak.

The IMT and its food sub-group should be cognisant of the parallel procedures that may be initiated internally by FSS through its IMF. These are in place to provide appropriate governance and legal oversight of food chain investigations during incidents that have the potential to significantly impact public health, and/or confidence in the food supply system. In these circumstances, it is important to maintain a two way exchange of information to ensure these different aspects of the investigations are aligned.

4.2.3 Preparations for the IMT

The main elements of foodborne outbreak investigations are detailed in sections 4.3-4.5. Evidence collected from these investigations is used by the IMT to:

- form working hypothesis(es) as to the most likely vehicle/source/cause of the outbreak and keep these under review as the outbreak evolves or new evidence arises,
- evaluate the working hypothesis(es) in light of new findings,
- inform the outbreak risk assessment and risk management decision making (see sections 5.5 and 5.6 below), and
- assess the effectiveness of any control measures implemented.

Tools for supporting IMTs in preparing for investigations into foodborne outbreaks are provided at Section 5 of this document. These include guidance to aid the IMT in considering the strength of the available epidemiological, food chain and laboratory evidence obtained during the investigations (5.3), and an algorithm which summarises the main elements of the investigation (5.4).

4.3 Epidemiological investigations

4.3.1 Descriptive epidemiology

Descriptive epidemiology, sometimes referred to as “data orientation”, is central to understanding the incident. The descriptive epidemiology is the basis for generation of hypotheses for the causes of the incident and will help direct control measures.

Case definition

Successful and efficient outbreak response relies on identifying and gathering information from as high a proportion of linked cases as possible. Failures in determining case definitions or case finding can result in missing relevant cases, or including cases which are not part of the outbreak. This may lead to erroneous conclusions or misdirected control measures.

A case definition is a set of criteria determining whether a person has the clinical and/or microbiological characteristics to be deemed a case, and whether they have the temporal, geographical or other characteristics to be deemed part of the outbreak. The initial case definition should be designed to capture all those who could reasonably be deemed outbreak cases, taking account of clinical, laboratory, geographical, temporal, and other relevant parameters, for example, attendance at a social or other function. It should be noted that if living in a particular area, or attendance at a function is a defining attribute of an outbreak case, confirmed or suspected cases who did not attend the function, while still cases, and of interest, are not, by definition, outbreak cases.

Case definitions should distinguish between confirmed and suspected cases, and suspected cases may be further categorised as possible and probable. Definitions should also discriminate between primary and secondary cases. Case definitions should be kept under review and be revised as appropriate as the investigation progresses.

The specific criteria used to establish a case definition will depend on the incident and will be influenced by the pathogen, in addition to other evidence that may be available such as whole genome sequencing (WGS) profile (see section 4.5.6 for further details), molecular typing information, and analysis of any chemical contaminant/toxin that may be associated with the illness.

Case finding

Initial notifications of cases may represent only a small proportion of individuals, so the IMT should consider options for identifying further cases. There are several reasons to carry out active case finding which can include:

- gaining additional epidemiological, microbiological or risk information to better characterise and therefore control the incident,
- identifying individuals who require medical intervention,
- monitoring effectiveness of control measures, or
- supporting the decision to declare the incident over.

Case finding can be undertaken through:

- enquiry of household and other contacts of known cases,
- review of other notifications/lab results,
- raising awareness with health and social care staff to identify further cases,
- enquiry of other groups who may be collecting useful information (such as occupational health departments or school absence rolls),
- and rarely other techniques such as media appeals or population screening.

Food exposure information

In foodborne outbreaks, the initial food exposure information is often obtained from cases via the routine enteric interview or surveillance questionnaires completed with suspected or confirmed cases. This initial data gathering may identify a potential single common exposure (or exposures) for further investigation e.g. similar food products or settings. It will also help to eliminate other potential exposure routes such as foreign travel.

NHS Board HPTs, LA EH Professionals or PHS may collect more detailed food exposure and other information through the completion of a trawling (or hypothesis-generating) questionnaire with the cases. These tend to be used when information gained from standard enteric interview or surveillance questionnaires is insufficient to support hypothesis generation/identification of sources. They are also useful during outbreaks where cases have been linked via molecular microbiology typing techniques across a broad geographical area. Trawling questionnaires can be resource intensive, and careful consideration should be given to their design and the value they are likely to add to investigations. Even though the trawling questionnaires are very detailed, it can be necessary to go back to cases to ask for additional details or clarify information, such as particular food brands or the component parts of a dish.

Trawling questionnaires are designed to capture in-depth details of foods consumed within and outside the home during the period at which they were likely to have become exposed (usually the incubation period). They also enable other information to be collected such as the demographic profiles of cases and details pertaining to other potential exposures, such as foreign travel and attendance at social or other events or following specific diets. At this stage a common food vehicle may be identified (or a number of possible vehicles), which can then be investigated in more detail.

Where a common restaurant or event has been identified, it is important to collect as much information as possible from the business to inform the questionnaires. This will include copies of paperwork such as receipts, orders, menus, and recipes as well as details of the portions of certain meals ordered and quantities of their component ingredients. It is also important to collect details of garnishes that could have been added to food and drink (including the preparation of ice used in drinks), side dishes that may have accompanied a meal, and dishes that may have been shared. Where possible, the caterer should also be asked to retain any remaining implicated foods to support sampling that may be required for on-going investigations.

Where permissions allow, additional information on foods purchased by cases at retail may be available via supermarket loyalty cards. Depending on the foods under investigation, and the profile of cases, it may also be helpful to compare the rate of consumption of a particular type of food by cases to estimates of the rate of consumption in the general population (e.g. using information available from the National Diet and Nutrition Survey, FSS's dietary tool Intake 24, or surveys of food purchasing and consumption). It is important to understand the limitations of these studies before taking this information into account for example the level of coverage of different sections of the population and different categories and brands of food.

As the outbreak investigation evolves and particular food(s) are suspected, the trawling questionnaire may be revised to collect additional details of particular foods and other biologically plausible vehicles that are emerging as common links to cases. However, it is important that the IMT does not prematurely focus on one particular product and is able to constantly evaluate its hypotheses as the investigation progresses.

Summarising the descriptive epidemiology

The epidemiological evidence needs to be updated throughout the investigation to ensure all of the relevant details are available to support IMT discussions and decision making. Summaries of evidence for consideration at each of the IMT meetings must include the most current status reports of the following:

- epidemic curve clearly identifying chronology of the different types of cases (i.e. confirmed/probable, primary/secondary). Cases may be graphed by date of onset, specimen date, or date of report.
- description of cases by age, sex, locality, and other variables (where relevant)
- hospitalisation rates and other relevant clinical information.
- a line list of cases including exposure to suspect foods. This comprises summary information on cases (persons unwell) affected by an outbreak, usually in a table format with each row containing information on each case and the columns containing information on a (risk and/or protective) factor/parameter of interest

4.3.2 Analytical epidemiology

The IMT should consider the need for analytical epidemiological studies, taking into consideration timescales, resources and the specific hypothesis it has developed. Analytical studies can be undertaken to test the hypothesis that a particular food identified from the descriptive epidemiology is the most likely vehicle of infection (or intoxication).

The type of analytical study undertaken will depend on the nature and size of the outbreak. The most commonly used are:

- Case-control studies; where outbreak cases are compared to healthy 'controls' and where controls are selected from the same population as the cases and differentiated from them only by their disease status).
- Case-case studies; where cases of a different infection are used instead of controls.
- Cohort studies; where the study population is clearly circumscribed- for example all the attendees at an event.

The type of study selected will depend on the circumstances of the outbreak and each has their advantages and disadvantages. In some cases it may be appropriate to conduct more than one type of analytical study in an outbreak investigation.
In some investigations it may be appropriate to undertake modelling work (e.g. Bayesian modelling) to estimate the proportion of the general population that would need to have eaten a particular food for the proportion of cases reporting the exposure to be considered more than expected.

There are a number of considerations in choosing an analytical study and ensuring its validity. The IMT should seek epidemiological and statistical expertise to advise on the type of analytical study that may be appropriate, and this may be accessed via PHS or the NHS board when available.

4.4 Food chain investigations

This section describes the specific investigations that are required to support hypothesis generation and control measures for mitigating public health risks during an outbreak of foodborne illness. These include food chain and other environmental investigations which aim to identify exposure routes and the circumstances which may have resulted in the contamination of implicated products.

4.4.1 Inspection of the food production environment

Food chain investigations should be initiated by LAs and/or FSS as soon as there is evidence which suggests a potential link to food. In the early stages of an outbreak, cases may be plausibly linked to a number of different foods or food businesses, so it is usually necessary for LAs and FSS to follow a range of leads.

LA EH Professionals should inspect implicated FBEs at the earliest opportunity and in accordance with the general principles outlined in the Food Law Code of Practice (Scotland). When FSS is the enforcing authority for an implicated FBE, inspections will be led under the direction of FSS Operational Delivery teams according to the applicable official procedures.

Although the type of information to be gathered during inspections will depend on the nature of the food businesses involved (e.g., caterers, retailers, distributors or food manufacturers), it is critical to verify compliance with food law, giving particular regard to the following list:

- the construction, size and general physical suitability of the unit in which the food business operates including pest proofing, water provision, waste storage, suitable finishes for fixtures and fittings, suitable food storage for the nature of the food business and design for food business operation.
- suitable permanent procedures based on Good Manufacturing Process (GMP), Good Hygiene Practice (GHP), and Hazard Analysis and Critical Control Points (HACCP) principles (including cleaning, storage, and cross contamination controls). These are requirements for an effective Food Safety Management System (FSMS) and apply to all operations within the food business from receipt of goods to the sale or onward supply of a food.
- suitable records for the operation of the business including training needed to support food law compliance, monitoring and corrective actions taken, and verification and validation of critical food safety measures by the business.
- records of staff illness and absences.
- potential risks that may be associated with suppliers to the business which are relevant to the implicated foodstuff and the official controls in place to mitigate these risks.
- food and environmental sampling as appropriate (see sections 5.4.2 and 5.4.3 below).
- paperwork relating to the sourcing of ingredients, distribution of products and customer records (to support traceability investigations).

The main aim of these investigations is to collect information which will provide Food Authorities and the IMT with a full understanding of production processes that are relevant to the implicated product or premises and the efficacy of food safety management and traceability systems that are in place.

4.4.2 Food chain trace forward/back

Once a food is suspected to be linked to cases of illness, the IMT should attempt to establish: how the food may have become contaminated, where the food or its ingredients originated from (trace back) and where the final product has been distributed to (trace forward). Comprehensive and accurate information on traceability plays a critical role in ensuring risk management decisions and actions are appropriately targeted and effective in mitigating further exposure, and it is therefore important that particular attention is paid to this aspect of the investigations. Foodborne outbreaks often involve complex supply chains and tracking the distribution of implicated products can be challenging. The collection of relevant records from all businesses involved in the production, distribution and sale of foods is essential in enabling the IMT to map the supply chain and verify the plausibility and strength of the epidemiological evidence. A food chain traceability chart can provide a helpful visual aid to inform the focus for further investigations.

4.4.3 Investigation of potential animal sources and environmental transmission routes

In some cases, it may be appropriate to seek specialist veterinary advice on the need for further investigations and sampling of animals and/or the environment to verify the plausibility of potential sources and transmission pathways which could be linked to the outbreak. Where the IMT considers that veterinary field investigations and/or animal sampling may be required then these should be discussed with a Scottish Government (SG) Veterinary Advisor at the earliest opportunity. Veterinary field investigations and animal sampling can be valuable tools in outbreak investigation. However, as these studies can be challenging and resource intensive, it is important that they are designed carefully to ensure they are feasible and that thorough consideration is given to the potential value they are likely to add to the overall investigation (see section 4.5.5).

4.5 Sampling and laboratory investigations

4.5.1 General

It is essential for LAs to alert the appropriate clinical specialist and PA/FE as early as possible in the investigation of an outbreak of suspected foodborne illness. Whilst most of these investigations will be led by microbiologists, it may also be necessary to call on additional expertise from, for example, a toxicologist.

Laboratory input is required for the following aspects of outbreak investigation:

- to advise on the appropriate sampling strategy including what types of samples to take and how to take them (clinical, food, water and environmental samples),
- to perform or arrange relevant analyses or microbiological or chemical investigations to be undertaken on samples,
- to liaise with the relevant reference laboratory and arrange for further identification and/or typing of isolates or samples,
- to advise on further sampling in light of initial results, and
- to report and interpret the results of analyses or microbiological examinations.

Sampling procedures must be subject to robust quality control by laboratories which have the appropriate UKAS accreditation. This is particularly important in relation to samples of food or environmental swabs which are taken to identify potential vehicles and sources of infection during an outbreak and to provide evidence that the FBO's food safety controls are insufficient to control further risks. In these cases, the PA test certificate provides critical evidence to support any legal action taken against FBOs which have been found to be non-compliant during the investigations.

4.5.2 Clinical samples

Samples from suspected cases should be submitted to the local diagnostic laboratory for appropriate testing following discussion with the clinical microbiologist. Sample containers and forms should be clearly labelled with patient details and sample date. It is important that laboratories can easily identify if the sample is part of a potential outbreak or incident, therefore, samples and forms should be clearly labelled to advise of this. If an 'outbreak number' is available then this should be included.

Some specialist investigations may require the local laboratory to forward clinical samples or isolates to a Reference Laboratory for further analysis. Clearance samples from recovered cases and asymptomatic contacts may also be required to exclude carriage and guide decision making on exclusions/restrictions if required. Consideration should also be given to the need for sampling of food handlers which may be associated with the outbreak. These samples should also be clearly labelled as being associated with a particular outbreak or incident.

It is important for the IMT to recognise that laboratory techniques are under constant development, and methodologies may differ across the various laboratories involved in an outbreak investigation (e.g. the use of faecal PCR versus culturing for certain organisms). Expert advice on the use of particular methods and the interpretation of results may be obtained through local NHS and National Reference laboratories.

4.5.3 Food samples

The primary objective of food sampling is to identify the causative agent of the outbreak in the suspected food stuff, one of its ingredients/components, and/or the environment in which it has been produced or prepared. Food sampling can also serve to provide important information relating to the efficacy of food safety management systems within food businesses associated with the incident, which can be valuable to investigations (e.g. to assess levels of hygiene indicator bacteria in products or food production environments). In this way, it can assist the IMT in determining the likelihood of the implicated food product becoming contaminated during its production.

It is often not possible to detect the causative organism, toxin or chemical contaminant in an implicated food, and there are a variety of reasons for this, including; the availability of relevant batches for sampling, the sporadic nature of contamination between batches, heterogeneous distribution of the causative agent within the matrix, and the levels of contamination in the food being too low to detect through available testing methods. The IMT should always bear in mind that failure to identify the causative agent in the food itself does not mean that the food should be ruled out as the vehicle. Neither does finding it unequivocally implicate a particular food product, which may have been contaminated after the event, or be one of a number of contaminated foods consumed or handled by cases.

Most outbreaks result from microbiological rather than chemical or toxicological contamination of food and so most investigations will involve input from a food microbiologist/food examiner. However, it is always important to consider the possibility of a chemical or toxin as the causal agent and whether additional food chemistry or toxicology expertise is needed to support the development of food sampling programmes and the interpretation of results generated.

Sampling of the suspected food vehicle should be undertaken as soon as suspected products and/or food businesses are identified, and results made available at the earliest opportunity. As soon as there is a reasonable suspicion that a particular FBE may be involved in an outbreak, then immediate arrangements should be made by the LA and/or FSS, in consultation with the relevant PA/FE, to develop an appropriate food sampling plan to support the investigations. When designing a sampling plan, LAs (in conjunction with the PA/FE) should carefully consider the following:

- the appropriate sampling points in the food production and supply chain,
- the number of samples that need to be taken,
- the quantity of material needed from each sample,
- the type of analysis and/or examination required,
- the procedure for reporting and interpreting results, and
- the need for formal sampling procedures (e.g. the presence of a witness) to support any legal action that may arise.

Samples should be as representative as possible of the implicated food or its ingredients, and in ideal circumstances should comprise at least 100 grams but if this is not possible advice on an appropriate sample size should be sought from PA/FE.

During outbreak investigations, it may be necessary to sample food which has been retained at the homes of outbreak cases or at restaurants where cases may have eaten implicated food as part of a meal. In these circumstances, it is important for the HPT and LA EH professional to work together to develop an appropriate sampling strategy; ensuring that the relevant PA laboratory is consulted on their requirements for testing. When testing relies on smaller samples of left-over food from meals, packets or tins, or, in some cases, remnants of discarded food, these should be sent to the laboratory in their containers where possible, taking precautions to prevent cross contamination. When samples are taken from the home of an outbreak case or restaurant, efforts should be made to identify whether any unopened products from the same batch are available which can also be tested to support investigations.

Section 38 of the Food Law Code of Practice (Scotland) provides detailed guidance on sampling and analysis undertaken for enforcement purposes. An authorised officer should take all samples for examination or testing in accordance with relevant regulatory requirements and submit them to an official laboratory (usually a PA laboratory) suitably accredited for the purposes of the particular test or examination required.

It should be noted that methods for the analysis/examination of certain pathogens and chemical agents may not be readily accessible from PA laboratories, particularly where these rely on specialist equipment and/or pathogen containment facilities. LAs should therefore consult with the PA/FE at the earliest opportunity to confirm whether it may be necessary to procure the services of another laboratory which is accredited for the appropriate method, with the necessary specialist expertise to advise on the interpretation of results. At this stage consideration should also be given to the need to refer samples to the relevant reference laboratory for any typing or WGS that may be required to support investigations.

Food and environmental sampling data play a critical role in the investigation of foodborne outbreaks, and robust, detailed records must be maintained and updated at each IMT meeting. The interpretation of sampling data can be particularly complex during outbreaks involving investigations at different stages of the food production chain; especially where businesses are located across multiple NHS Board and LA areas. The IMT must have access to current, accurate information pertaining to the testing of samples taken from food, food production environments, and, where appropriate, animals, which is correctly mapped to the results of typing or sequencing of isolated pathogens, and any relevant metadata relating to samples (e.g. product, matrix, and quantity of sample tested and premises where the sample was taken). Responsibility for managing sampling records associated with food chain investigations lies with the LA EH professional (when an IMT has been established for a localised outbreak) and FSS (during multi-region outbreaks). Where convened, the IMT Food Sub-Group will support the collation of sampling reports generated by LA EH Professionals, veterinary specialists, and relevant laboratories to ensure results are reported to the main IMT in a timely and co-ordinated manner.

The LA and/or IMT Food Sub Group will provide a highlight report to the IMT containing a written summary of the investigations, key findings and any action taken. A template is provided at Section 5.2 of this document which can be adapted for this purpose. Where appropriate, these reports should also be provided to FSS for consideration as part of any internal IMF procedures they have initiated during the incident.

4.5.4 Environmental samples

Sampling of the food production environment can provide useful information relating to potential sources of contamination and whether there may be an endemic issue in the food production system which needs to be addressed to prevent future incidents. Similar to food sampling, LAs should plan environmental sampling through consultation with the PA/FE and other relevant experts (e.g. UKHSA) to ensure the results are of value to outbreak investigations. When designing an environmental sampling plan, it is critical to understand the environment and the potential routes through which the food could have become contaminated.

Prior to undertaking environmental sampling, it is particularly important for LAs to have details of any cleaning procedures that may be in place at the premises, and the evidence which is available to verify their effectiveness. Consideration should also be given to the potential for pathogens of interest to become resistant to chemicals/agents that are in use. Environmental sampling should be undertaken as soon as possible, and ideally before any additional cleaning is implemented by the business, particularly deep cleaning programmes which are designed to eradicate contamination. Where possible, consideration should also be given to sampling before and after the FBO undertakes their own cleaning and disinfection procedures, as this can be valuable in assessing efficacy against microorganisms of interest.

Care must be taken to ensure all environmental sampling is undertaken in a manner which does not introduce contamination to clean areas. Samples should be taken (usually through swabbing) from all areas in the food production environment which have the potential to harbour bacteria. These include (but are not limited to) work surfaces, chiller units (and condensate), food equipment, utensils, packaging and containers. Complex equipment that may be difficult to dismantle and clean thoroughly should also be considered, such as slicers, vacuum packers, belt machinery and trolleys (including their wheels). Staff workflow should be reviewed to assess the need to swab surfaces which have been touched by food handlers including footwear, door handles, refrigerators and switches, as well as cleaning equipment, sinks and cloths. Floors, drains and sewerage systems are also important points for environmental sampling, particularly for certain pathogens such as Listeria monocytogenes which can produce biofilms and are known to persist in these environments for prolonged periods of time.

4.5.5 Veterinary samples

Requests for testing of samples from animals as part of the investigation of a suspected foodborne outbreak in Scotland should be made by following the pathway outlined in Section 4.4.3 above. The role and value of this sampling would be considered on a case-by-case basis, and advice should always be sought from a Scottish Government Veterinary Advisor before taking it forward.

If there is any suspicion of a statutory notifiable animal disease, primary responsibility for the investigation and, if required subsequent control steps, would lie with the Animal and Plant Health Agency (APHA). A list of zoonotic diseases reportable and notifiable to APHA can be found in the document "Guidelines on the roles and responsibilities of agencies involved in the Investigation and Management of Zoonotic Disease in Scotland":

Veterinary sampling should be coordinated in Scotland and at UK level with close liaison between the relevant public health authorities. In instances where non-statutory infectious agents are suspected (e.g. STEC, Cryptospiridium), APHA has no statutory duty to investigate or collect samples, but may be consulted in an advisory capacity. Further provision is made by Scottish Government's Animal Health and Welfare Division (SGAHWD) under its veterinary surveillance arrangements with Scotland's Rural College (SRUC), for sampling of animals in support of public health investigations.

When assessing the need for veterinary sampling, the IMT should give careful consideration of the circumstances of the outbreak, the results of ongoing active and passive animal disease surveillance, legal considerations and the likelihood that the results of sampling will materially improve the management of the current and/or future outbreaks. Many of the organisms most frequently implicated in foodborne outbreaks are commonly associated with animals and their environments, often without causing clinical signs of illness or reducing productivity. It is also important to bear in mind that the carriage of zoonotic pathogens can be transient in animals, and not all animals within a herd/flock will be shedding at any one time. Therefore whilst the testing of animals linked to an outbreak can provide useful corroborating evidence on potential sources and transmission routes, these results cannot be used in isolation to infer the likelihood of contamination when the suspected food was produced.

In the event that the IMT agrees that animal sampling would be useful to investigations, it should develop a strategy for sampling, laboratory testing and reporting in consultation with the Scottish Government Veterinary Advisor, APHA, the field and laboratory veterinary team (most likely the local SRUC Disease Surveillance Centre), and, where appropriate, the animal keeper's private veterinarian.

4.5.6 Molecular typing and Whole Genome Sequencing (WGS)

In Scotland, laboratories routinely send various clinical isolates (e.g. Salmonella, Shigella, STEC and Listeria), and, in some cases, stool samples, to the relevant reference laboratories for further microbiological characterisation, molecular typing and WGS. Typing or WGS of clinical isolates of other organisms or isolates from other sources (e.g. food or environmental samples) can be arranged with the appropriate reference or specialist testing laboratory. It should be borne in mind that typing/WGS results may not be available at the early stages of an investigation, and the analysis of results takes time and may need to be reviewed in light of new evidence. The relevant reference laboratory can advise on the availability of typing/WGS methods and anticipated timescales for results. Section 6.1.3 contains further information on reference laboratory services for certain foodborne pathogens.

Microbiological characterisation of foodborne pathogens has conventionally encompassed a range of phenotypic (e.g. phage typing and serotyping) and molecular methods (e.g. Pulse Field Gel Electrophoresis (PFGE), Multiple Locus Variable-number Tandem Repeat Analysis (MLVA), Multilocus Sequence Typing (MLST)). Advances in high-throughput sequencing technologies and an accompanying decrease in costs has led to increased adoption of WGS which is now routinely used for four bacterial pathogens; Salmonella, Shigella, STEC and Listeria. This transition to WGS is likely to continue and is expected to replace most other typing methods in due course.

Typing and WGS can be valuable tools in foodborne outbreak investigations for a number of reasons. The results enable the molecular characterisation of isolates from cases or potential vehicles or sources (food, environmental and veterinary), and provide useful information that can be used to generate hypotheses based on comparison with historical isolation of similar subtypes from human, food, animal or environmental sources. Cases may be included or excluded as part of an outbreak on the basis of typing/sequencing, and this can assist in appropriately targeting investigation resources. Moreover, isolation of an organism from the suspect vehicle or source which is considered to be genetically indistinguishable from the organism isolated from outbreak cases can provide strong (though not necessarily conclusive), evidence in support of an outbreak hypothesis.

The increasing application of WGS to understand pathogen source attribution has enabled more discriminatory characterisation of clinical strains, improving our ability to link cases, detect outbreaks and identify associations with strains found in contaminated food. The reference laboratories in Scotland work closely with their counterparts at UKHSA for the comparison of WGS profiles for isolates in Scotland with those in the rest of the UK for the timely detection of cases that are part of UK wide outbreaks. The digital nature of WGS data facilitates data transfer and sharing, as well as enabling comparisons of sequence profiles across a number of other countries and supports the identification and management of multi-country outbreaks, which is vital given the international nature of food supply chains. However, typing/WGS results must not be considered in isolation and must always be interpreted in the context of the clinical, epidemiological (including pathogen biology/genetics that shape the genome), food chain, environmental, and other evidence collected by the IMT.

4.6 IMT risk assessment

The outbreak investigation will be informed through the collective expertise of the IMT membership following the principles set out in section 7.5 of the MPHI document. The outbreak investigation will support risk assessment by helping to establish:

- whether exposure is on-going
- the impact of exposure (numbers affected and severity)
- the food vehicle and/or source of infection

The outbreak investigation is underpinned by three strands of evidence – the epidemiological evidence, the outcome of food chain and other environmental investigations, and results from laboratory investigations (sampling and analysis). Points for consideration within each of these evidence strands are outlined in Sections 5.3 and 5.4 of this document.

In addition, impacts on public health are informed through food safety risk assessment undertaken by FSS, following the Codex principles of Hazard Identification, Hazard Characterisation, Exposure Assessment and Risk Characterisation.

The IMT should continue to evaluate the risk to the public in relation to the outbreak and the effectiveness of any control measures on an on-going basis by appraising the available evidence and reaching a collective view as to whether it indicates that there is an on-going significant threat to public health. Each update and amendment to decision making must be clearly documented in all IMT minutes.

4.7 Risk management

The objective of risk management is to implement control measures which will reduce the risk to public health. Control measures may be directed at the suspected or implicated vehicle or source of the exposure and/or at affected persons to prevent secondary spread. Control measures should be guided by the risk assessment and findings from the investigation and be kept under review.

As soon as the IMT considers there is sufficient evidence that a food vehicle, source, or food business is implicated in an outbreak it should take all possible steps to ensure appropriate control measures are taken to mitigate further public health risk. It is not possible to be prescriptive as to what constitutes 'sufficient evidence' for action in a foodborne outbreak investigation. The decision to act and the nature of that action should be based on all the information available at the time including the assessment and severity of the ongoing public health risk and the weight of the evidence (epidemiological, food chain and laboratory investigations) implicating the food vehicle, food business and source. Section 5.3 of this document can be referred to by IMTs to support these assessments. If evidence and expert opinion point to a potential risk to life or health but scientific uncertainty persists, the IMT should adopt the precautionary principle when determining risk management measures or other actions to ensure the protection of public health. It is also recognised that there may be circumstances during the food chain/environmental investigation, where LA or FSS would be failing in their statutory duties if immediate enforcement action is not taken. Where such action is taken, the action and its rationale should be reported to the IMT at the earliest opportunity.

The IMT may recommend various measures to control/reduce risk in the management of public health incidents and these are outlined in section 7.6 of the MPHI guidance. Specific control measures for foodborne outbreaks are described in the sections below. FSS will provide advice and assistance to the LAs in relation to appropriate enforcement measures and other legal matters which may arise during investigations of the implicated food business.

Public health protection is the primary focus for the IMT during the management of a foodborne outbreak, and is the key driver for all actions taken. LAs and FSS have responsibility for ensuring control measures are implemented which prevent unsafe food being placed on the market; ideally with the co-operation of the implicated FBO. These measures must be carried within the appropriate legal frameworks and will depend on a number of factors in addition to the IMT's recommendations including; actions already taken by the FBO to mitigate further risks, whether contamination risks affect only particular batches or multiple products, and the enforcement options that are available in law.

It is important to recognise that enforcement actions taken by FSS/LAs to control the outbreak can have significant consequences for implicated FBOs and decisions taken by the IMT may form an important part of any legal proceedings (criminal investigations or civil litigation) relating to the incident. It is therefore imperative that all of the evidence used to inform the IMT's risk assessment and the conclusions used to inform their risk management recommendations are fully transparent and recorded.

If member organisations within the IMT disagree with decisions on risk management, the IMT chair should be informed of the rationale for the differing opinions and this should be minuted. If there is a disagreement that cannot be resolved by the IMT chair, then the issue must be raised at a higher executive level in the relevant organisations. Section 6.8 of the MPHI guidance outlines how disagreements over risk management should be handled at operational and Director/CEO level, and the need for senior engagement with other organisations to support dispute resolution.

4.7.1 Controlling the food vehicle and/or the source of the outbreak

Prohibiting further food production

The LA EH professional (supported by FSS when appropriate) will evaluate whether use of food law powers including, but not limited to, closure of a food business, is appropriate with due consideration to the advice, guidance and assistance of the IMT. The Food Law Code of Practice (Scotland) outlines specific criteria to be considered in determining appropriate enforcement action to be taken.

The FBO may agree to voluntarily stop relevant production processes or cease its food business operation entirely as a means of mitigating the food safety risk and allowing investigations to be undertaken. Such voluntary agreements must be confirmed in writing and with an agreement not to re-instate production/re-open the business without the approval of the Food Authority. LA EH Professionals undertake checks to ensure compliance with any voluntary agreement.

If voluntary measures are not appropriate, the LA EH Professional may need to consider the use of enforcement powers, and these will depend on the nature of the food safety risk associated with the outbreak. Remedial Action Notices (RANs) can be used to prohibit the use of any equipment or any part of the establishment or process in circumstances where there has been a breach of food law. Where it is considered that there may be an imminent risk to public health, a Hygiene Emergency Prohibition Notice (HEPN) may be used to prohibit the operation of the food business (including equipment) in whole or in part.

Product withdrawal and recall

The withdrawal or recall of products facilitates the removal of potentially unsafe food from the distribution chain alone (withdrawal), and from the distribution chain and consumers who have purchased products which have the potential to cause illness (recall).

The FBO usually instigates a Product Withdrawal to remove food that has not reached the consumer but is still in the distribution chain. The relevant LAs, FSS and the FBO's customers must be informed by the FBO that a withdrawal is taking place. When the implicated food has been placed on the market, and may therefore already have been purchased by consumers, a Product Recall may be required and this is instigated by the FBO.

Product Recall Information Notices (PRIN), Allergy Alerts (AA) or Food Alerts for Action (FAFA), provide a mechanism for informing the consumer, competent authorities and other FBOs to take appropriate action to ensure public health risks are minimised.

The FBO is responsible for ensuring that all implicated products have been effectively withdrawn and/or recalled from the market and accurately communicating the reason for the withdrawal/recall. LAs and FSS have similar responsibilities as regulators. Depending on the circumstances surrounding a product recall, FSS may issue a PRIN via its website and issue to all interested parties, including consumers.

The Food Law Code of Practice (Scotland) provides further information on withdrawals and recalls.

(See also section 4.8.6 of this document).

Seizures/detention of implicated products

LA EH professionals have powers to inspect, seize, and arrange the temporary detention or removal and safe disposal of potentially contaminated foodstuffs. The FBO must also provide all relevant records and documents, if requested by the LA. FSS has similar powers available for the approved food businesses they are responsible for. LAs and FSS will carefully consider the evidence required to support the seizure/detention action as FBOs are entitled to compensation where such action has been found to be unwarranted.

The Food Law Code of Practice (Scotland) contains further information on detention and seizure.

4.7.2 Preventing secondary/onward spread

Exclusion/restriction of cases and contacts

Cases and contacts of cases of infectious intestinal disease may pose a risk of onward transmission of the infection and therefore require a risk assessment and appropriate management. See section 6.1.3 for exclusion information for individual pathogens. The degree of risk of spreading infection posed by cases is influenced by their clinical state, their standards of hygiene, their closeness of contact with others and the infectious period of the associated pathogen and their occupation including any voluntary work. Typically, cases with diarrhoea present a far greater risk of spreading infection than symptom-free excreters but even symptom-free excreters with poor or doubtful standards of personal hygiene pose a risk.

In addition, all cases with diarrhoea or vomiting should be advised to remain off work/school and avoid social engagements until 48 hours after diarrhoea and/or vomiting have ceased. Some people may pose an increased risk of spreading infection (Table 1). These people may require exclusion from work or educational or childcare establishments – or be restricted from carrying out certain activities or duties - until microbiological clearance has been achieved. It may also be necessary to exclude or restrict close contacts of cases until they have achieved microbiological clearance. Furthermore, if convened in an outbreak situation, an IMT may decide to deviate from standard advice and recommend additional measures, including clearance sampling to influence exclusion advice.

The importance of scrupulous hand hygiene - washing hands thoroughly with warm running water and liquid soap – should be stressed to cases and their contacts. Hand washing should be carried out regularly and always after using the toilet and before handling, preparing or eating food. Hand washing should also be performed after any other activity where faecal contamination is a possibility, for example after handling soiled linen or cleaning the toilet, after attending to someone with diarrhoea or vomiting, and after assisting younger children with toileting, including nappy changing.

Each case and their contacts should be considered individually taking into account:

- the risk category of the case/ contact (see Table 1).
- the pathogen and its infectivity.
- the age, capacity to understand, and hygiene standards of the case.
- the type of workplace or educational establishment.
- the exact nature of the work/activities the case will be engaged in including any voluntary work.

NHS Board competent persons have powers under part 4 of the Public Health etc. (Scotland) Act 2008 to:

- make an ‘exclusion order’ which will exclude a person from any place or type of place specified in the order and impose such conditions (if any) on the person as is considered appropriate.
- make a ‘restriction order’ which will prohibit a person from carrying on any activity specified in the order and impose such conditions (if any) on the person as is considered appropriate.

When using exclusion or restriction orders under the Act, NHS Boards must follow the accompanying Public Health (Scotland) Act 2008 Implementation Guidance published by Scottish Government. NHS Board competent persons must review exclusion and restriction orders at least every three weeks. They must clearly document any decision on exclusion/restriction, and the risk assessment it is based on.

Further information on recommended exclusion/restriction policies and microbiological clearance criteria for specific pathogens is included in Section 6.1.3.

Table 1: Groups at risk of spreading infection

Risk group	Description	Additional comments
A	Any person of doubtful personal hygiene or with unsatisfactory toilet, hand-washing or hand drying facilities at home, work or school.	Risk assessment regarding access to hygiene facilities should consider the availability of toilets/hand washing/hand drying facilities in a work/educational setting. Specific consideration should be given to children up to the age of 10 years - an individualised risk assessment should be performed, dependant on infection.
B	Children who attend pre-school, nursery.	For all pre-school aged children, risk assessment for exclusion and clearance purposes should also include consideration of other group settings such as playgroups, parties and sports clubs.
C	People whose work involves preparing or serving unwrapped ready to eat food.	Consider informal food handlers e.g. someone who helps to prepare food for charity and community events.
D	Clinical and social care staff in high risk care facilities who have direct contact with highly susceptible patients or persons for whom a gastrointestinal infection would have particularly serious consequences.	Risk assessment should consider activities such as helping with feeding or handling objects that could be transferred to the mouth.

Raising public awareness

Public communication in foodborne outbreaks is important to provide clarity to the public in what is often an evolving and uncertain situation. It can help to manage risks by:

- Providing advice to cases, their contacts, and the public on how to avoid or reduce the risk of exposure and how to reduce the risk of onward spread.
- Raising public awareness and encouraging those who may be affected to seek appropriate, prompt healthcare advice.
- Supporting case-finding activities.
- Providing information on food alerts or recalls, and consumer advice on what action to take regarding implicated products.
- Providing assurance to the public that appropriate steps are being taken by the relevant organisations to mitigate the risks as much as possible.

Section 7.7 of the MPHI guidance and section 4.8 of this document provide guidance on risk communication in public health incidents including communications with the public and patients.

4.7.3 Patient assessment and care measures

Foodborne outbreaks have the potential to expose many people to infection and to result in significant pressure on primary care and hospital services. Section 7.6.2 of the MPHI document outlines patient assessment and care measures that the IMT should be consider in the management of public health incidents, including foodborne outbreaks.

4.8 Risk communication

4.8.1 General

The general principles of risk communication during public health incidents, including to cases, the public and healthcare professionals, are set out in section 7 of the MPHI guidance. This section describes how these are applied during the management of foodborne outbreaks in Scotland to ensure appropriate communication arrangements are implemented by each of the parties involved.

4.8.2 Communications – roles and responsibilities

The IMT oversees public communications and media-handling during foodborne outbreaks, in accordance with the procedures outlined in Sections 7.7.4 and 7.7.5 of the main MPHI document. The overall content and tone of public messaging, as well as the methods for disseminating key messages, will be mutually agreed and jointly developed by the communications teams from all agencies represented on the IMT. The IMT Chair will provide oversight of all communications to ensure consistency of messaging and will ensure all decisions on risk communication are recorded.

Communications professionals from the lead agency should attend IMT meetings from the outset of investigations and take responsibility for liaising and sharing communication outputs with teams from other key agencies'; bringing in additional expertise where required. There should be a standing 'Communications' agenda item at each IMT meeting to enable the Communications teams to provide regular updates and recommend and agree on communication handling strategies with the IMT.

The communications response will be tailored according to the nature and scale of an outbreak. Often foodborne outbreaks are managed at a local level where the IMT and related communications are led by the relevant NHS Board. Where the incident involves more than one NHS Board or LA area, or during more complex or high profile incidents, the IMT should consider the formation of a communications sub-group, involving representation from all the key agencies' communications teams, with its chair reporting to the IMT.

The IMT will agree the initial communications strategy and core messages, and these should be reviewed at each IMT meeting, with input from all of the different agencies involved. PHS/NHS Boards will provide expertise on the spread of the disease/outbreak and public health advice, and FSS/LAs will lead on the content of communications relating to food safety risks and advice and updates regarding the implicated food and FBO.

During foodborne outbreaks it is important for IMT members to recognise that FSS is responsible for all communications pertaining to the recall or withdrawal of food from the market. FSS and LAs will be required to release their own communications in addition to those issued through the IMT. These include food alerts and enforcement notices (e.g. Product Recall Information Notice (PRIN), Food Alert for Action (FAFA); and Hygiene Emergency Prohibition Notices; HEPNs). These are drafted and issued by FSS and LAs and shared with the IMT as appropriate, to ensure that there are no contradictions in content or tone with other communications issued during the investigations.

4.8.3 Media handling

During foodborne outbreaks, communication to the public or to targeted audiences must be clear, concise, coordinated and consistent, with core messaging attributed to the IMT as the one voice of the incident. The IMT should agree a communications plan comprising the following:

- Written materials e.g. draft releases, social media content, public statements.
- Spokespeople for the incident and whether interview bids will be accepted and by whom (ensuring nominated persons have received appropriate media training).
- Q&A and briefings.
- Where appropriate, depending on the nature of the incident, co-branding of communications to ensure membership and joint decision-making of an IMT is clear to the media and public.
- Where appropriate, a plan for testing proposed messaging with the relevant audiences as appropriate to identify potential barriers to understanding, cultural differences, and language variances that could prevent effective communication. This information should be fed back to the IMT so that messaging can be adjusted if required.
- Where appropriate, a plan for testing the effectiveness of communications at regular intervals, to ensure messages are reaching the desired audiences and are understood. The findings from these exercises should also be reported to the IMT in order to refine strategies and inform future tactics.

In multi-region foodborne outbreaks PHS and FSS will develop a joint communications plan and toolkit that IMTs should use to support media handling. This will include agreed media lines, notes to editors and Q&A documents. To support the management of local foodborne outbreaks, NHS Boards and LA communications teams should develop their own joint communication plans and/or toolkits.

It may be desirable for other organisations represented on the IMT to respond to press enquiries which specifically relate to their operations or legal responsibilities. Arrangements should ensure that such organisations can respond promptly to enquiries without straying from, or indeed contradicting, the core IMT messaging, including the public health risks and the measures being taken to reduce them.

4.8.4 Inter-agency communications

The IMT should consider at an early stage the need for communication with relevant agencies outwith Scotland (e.g. FSA, UKHSA and equivalents in Wales and Northern Ireland) as affected foods may have been sourced from or be distributed to countries outwith Scotland. The IMT should develop a list of key stakeholders/ interested parties at the outset of the outbreak, and ensure that this is kept under review throughout the investigations.

FSS (in conjunction with the FSA), will issue information relating to products that have been implicated in a foodborne outbreak to other countries. This allows authorities to exchange information about measures taken when responding to serious risks detected in relation to food or feed and helps other UK nations and European member states to act more rapidly and in a coordinated way.

Where appropriate, public health alerts can be sent to EU member states via the European Commission's Early Warning and Reports System (EWRS) - see Annex A of the MPHI document for further information. UKHSA is the UK Competent Body for the EWRS system. PHS will liaise with UKHSA if there is need to issue an EWRS in relation to an outbreak of foodborne illness in Scotland.

4.8.5 Briefing for ministers and other government officials

NHS Boards and PHS must inform the Scottish Government Health and Social Care Directorate (SGHSCD) of suspected public health incidents as set out in the MPHI document. NHS Boards and PHS should inform a SGHSCD representative, and where appropriate, the Senior Medical Officer (SMO) or policy officer will brief ministers in line with Scottish Government protocols.

FSS has a responsibility to brief the relevant ministers in relation to all food safety incidents, including those linked to foodborne outbreaks. Key members of the IMT (including the IMT Chair and relevant Food Authority) should discuss all correspondence with ministers and government officials throughout the outbreak investigations, so that there are no conflicting messages given to ministers.

4.8.6 Communication of food recalls and withdrawals

FSS is responsible for issuing two types of food alerts:

- A Product Recall Information Notice (PRIN) –These relate to situations where food is being recalled from the consumer by the FBO, where no specific action is required to be undertaken by the LA.
- A Food Alert for Action (FAFA) is issued in circumstances where specific action/intervention by LAs is required.

These notices and alerts are often issued in conjunction with a product withdrawal or recall by a manufacturer, retailer or distributor.

FSS publishes such alerts on its website (and FSA's website for UK wide incidents) and informs anyone who subscribes to receive news and food alerts on the FSS website including LAs by email and text. FSS also notifies the media and consumers of food alerts via social media.

It is the manufacturer's, retailer's and/or distributor's responsibility to issue notices relating to a product recall at the point of sale, and to issue accompanying communications to ensure consumers are aware.

4.9 Lessons learned and incident management report

The IMT will agree collectively when it is appropriate to announce the end of an outbreak. These decisions will be taken on a case by case basis, based on the evidence, but in general a foodborne outbreak will be considered over when new illnesses stop being identified and implicated food products are no longer on the market or in people's homes. As with all public health incidents, the IMT should hold a debrief at the end of the outbreak to ensure lessons learned are captured and related recommendations made. An IMT or Situation Background Assessment Recommendations (SBAR) report may be written in line with guidance contained in section 7.8 of the MPHI document.

The IMT report should be drafted with input from all relevant parties, with specific input by FSS and LAs on details pertaining to food chain investigations to ensure these are accurately reflected. Reports should be issued to the relevant NHS Board meeting or an NHS Board committee as per agreed local processes e.g. clinical governance committee for their information and to provide assurance that the outbreak has been managed in accordance with best practice. The IMT Chair/NHS Board has ultimate responsibility for deciding on the appropriate distribution of the final report.

The IMT Chair/NHS Board should provide copies of the final report to key partners including FSS, the SHPN-Gastrointestinal and Zoonoses (SHPN-GIZ) Group, and the Executive of the Scottish Food Enforcement Liaison Committee (SFELC) to promote discussion on lessons learned and the sharing of best practice.

5. Supporting tools

This section provides the following tools and templates to support IMT members during investigations of a foodborne outbreak, which link to the procedures described in this guidance.

- 5.1. Terms of reference and sample agenda for the IMT food sub-group
- 5.2. Sample highlight report relating to food chain investigations to be brought to the IMT
- 5.3. Weight of evidence considerations in a foodborne outbreak
- 5.4. Management of foodborne outbreaks algorithm

5.1 Terms of reference and sample agenda for the IMT food sub-group

5.1.1 IMT food chain investigation sub-group sample terms of reference

Scope:

To review the findings of food chain investigations in the context of the outbreak, and to consider any further investigations or control measures which are necessary to support the outbreak investigation and to protect public health. This will include; detailed evaluation of the food safety management/HACCP systems in place at the food business, the suitability of procedures undertaken by the FBO to validate and verify food safety, the need for sampling of products and the food production environment, traceability investigations to establish the distribution of implicated products, and enforcement action required to address non-compliances.

Remit:

- To consolidate and record the findings of investigations relating to all stages of the implicated food chain, including environmental.
- To review the finding of the investigations carried out by the food enforcement authority on the FBO's food safety management system.
- To consider appropriate control measures and enforcement action required at the food business to protect public health from unsafe food, including the use of emergency prohibition procedures as outlined in the Food Law Code of Practice (Scotland).
- To provide a written update to the main IMT summarising its investigations, key findings to date, and highlighting any areas that require further discussion by the wider group.

Chair and secretariat arrangements:

For localised outbreaks (i.e. those involving food which has been distributed within a single LA area), the relevant LA EH Lead Officer for Food Law would usually chair meetings of the sub-group. Where outbreaks involve foods which have been produced and/or distributed outwith a single Local Authority, FSS would usually chair sub-group meetings. Secretariat duties will be provided by the chairing organisation, as appropriate.

Decision making:

The sub-group will record all decisions in its minutes and submit a summary to the IMT Chair and secretariat for further distribution as necessary. The sub-group chair will provide a verbal update at each IMT meeting.

Frequency of meetings:

The sub-group will usually meet prior to each meeting of the IMT as required, allowing sufficient intervals to enable the necessary food/environmental investigations to take place.

Record of meetings:

The Chair of the sub-group will be responsible for providing a verbal update at each IMT meeting. They will also submit, to the IMT Chair, the minutes of meetings, which should include a summary of investigations, key findings to date and any areas that require further discussion by the wider IMT.

Confidentiality and data protection:

It is likely that information may be of a sensitive or confidential nature and/or subject to data protection law. It is vital that all members understand their responsibility to treat as confidential, information that may be available to them, or obtained by them, or that may be derived whilst working in the sub-group.
Members must not breach their duty of confidentiality by disclosing, or using in an unauthorised manner, confidential information, or providing access to such information by unauthorised people or organisations. Information considered to be confidential or sensitive may, however, be required to be disclosed by law, by court of competent authority, by a requirement of a regulatory body. Proceedings of the sub-group will also be subject to Freedom of Information (Scotland) Act 2002 or The Environmental Information (Scotland) Regulations 2004 (subject to certain exemptions).

5.1.2 IMT food chain investigation sub-group sample agenda

1. Title of Incident
2. Date:
3. Attendees:
4. Introductions, confidentiality statement and declaration of any conflicts of interest
5. Agree minutes of previous meeting
6. Actions from previous meeting
7. Updates since previous meeting (to include, as appropriate):
    a. Overview of implicated food business(es) including potential conflicts and issues which may hamper co-operation
    b. Details of last inspection of food premises
    c. Evaluation of business's food safety management system/HACCP
    d. Results of sampling undertaken by the FBO
    e. Affected batches – product codes
    f. Traceability of affected batches

g. Official food or environmental sampling requirements and associated results

h. Further investigations required

i. Implemented control measures including enforcement and the need for any additional actions

8. Summary of key findings/areas for discussion at IMT

5.2 Sample highlight report of food chain investigations to be brought to the IMT

Information to be brought to the IMT relating to food chain investigations led by the LA EH professionals/FSS /IMT sub-group:

1. Details of FBO/FBOs

2. Relevant findings from historical visits to the FBE/FBEs

3. Consumer complaints

4. Details relating to inspections of the food business operator during the outbreak investigations including relevant information pertaining to the food safety management system and any formal enforcement actions that have been taken.

5. Details of food/environmental samples taken (by both food authorities and the FBO's own sampling) including description of product, date of sampling, where the sample was taken and how it was taken, and results.

6. Food distribution information (trace forward/trace back: description of supply to wholesalers, retailers and caterers)

7. Where an implicated product (or products) has been identified:
    a. Product name
    b. Packaging sizes affected and photographs of products
    c. Batch numbers affected
8. Other relevant details e.g. staff sickness/absence

9. Summary of key findings and areas for discussion at IMT

5.3 Weight of evidence considerations in a foodborne outbreak

Evidence collected from the three strands of the outbreak investigation - **epidemiological, food chain (including trace forward/trace back), and laboratory investigations (results of sampling and analysis)** - will be used by the IMT to:

- Generate an outbreak hypothesis
- Inform the risk assessment
- Inform risk management
- Inform further investigations
- Assess effectiveness of any control measures implemented
- Agree communications

Over-reliance on particular routes of enquiry can be misleading and it is therefore important for the IMT to ensure that all three strands of evidence are drawn together in their decision making.

Tables 2-4 below are intended as a guide to assist IMTs in assessing the combined strength of the epidemiological, food chain and laboratory evidence that is obtained during the investigations. They outline some of the criteria that are important to consider throughout an outbreak investigation, with examples of evidence that would support each of these criteria being met. These are not exhaustive and should not be used as a checklist. Not all criteria need to be met for a specific food business, vehicle, or source to be implicated in an outbreak, and in most cases it will be necessary to take other factors into account, including professional judgement, to inform decision making.

Table 2: Criteria to consider when assessing the weight of evidence obtained from the epidemiological investigations during an outbreak of foodborne illness.

Criterion	Examples of supporting evidence
Biological plausibility Is it biologically plausible that a given food item is the vehicle of infection/ contamination?	• The suspected food type has been implicated in previous similar foodborne outbreaks or from studies of sporadic cases e.g. in published literature or outbreak reports.* • The pathogen or contaminant responsible for the outbreak has been previously identified in the suspected food type or its component ingredients.* • The pathogen is known to occur or the contaminant used in the suspected food product's country of origin. • The suspected food type can support survival and/or growth of the pathogen. *Note - it is possible for a novel food vehicle to be identified in any outbreak investigation and therefore not to appear in published literature or previous reports.
Consistency Is a given food item consistently reported across different cases/populations? Is the temporal and/or spatial clustering of cases consistent with the availability/distribution of a particular food product?	• Most primary cases report consuming or handling a specific food item during the suspected incubation period. * • The proportion of cases reporting exposure to the food is higher than would be expected in the general population (based on food consumption data e.g. from national food surveys or surveillance databases). • Cases with unique or restricted diets report consuming the same food item as other cases within their incubation period. • Where there are two or more clusters of cases (e.g. restaurant outbreaks) involved, findings are consistent across locations. • There is temporal or geographic clustering of cases that correlates well with the availability or distribution of a particular brand, batch or otherwise specific food item, taking into account the shelf-life of the suspected product. * If the pathogen or agent is not known but the clinical details suggest a short incubation period, information should be gathered about all meals eaten during the 72 hours before the onset of illness.
Specificity Does the information provided indicate a single specific food product as the vehicle of infection?	• The food item consistently reported by cases is specific e.g. "ready to eat prawn pasta salad from the same manufacturer/retailer/restaurant, rather than imprecise e.g. "fish", food item purchased from specialty store, food item consumed at same restaurant. • The population affected is specific to the target population for the food product e.g. formula consumed by infants, products marketed as vegan. • Most cases reported consuming the food item of interest at higher than expected frequency while all other plausible food items are reported at expected frequency. • Most cases can provide the brand name and/or batch number of a specific food produce and report consuming the same brand/batch number. Till receipts or loyalty cards, or on-line shopping records can sometimes be used to identify brand names/batch codes of specific items purchased by cases during a time period of interest.

Strength of Association What is the level of confidence that a given food item is associated with the outbreak?	• The descriptive epidemiology shows a strong statistically significant association between the consumption of a single food product and the foodborne illness. • A well conducted analytical epidemiology study is undertaken which identifies a statistically significant association between exposure and being a (primary) case.
Temporal Do cases report eating food within the incubation period?	• Most cases report consuming the suspect food item within the normal incubation range for the pathogen (see sections 6.1.3 for incubation ranges of common foodborne pathogens and 6.2.2 for chemicals and toxins). If time between consumption and symptom onset for cases is clustering around the average incubation for the pathogen or toxin/contaminant then this adds increased weight to the evidence.
Dose-Response Does the strength of the association increase with increasing consumption of the food item?	• Detailed information on the frequency of consumption or quantity of a food item consumed within the incubation period is not usually available from standard food history questionnaires. For this reason finding a dose-response relationship is extremely rare during outbreak investigations, and therefore absence of this evidence does not undermine the investigation. However, where it is possible to undertake these calculations as part of an analytical study, and the strength of a statistical association between a food item and the number of cases is found to increase with increasing consumption of the food item, this will add additional weight to the evidence. This may be particularly useful when the causative pathogen has a relatively large infectious dose and when the food is a commonly consumed food item.
Consideration of alternative explanations/outliers To what extent have other plausible hypotheses been investigated?	• Detailed, extensive food histories with or without analytical studies have ruled out other exposures (e.g. environmental or animal contact) that may be commonly associated with the illness. • A case or cases report that they have handled the implicated food, or there is evidence that they could have become exposed through cross contamination in the kitchen environment. • A case or cases report that they have come into contact with someone who has eaten or handled the implicated food (i.e. that they could be a secondary case). • Products are identified which contain the implicated food as an ingredient.

Table 3. Criteria to consider when assessing the weight of evidence obtained from the food chain investigations during an outbreak of foodborne illness.

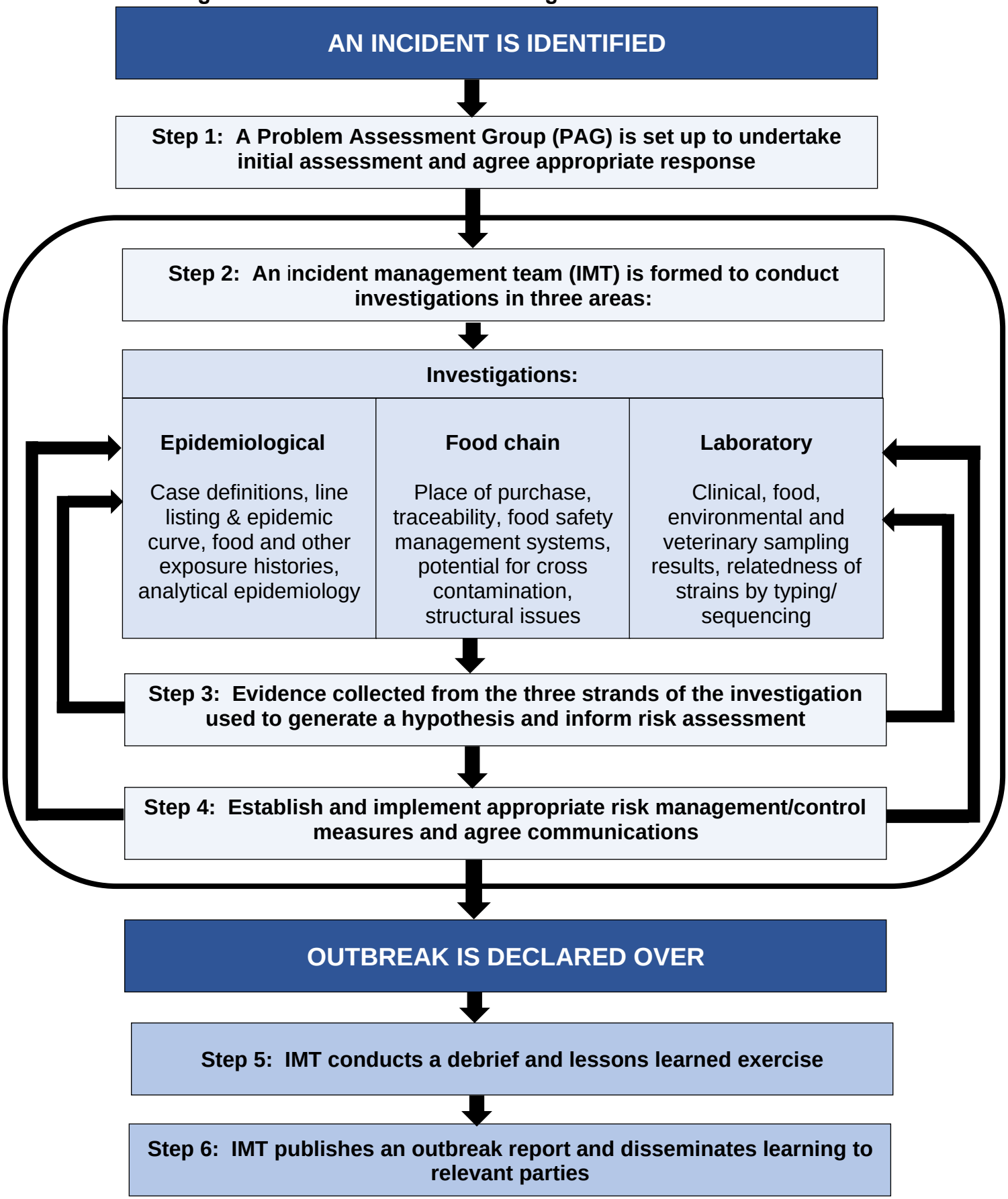
Criterion	Examples of supporting evidence
Traceability Can all points in the production and distribution chain of suspected food item be identified (trace-back and trace-forward)?	• Packaging information relating to the producer and supplier of the food • Packaging information relating to batch codes, production dates, and durability (use-by/best before) • Details from menus (if the food is linked to a caterer or institution such as healthcare setting, care home or nursery) confirming that the implicated product was served. • Receipts and records of purchase and supply held by the FBO(s) or consumer. • Verbal information relating to the stages and associated businesses involved in the production, distribution and sale of the product. • Information held by retailers from membership/loyalty cards which confirm that cases or those connected to the outbreak purchased implicated products. • Verbal description by the consumer which implicates a point of purchase or brand of food.
Food Safety Management System (FSMS) or Hazard Analysis and Critical Control Point (HACCP) Plans Is there evidence that the food has not been produced and handled safely before reaching the consumer?	• Quality of documentation relating to the FSMS and /or HACCP plans applied during the production of the implicated food product, and at other businesses involved in its processing, distribution and sale. • Evidence that the relevant hazards have been identified at all stages in the food chain and that there are robust measures in place to control them. • Evidence that the business responsible for the production of the food has appropriate sampling plans and other checks in place to validate and verify the FSMS / HACCP (e.g. temperature control records, shelf life verification and end product testing records) • Evidence that the FSMS/HACCP in place are regularly reviewed and that staff are trained and competent.
Reports of Food Law inspections undertaken by LAs Have any issues previously been identified at the implicated food business? Has anything changed between the last inspection and the outbreak that would give rise to concern?	• Relevant findings from historical LA inspections of the implicated food business (es) including the risk rating of the premises and previous enforcement actions. • Findings from recent LA inspections during the outbreak investigations which point to a problem. • Any changes in processes, products, recipes, supplier etc. between such inspections. • History of non-compliance, involvement in previous incidents/outbreaks, and trends in consumer complaints made about the FBO.

	• Evidence of issues with staff sickness/absence. • Changes in staffing since the previous inspection. • Complaints to retailers or caterers who stock the implicated product.
Information from cases on their food handling practices Is it plausible that consumer practice resulted in a food safety risk?	• Information relating to product storage following purchase, including how it was transported to the home, whether it was eaten within its use by date, fridge storage temperatures, and details of freezing/defrosting. • Information on end users' /packaging instructions. • Details relating to how the product was handled and cooked prior to consumption and if end user instructions were followed. • Details of other foods being prepared at the same time and not eaten by the affected person but may have been a source of cross contamination.

Table 4: Criteria to consider when assessing the weight of evidence obtained from the sampling/laboratory investigations during an outbreak of foodborne illness.

Criterion	Examples of supporting evidence
Laboratory testing and typing results Do results from clinical, food, environmental or animal sampling support the outbreak hypothesis?	• Typing of human isolates shows a high degree of relatedness between cases indicating a common source of infection. If typing identifies a rare or novel strain of the organism, then this adds further weight to the evidence. Available typing methods and the discriminatory power of these will vary between organisms. The relevant reference laboratory will advise on this and assist with the interpretation of results. • Sampling of food, the food production environment and/or other relevant parts of the food chain has identified the outbreak organism. If molecular typing shows a high degree of relatedness between these isolates and those from the outbreak cases, this lends even greater weight to the evidence. • The strain identified has previously been isolated from food/environmental testing at the business (either routine testing or as part of outbreak investigations). • Testing of the suspected product (and/or other foods produced by the FBO) shows evidence of microbiological pathogens other than the outbreak organism (including other strains or different types of pathogen), or unacceptably high levels of indicator organisms, indicating the potential for pathogens to enter the food production process. • The outbreak organism / strain is one that is known to occur in the country of origin of the suspected food item. If the strain is one that is rarely seen in the UK but is commonly found in the country of origin of the food item, this adds increased weight to the evidence.

5.4 Management of foodborne outbreaks algorithm



6. Supporting information

6.1 Supplementary guidance relating to control measures which are relevant to outbreaks of foodborne illness

6.1.1 Background

It should be noted that the information included in this supplementary guidance is not exhaustive. The pathogens described in Section 6.1.3 were selected to reflect the more common causes of foodborne outbreaks in Scotland or because of their potential to cause more severe disease should they occur. The list will be updated as appropriate in light of new information on foodborne outbreaks reported in Scotland.

The tables in Section 6.1.3 can be used to support incident management and should be read in conjunction with the Standard Control Measures below.

See Appendix 4 for details of guidance development methodology and key references used.

6.1.2 Standard control measures

Standard Control Measures are general hygiene controls in food processing and temperature controls which are capable of preventing the transmission or growth of foodborne pathogens or the formation of associated toxins. They are a requirement of food law and must be implemented and maintained by Food Business Operators (FBOs) as part of Food Safety Management System (FSMS) based on the principles of Hazard Analysis and Critical Control Points (HACCP). Standard Control Measures would typically include the following:

Sourcing food (ingredients etc) from reputable suppliers:

- Food must be protected from the risk of contamination during each step in the food chain, from primary production (e.g. farms and fisheries) through to processing, catering and retail.
- FBOs are legally required to ensure the food they place on the market is safe, so need to understand their supply chains and have confidence that their suppliers have taken appropriate controls to ensure food safety.

Ensuring foods are cooked and stored at temperatures which will eliminate/control the growth of pathogens:

- Simmering/boiling (100^{o}C)
- Reheating at not less than 82oC *
- Cooking at 75oC or above (or an equivalent time/temperature combination to kill pathogens)
- Hot Holding at not less than 63oC *
- Cooling food as quickly as possible followed by refrigeration (typically cooling within 90 minutes to room temperature and then refrigerated)
- Refrigeration at 5oC or below
- Freezing at -18oC or below

* Denotes a legal requirement for minimum temperature

Preventing cross contamination during the storage and preparation of food:

- Food businesses must ensure they have a system to prevent cross contamination from raw foods (including fresh meats, shell eggs and unwashed raw vegetables) to ready to eat (RTE) foods either directly through contact or indirectly via equipment, cloths or food handlers. This is likely to include separation of processes into high care and low care areas for high risk RTE foods.
- Food businesses must apply procedural and process controls typically including cleaning and disinfection of food preparation surfaces and equipment, heat treatment and separation of raw and ready to eat foods.

Ensuring food handlers are trained in effective food safety management including personal hygiene:

- Food handlers trained in food handling and hygiene controls are an essential part of a safe food business. Food handler training is required and will cover personal hygiene standards, especially the importance of hand washing, reporting illness and the safe handling of food.
- Food businesses should take measures to prevent the spread of infection by requiring staff to report illness, particularly diarrhoea and vomiting. Staff reporting these symptoms must be excluded from food handling until 48 hours after diarrhoea and/or vomiting has ceased. In some cases, depending on the pathogen involved, food handlers may require to be formally excluded by the NHS Board CPH/CPHM pending microbiological clearance as detailed in the pathogen-specific tables below. Guidance on best practice on Fitness to Work for Food Handlers can be found on the FSS website.

It should be noted that the Standard Control Measures detailed above are a guide, and the list is not exhaustive. Food businesses have additional requirements they must meet in terms of construction, pest proofing, waste control and other areas. Some are also legally required to undertake testing to demonstrate that their products comply with microbiological safety standards defined in food hygiene legislation. Food businesses are responsible for meeting all statutory food law requirements and EH professionals regulate these during inspections and other visits and interactions.

6.1.3 Specific control measures for different foodborne pathogens

The specific control measures listed within each pathogen-specific table provided in the following sections, are provided to highlight additional considerations, where necessary.

Pathogen	Bacillus cereus
Microbiology	Gram-positive rod that forms heat-resistant spores which can survive in the environment. Can result in two types of food poisoning a) Diarrhoeal; due to production of heat-labile enterotoxins in the gut b) Emetic; due to production of heat-stable toxin (cereulide) in food.
Temperature range/pH	Growth can occur between 4-55°C (optimum 30-40°C) and pH 4.3-9.3. As well as being heat-resistant; spores survive freezing and drying. Some strains require heat activation for spores to germinate.
Reservoir/source	Widely distributed in the environment, including in soil, sediments, dust and vegetation.
Mode of transmission and commonly associated foods	Through ingestion of food containing B. cereus vegetative cells which can produce enterotoxins in the gut ('diarrhoeal' form) or from ingestion of food containing the heat-stable toxin cereulide ('emetic' form). Spore containing foods that have been heated and then cooled/stored at ambient temperatures for prolonged periods provide an environment for the germination of spores into vegetative cells and bacterial growth +/- toxin production. Foods typically involved include starchy products e.g. rice, spices, dried foods, as well as meat, fish, milk and dairy products.
Infectious dose	Diarrhoeal form symptoms arise after ingestion of large numbers of bacteria (typically > 105 cfu/g) and emetic form arises from the preformed toxin, rather than the bacteria directly
Incubation period	Typically between 0.5-6 hours (emetic) or 6-24 hours (diarrhoeal).
Symptoms	Emetic form- nausea and vomiting (occasionally diarrhoea). Diarrhoeal form- abdominal pain and diarrhoea. Severe disease and mortality are rare.
Duration of illness	< 24 hours (emetic), usually 24-36 (diarrhoeal).
Infectious period	N/A: Not spread from person-to-person.
Laboratory diagnosis	B. cereus may be found in small numbers in the faeces of healthy people. In cases of suspected food poisoning, quantitative culture from faeces and, where available, vomit may be attempted. This must be discussed with the local microbiology department in advance as B. cereus culture is not a routine investigation in most clinical diagnostic laboratories. Isolates from outbreak investigations can be referred to UKHSA for molecular typing.
Food & water testing	Food can be examined for the presence of B. cereus; sample size should be a minimum of 25g, but ideally 100g. Samples should be submitted to the local Public Analyst laboratory for examination.
Specific control measures	Standard control measures apply. Key control measures include the following; Effective temperature control of cooked food (e.g. keeping food in the range of ≤ 5°C or ≥ 63°C); and hot food being cooled rapidly to ≤5°C, to prevent bacterial growth and spore germination. The toxin associated with the emetic form is heat-resistant therefore reheating food will not inactivate it if present. Therefore precautions, such as appropriate handling and storage of cooked starchy foods (notably rice) should be taken to prevent toxin production and accumulation.
Exclusions:	Cases: Until 48 hours after diarrhoea and/or vomiting have ceased. Contacts: Not required.

Pathogen	Campylobacter species
Microbiology	Helical Gram-negative motile bacteria. C. jejuni, and less commonly C. coli are the usual causes of Campylobacter diarrhoea. Other species, including C. lari, C. fetus and C. upsaliensis have also been associated with illness.
Temperature range/pH	Optimum temperature for growth is 42-45° C, no growth at < 28° C. Optimum pH for growth is 6.5-7.5; very sensitive to pH < 6.5.
Reservoir/source	C. jejuni is associated primarily with poultry, but also cattle, sheep and domestic pets. C. coli is associated with pigs and poultry. Untreated water sources can become contaminated with the organism.
Mode of transmission and commonly associated foods	Principally through ingestion of contaminated food (particularly undercooked poultry/poultry products e.g. chicken liver pâté). Other food sources include raw/undercooked meat and unpasteurised milk. Spread to other foods by cross-contamination e.g. unsafe food handling procedures, contamination with untreated water or contact with animals can also occur. The organisms do not multiply in food. Person-to-person spread is uncommon.
Infectious dose	Considered to be relatively low for C. jejuni; between 500-800 organisms.
Incubation period	1-10 days, but typically 2-5 days. Incubation period may be slightly longer in children.
Symptoms	Abdominal pain, diarrhoea (which may be bloody), headache and fever. Vomiting is uncommon. Most infections are self-limiting. Rare post-infectious complications include reactive arthritis, irritable bowel syndrome and Guillain-Barré syndrome. Asymptomatic infection also occurs.
Duration of illness	2-10 days, but typically around 6-7 days.
Infectious period	Protracted excretion is known to occur, but person-to-person spread is uncommon.
Laboratory diagnosis	Culture for campylobacter is carried out on all stool samples submitted to diagnostic microbiology laboratories. PCR analysis from stool samples may also be available.
Food & water testing	Food can be examined for the presence of Campylobacter spp. Sample size should be a minimum of 25g, but ideally 100g. Water samples require a minimum of 1L. Samples should be submitted to the Public Analyst laboratory for examination.
Specific control measures	Standard control measures apply. Key control measures include avoidance of eating undercooked poultry (especially chicken livers and chicken liver pâté), avoiding cross-contamination from raw poultry and avoiding consumption of unpasteurised milk.
Exclusions:	Cases: Until 48 hours after diarrhoea and/or vomiting have ceased. Contacts: Not required.

Pathogen	Clostridium botulinum
Microbiology	Gram positive, spore-forming, anaerobic, motile rods that produce seven neurotoxins (A-G); most commonly A, B, E and occasionally F. Other neurotoxin producing Clostridium species; C. butyricum, C. baratii and C. sporogenes have also rarely been implicated in cases of botulism.
Temperature range/pH	Proteolytic and non-proteolytic strains vary by ability to withstand extremes of temperature and pH. Proteolytic strains grow at 12-48°C, with optimal growth between 35- 45°C and require a minimum pH of 4.6. Non-proteolytic strains grow at temperatures as low as 3.3°C with optimal growth between 28-30°C and require a pH greater than 5. Toxins are heat-labile. Spores are typically resistant to cooking, drying and freezing.
Reservoir/source	Widely distributed in nature (mostly as spores), particularly in soil and aquatic/marine sediments. Also found in intestinal tracts of animals, fish, birds and insects.
Mode of transmission and commonly associated foods	There are two types of botulism that can be acquired through food: 1) Foodborne: Ingestion of pre-formed toxin in food. Toxin may be formed when food is processed and stored under specific conditions including; a pH of > 5, low salt and sugar content and anaerobic conditions (found in e.g. canned, bottled or vacuum/ modified atmosphere packed foods and homemade preserves), and is not sufficiently heated prior to consumption. These conditions are most often present in raw or under-processed foods. 2) Infant: Ingestion of spores rather than pre-formed toxin is responsible for illness. Honey is particularly associated with infant botulism.
Infectious dose	Ingestion of small doses (1 - 3 nanograms of toxin per kilogram of body mass) can be lethal.
Incubation period	Limited evidence is available, but is considered to be between 2 hours to 8 days (usually 12-36 hours) for foodborne botulism, and potentially longer for infant botulism.
Symptoms	Foodborne botulism is characterised by descending, flaccid paralysis, leading to respiratory failure and death if supportive care is not provided. Early symptoms include fatigue, weakness and vertigo, usually followed by blurred vision, dry mouth and difficulty in swallowing and speaking. Vomiting, diarrhoea or constipation may also occur. Infant botulism ranges from a mild illness to severe forms with complications including respiratory failure. Early symptoms include an inability to suck and swallow, altered cry and weakness.
Duration Of illness	Can be months, with residual weakness common following recovery.
Infectious period	Foodborne botulism: no person-to-person spread. Infant botulism: prolonged excretion may occur; nosocomial transmission has been reported within a neonatal unit.
Laboratory diagnosis	Botulism is a clinical diagnosis and treatment with antitoxin should not be delayed whilst awaiting laboratory results. Local microbiologist should discuss suspected cases of botulism with the Gastrointestinal Bacteria Reference Unit (GBRU) at UKHSA Colindale, prior to the sending of clinical specimens or samples.
Food & water testing	Testing is not currently carried out by Public Analyst Laboratories in Scotland. Please discuss with local Public Analyst laboratory as testing may be carried out at UKHSA Colindale or other specialist laboratories.
Specific control measures	Standard control measures apply. Key control measures for food producers of canned, bottled, vacuum packed/modified atmosphere and preserved foods include appropriate acidity, available water (Aw), use of heat treatment and/or temperature control, to limit the risk of spore germination and toxin production. In addition, infants < 12 months should not be fed honey.
Exclusions:	Cases: Foodborne botulism: Not required. Infant botulism: A risk assessment should be carried out and expert advice sought from PHS before return to a childcare setting. Contacts: Not required.

Pathogen	Clostridium perfringens
Microbiology	Enterotoxin producing Gram-positive, non-motile, anaerobic, spore-forming bacilli. Strains are categorised into toxin types, with only some capable of causing human illness.
Temperature range/pH	Growth between 12°C–60°C, optimum between 43°C–47°C. pH 6-7.
Reservoir/source	Normal inhabitant of the gastrointestinal tracts of humans and animals. Also found in soil, marine/aquatic sediments and dust.
Mode of transmission and commonly associated foods	Ingestion of food that has been cooled/stored at ambient temperatures for prolonged periods after cooking, permitting the germination of spores into vegetative toxin producing bacteria. Foods typically involved include meats/meat products, and cases have in particular been associated with foods held warm such as at meats at hot buffets.
Infectious dose	Relatively high, typically >105 bacteria/g of food. Toxin production occurs in the intestine.
Incubation period	A range of 2-36 hours, but typically 10-12 hours.
Symptoms	Sudden onset abdominal pain, followed by nausea and diarrhoea. Vomiting and fever typically do not occur.
Duration of illness	1-2 days, but typically < 24 hours.
Infectious period	N/A: person-to-person transmission is not considered to occur.
Laboratory diagnosis	Stool culture for C. perfringens is not a routine investigation for clinical diagnostic laboratories. Discuss with laboratory before sending samples. The Gastrointestinal Bacteria Reference Unit (GBRU) at UKHSA Colindale offers PCR and molecular typing for outbreak investigations.
Food & water testing	Food can be examined for the presence of C. perfringens; sample size should be a minimum of 25g, but ideally 100g. Water samples can also be examined, requiring a minimum volume of 100ml. Samples should be submitted to the local Public Analyst laboratory for examination.
Specific control measures	Standard control measures apply. Key control measures include effective temperature control of cooked food to prevent spore germination and growth e.g. hot holding at ≥ 63°C or rapidly cooling to ≤ 5°C. Food being reheated must achieve a minimum core temperature of 82°C.
Exclusions:	Cases: Until 48 hours after diarrhoea and/or vomiting have ceased. Contacts: Not required.

Pathogen	Cryptosporidium species
Microbiology	Protozoan parasite producing oocytes which measure 4-6 µm. C. parvum and C. hominis are the most common species which can cause illness. Other species also thought to cause illness include C. meleagridis, C. felis, C. canis, and Cryptosporidium rabbit genotype.
Temperature Range/pH	Oocysts can survive a range of temperatures (including freezing) and pH levels. Temperatures > 70°C and a pH of < 4 or > 11 are considered to be sufficient to inactivate the organism.
Reservoir/Source	Gastrointestinal tract of humans (C. hominis and C. parvum) and various animals (C. parvum), particularly cattle and sheep. Pet animals can carry other Cryptosporidium spp. such as C. felis (cats) and C. canis (dogs) but these are rarely associated with human infection, and are typically associated with infection in immunocompromised individuals.
Mode Of Transmission and Commonly Associated Foods	Direct transmission from contact with faeces of infected animals or humans, or indirect transmission via contaminated food/water (including swimming pools). Published foodborne outbreaks have been associated with inadequately treated drinking water and fresh produce. Particularly associated foods include raw vegetables/salads/herbs (e.g. due to irrigation with contaminated water).
Infectious Dose	Not well documented in the literature. Infectious dose is species dependent with as few as 10 oocysts for C. hominis and C. parvum.
Incubation Period	Typically < 2 weeks, with an average of approximately 7 days.
Symptoms	The major symptoms are abdominal pain and watery diarrhoea. These are preceded by anorexia and vomiting (particularly in children), and typically general malaise and less commonly fever in adults. Symptoms often wax and wane. Immunocompetent individuals are often asymptomatic, but illness may be severe (and intractable) in those who are immunocompromised.
Duration Of Illness	Variable; typically < 30 days in immunocompetent individuals, with a median of 7-11 days reported in several UK studies.
Infectious Period	Individuals are infectious whilst symptomatic and may remain infectious for weeks to months after symptoms resolve, due to continued excretion of oocysts.
Laboratory Diagnosis	Microscopy is routine in clinical diagnostic laboratories as well as enzyme immunoassays (EIA) and some may offer PCR, but these will not identify to species level. In outbreak situations, samples can be sent to Scottish Parasite Diagnostic and Reference Laboratory (SPDRL) for speciation and further typing.
Food & Water Testing	Appropriate food and water samples should be discussed with the local Public Analyst Laboratory; Scottish Water are accredited to carry out detection and enumeration of Cryptosporidium oocysts in raw, drinking, and recreational waters. To note, water sampling requires large volumes and use of specialist equipment.
Specific Control Measures	Standard control measures apply. Use of potable water in food processes and the source/quality of water used for irrigation are important considerations for foodborne outbreaks. Oocysts are resistant to chlorine.
Exclusions	Cases: Until 48 hours after diarrhoea and/or vomiting have ceased. Cases should avoid use of swimming pools until two weeks after the first normal stool. Contacts: Not required.

Pathogen	Giardia duodenalis (syn Giardia lamblia syn. Giardia intestinalis)
Microbiology	Flagellated protozoan parasite. Vegetative trophozoites range from 10-20 µm in length and environmentally resistant cysts range from 7-19 µm.
Temperature range/pH	Not clear from the literature. Depends on various factors such as the environment it is found in, whether in water or adhered to a surface, and ambient temperature, with temperature appearing to be the most critical factor in survival of cysts.
Reservoir/source	Humans, companion animals, livestock and some wildlife.
Mode of transmission and commonly associated foods	Transmission is by the faecal-oral route due to ingestion of cysts. Published outbreaks have primarily been associated with consumption of contaminated water (or contact with recreational water). Other modes include direct contact with colonised animals or their faeces and eating faecally contaminated food. Person-to-person spread can also occur.
Infectious dose	Considered to be very low, estimated to be 10 - 100 cysts.
Incubation Period	3-25 days (usually 7-10 days).
Symptoms	There is a high rate of asymptomatic/subclinical carriage associated with infection. Symptoms include abdominal pain and diarrhoea (foul- smelling, greasy stools), as well as flatulence and weight loss.
Duration of illness	Typically > 1 week, but often considerably longer if untreated. Long term chronic carriage and relapses are known to occur.
Infectious period	The period of communicability extends throughout the course of infection/carriage and is greatest when the case is symptomatic.
Laboratory diagnosis	Testing methods and protocols (e.g. microscopy versus EIA versus PCR and all samples versus selective samples, based on travel/clinical history) vary across diagnostic laboratories in Scotland. In a suspected outbreak situation, examination of additional samples should be discussed with the clinical microbiology laboratory.
Food & water testing	Testing is not currently carried out by Public Analyst Laboratories in Scotland. Please discuss with local Public Analyst laboratory as testing may be carried out at UKHSA Colindale or other specialist laboratories.
Specific control measures	Standard control measures apply. Use of potable water in food processes and the source/quality of water used for irrigation are important considerations for foodborne outbreaks, additionally, correct hygiene standards of food handlers should be maintained. Cysts are resistant to chlorine.
Exclusions	Cases: Until 48 hours after diarrhoea and/or vomiting have ceased. Cases should avoid use of swimming pools until two weeks after the first normal stool. Contacts: Not required.

Pathogen	Hepatitis A Virus
Microbiology	The hepatitis A virus (HAV) is a small, non-enveloped, single stranded RNA virus in the genus Hepatovirus. HAV is classified into five genotypes, with genotypes I, II, III (divided into subtypes A and B) being capable off infecting humans.
Temperature range/pH	HAV is stable at ambient temperatures and can tolerate low pH, drying, freezing and many detergents.
Reservoir/source	Humans and primates.
Mode of transmission and commonly associated foods	Typically person-to-person spread via the faecal-oral route. Foodborne outbreaks are also known to occur. Published outbreaks have been associated with contamination of ready-to-eat foods by infected food handlers working in various settings. Outbreaks have also been linked to foodstuffs (including shellfish, fresh and frozen berries etc, which either have been contaminated through their handling or through contact with human waste further upstream in the food production)
Infectious dose	The minimum infectious dose is not known but considered to be low.
Incubation period	Range of 15-50 days, but typically around 28 days.
Symptoms	Initial symptoms are non-specific, such as fever, nausea, vomiting and fatigue. Later, gastrointestinal symptoms develop, as well as abdominal tenderness, hepatomegaly, or splenomegaly. Jaundice also manifests in 40 – 70% of those with symptoms. Asymptomatic infection is common in children, with a much smaller proportion of those becoming jaundiced.
Duration of illness	-For most individuals, symptoms last for several weeks, although relapse is possible for up to 6 months. More severe illness is associated with those with liver disease.
Infectious period	-Generally, from two weeks before the onset of jaundice until one week after. The concentration of virus in the stool declines after jaundice appears but may persist for more than 40 days. Children may excrete the virus for longer than adults, although a chronic persistent state is not considered to exist.
Laboratory diagnosis	Acute infection is typically diagnosed in local laboratories by presence of Hepatitis A IgM in serum. Molecular typing of isolates may be available to assist in outbreak investigation. Advice should be sought on a case-by-case basis from the regional specialist virology laboratory/centre.
Food & water testing	Testing is not currently carried out by Public Analyst Laboratories in Scotland. Please discuss with local Public Analyst laboratory as testing may be carried out at UKHSA Colindale or other specialist laboratories.
Specific control measures	Food Standard control measures apply in terms of prevention of contamination of foods. Particular attention should be given to potential for contamination of food from infected food handlers HAV requires high temperatures to be inactivated - the UK Advisory Committee on the Microbiological Safety of Food advises temperatures greater than 85°C for 1 minute. HAV can be inactivated by disinfecting surfaces with 1:100 dilution of sodium hypochlorite for at least 1 minute. Other: Immunisation of contacts and others is an important control measure; see. UKHSA Public Health Management and Control of Hepatitis A, 2017 guidance for further details.
Exclusions:	Cases: Exclude cases from work, school or nursery until 7 days after the onset of jaundice or in the absence of jaundice, from the onset of symptoms such as fatigue, nausea or fever. See UKHSA Public Health Management and Control of Hepatitis A, 2017 guidance for further details. Contacts: Management of contacts is complex and may include vaccination and immunoglobulin (HNIG) +/- exclusion. See UKHSA Public Health Management and Control of Hepatitis A, 2017 guidance for further details.

Pathogen	Hepatitis E Virus
Microbiology	Hepatitis E Virus (HEV) is a non-enveloped, single stranded RNA hepevirus. Genotypes 1-4 are associated with human infection.
Temperature range/pH	Not well established. Research has indicated HEV thermal resistance is greater than previously reported, with typical cooking temperatures (70 - 85℃) potentially being insufficient to eliminate the virus.
Reservoir/source	Infections in the UK and Europe are predominantly associated with genotype 3 which is zoonotic and is found in humans and other mammals. Pigs are considered to be the principal reservoir of infection. Genotype 4 is also zoonotic and is found primarily in Asia. Genotypes 1 and 2 are only found in humans and are prevalent through the Indian Subcontinent, parts of South-East Asia, North and Central Africa and Central America.
Mode of transmission and commonly associated foods	Genotype 3 is the most common strain in UK and Europe and is primarily foodborne. The majority of cases are sporadic and are thought to be particularly associated with consumption of pork/pork products. Reported outbreaks are uncommon. Published foodborne outbreaks have been associated with pork products, often consumed undercooked or raw. Shellfish are another potential source. Person-to-person transmission is rare. Genotype 1 and 2 infections are transmitted via the faecal-oral route and are common in developing countries, particularly in areas with poor sanitation where large outbreaks can occur due to faecal contamination of drinking water supplies.
Infectious dose	Not known to high degree of certainty.
Incubation period	Can range from approximately 15- 60 days (average 40 days).
Symptoms	In most cases infection is asymptomatic. Symptoms when present are typically self-limiting, with jaundice, and less commonly fever, nausea, abdominal pain, vomiting and anorexia. Neurological symptoms can occur in approximately 5% of cases. Chronic infection with cirrhosis is known to occur in immunocompromised individuals with genotype 3 or 4 infection. Genotypes 1 and 2 are particularly associated with poorer outcomes in pregnant women.
Duration of illness	Typically 1-4 weeks, but can be longer. Chronic infections are known to occur in immunocompromised individuals with genotype 3 or 4 infection.
Infectious period	Not well established.
Laboratory diagnosis	Acute Hepatitis E is diagnosed from blood samples by serology +/- PCR. Testing for hepatitis E is not routine in diagnostic laboratories - discuss with local microbiologist/virologist before sending samples. Molecular typing of isolates may be available to assist in outbreak investigation. Advice should be sought on a case-by-case basis from the regional specialist virology laboratory/centre.
Food & water testing	Testing is not currently carried out by Public Analyst Laboratories in Scotland. Please discuss with local Public Analyst laboratory as testing may be carried out at UKHSA Colindale or other specialist laboratories.
Specific control measures	Standard control measures apply. However, it should be noted that the limited information available suggests that HEV is thermally stable and may survive standard time / temperature combinations used for cooking some products.
Exclusions:	Cases: No formal exclusion is required, but good personal hygiene is recommended. Food handlers, in particular, should comply with routine good food practice and standard infection control advice. Contacts: Not required.

Pathogen	Listeria monocytogenes
Microbiology	Gram-positive, non-spore-forming, facultatively anaerobic rod. Other species of Listeria have also been associated with human illness but these are considered to be very rare.
Temperature range/pH	Optimum growth at 30 -37°C. May survive at temperatures below 0°C and can grow from fridge temperatures up to 45°C. pH 4.0-9.5.
Reservoir/source	Widely distributed throughout the environment, including vegetation, soil, water and animal faeces. Humans and various animals can also act as a reservoir. It is often associated with contamination in food processing facilities where it may become persistent.
Mode of transmission and commonly associated foods	Usually foodborne. Published outbreaks have most often been associated with chilled, ready-to-eat foods. These include smoked fish, cooked shellfish, pate, cooked/cured meats, both pasteurised and unpasteurised cheeses (particularly soft / semi-soft), pre-packed sandwiches, prepared salads, ice creams and pre-cut fruit. Person-to-person transmission is confined usually to vertical transmission from mother to child in utero or during birth. Nosocomial transmission in the neonatal setting (e.g. through cross contamination of equipment) has occasionally been reported in the literature.
Infectious dose	Considered to vary depending on the strain and susceptibility of the host. In healthy individuals the infectious dose is likely to be quite high (>105 cfu/g), whereas invasive infection can occur in immunocompromised individuals exposed to lower levels.
Incubation period	3-70 days, but most commonly 2-3 weeks for invasive listeriosis. Non-invasive listeriosis has a shorter incubation period with 18-28 hours reported from outbreaks.
Symptoms	Often asymptomatic in healthy individuals. Non-invasive listeriosis symptoms include diarrhoea, fever, headache and myalgia. Invasive listeriosis may be seen in immunocompromised individuals (including those with underlying health conditions, pregnant women, the elderly and neonates) presenting with fever, myalgia, septicaemia or meningitis and is categorised as a high severity illness. Infection in pregnancy may result in spontaneous abortion, stillbirth or neonatal infection.
Duration of illness	Variable depending on disease manifestation/immune status.
Infectious period	N/A.
Laboratory diagnosis	All diagnostic laboratories can isolate L. monocytogenes. This is usually from a normally sterile site e.g. blood culture, CSF, peritoneal or amniotic fluid. All isolates should be routinely sent to the UKHSA Gastrointestinal Bacteria Reference Unit (GBRU), for molecular typing.
Food & water testing	Food samples can be tested for Listeria spp. at Public Analyst Laboratories. A minimum of 100g of food sample is required for testing. Public Analyst Laboratories can arrange for molecular typing, at UKHSA if required.
Specific control measures	Standard control measures apply, including careful attention to appropriate and thorough environmental cleaning, and awareness of the environmental niches that Listeria spp. can survive in. High risk foods must be kept under chilled conditions and not consumed after their use-by dates. Legislation allows for 100 cfu/g to be present in ready-to eat foods.
Exclusions:	Cases: Until 48 hours after diarrhoea and/or vomiting have ceased. Contacts: Not required.

Pathogen	Norovirus
Microbiology	RNA calcivirus. Classified into at least seven different genogroups (GI to GVII); genogroups I, II, and IV can infect humans.
Temperature range/pH	Not well established. Shown to survive refrigeration and freezing. The virus can remain infective at 60°C for 30 minutes and can survive some pasteurisation and steaming processes. It is also considered to be resistant to acidic pH (between pH 4 - 7), even showing relative tolerance at pH 2.
Reservoir/source	Humans are the only known reservoir. Can survive a long time in the environment.
Mode of transmission and commonly associated foods	Through direct person-to-person contact and indirect transmission via contaminated food, water, fomites or environmental surfaces. Published outbreaks have been associated with contamination by infected food handlers during preparation and service of various foodstuffs. Outbreaks have also been linked to shellfish (particularly oysters) by exposure to contaminated seawater in shellfish growing beds, and soft fruits/salad (incl. strawberries, raspberries) contaminated with human waste (typically via infected workers harvesting fresh produce) further upstream in the food distribution system.
Infectious dose	Considered in some instances to be as low as 10 virus particles, depending on the immune status of the individual, and the food matrix which is consumed.
Incubation period	Typically 10-50 hours.
Symptoms	Rapid onset diarrhoea and/or vomiting which is often projectile and may be accompanied by nausea, headache and abdominal cramps. Symptoms are usually self-limiting.
Duration of illness	Ranges from approximately 12 hours to 4 days.
Infectious period	Most communicable during acute stages of disease, but virus may be shed for 2-3 weeks after symptom resolution. Shedding is maximal when diarrhoea is present and in the first couple of days following resolution of symptoms.
Laboratory diagnosis	Testing must be discussed with the local microbiology department in advance as this is not a routine investigation in most clinical diagnostic laboratories, other than in a suspected outbreak situation or for specific clinical groups. Some diagnostic laboratories offer PCR on stool samples as standard. Molecular typing of isolates may be available to assist in outbreak investigation. Advice should be sought on a case-by-case basis from the regional specialist virology laboratory/centre.
Food & water testing	Testing is not currently carried out routinely by Public Analyst Laboratories in Scotland. Please discuss with local Public Analyst laboratory as testing may be carried out at UKHSA Colindale or other specialist laboratories. The only laboratory currently accredited to carry out norovirus quantification (ISO 15216-1) is CEFAS (England). It is important to note that, as with most virus testing, the tests quantify norovirus genetic material, which includes both viable and inactivated norovirus particles.
Specific control measures	Standard control measures apply. Key control measures include careful attention to appropriate and thorough environmental cleaning (as per the Scottish National Infection Prevention and Control manual). Identification and exclusion of symptomatic staff is also key. In food, modelling indicates that a 6 log reduction (practical elimination) of norovirus may be achieved after approximately 12.5 minutes at 80ºC, and 2 minutes at 90℃
Exclusions:	Cases: Until 48 hours after diarrhoea and/or vomiting have ceased. Contacts: Not required.

Pathogen	Salmonella Typhi and Paratyphi
Microbiology	Gram-negative, facultatively anaerobic, motile, non-spore-forming rod. Typhoid and paratyphoid fever are caused by systemic infection with Salmonella enterica serovars Typhi and Paratyphi A, B or C, collectively referred to as enteric fever
Temperature range/pH	The reported temperature range for Salmonella enterica spp. is 5 – 46.2°C, with the optimal temperature for growth between 37 and 42 °C. Salmonella can survive freezing and long-term frozen storage. Salmonella spp. will grow in a broad pH range of 3.8–9.5, with an optimum pH range for growth of 7–7.5
Reservoir/source	Humans are the only reservoir for S. Typhi and S. Paratyphi..
Mode of transmission and commonly associated foods	Transmitted predominantly through sewage contamination of food and water and through person to person contact. Individuals that are ill can spread the disease, but also individuals that have recovered, but are still shedding the pathogen in their faeces. Infections in the UK are typically associated with overseas travel. Food-handlers carrying the pathogen can also be a source of food contamination.
Infectious dose	The infectious dose is considered to be large. The infectious dose for S. Typhi has been reported to vary between 1000 and 1 million organisms in healthy individuals. Infections can occur with ingestion of fewer than 1000 organisms, especially in immunocompromised individuals. The infectious dose for S. Paratyphi is considered to be higher than for S. Typhi.
Incubation period	3-60 days (usually 8-14 days) for S. Typhi and 1-10 days (usually 4-5 days) for S. Paratyphi.
Symptoms	Systemic illness with insidious onset of sustained fever, marked headache, malaise and abdominal pain. Other symptoms that may be present include anorexia, relative bradycardia, splenomegaly, rash (rose spots) and a non-productive cough in the early stages of illness. Constipation is also a frequent early symptom, but most patients will experience diarrhoea at some point during the illness. Complications may arise, typically in the third week of disease and include renal failure and GI perforation.
Duration of illness	Typically several weeks to months. Chronic carriage is defined as shedding which continues for longer than one year. Relapse can occur in a small proportion of cases.
Infectious period	Considered to occur from the first week of symptoms and last until microbiological clearance. Approximately 10% of untreated cases will excrete the bacteria for > 3 months and 2-5% will become chronic carriers.
Laboratory diagnosis	Culture for Salmonella spp. (including S. Typhi and S. Paratyphi) is carried out on all stool samples submitted to diagnostic Microbiology laboratories. Some laboratories also offer stool PCR testing. Isolates may also be cultured from other specimens including blood and other sterile sites. Positive isolates are sent to the Scottish Salmonella, Shigella &. C. difficile Reference Laboratory (SSSCDRL) for further typing.
Food & water testing	Testing is not currently carried out by Public Analyst Laboratories in Scotland. Please discuss with local Public Analyst laboratory as testing may be carried out at UKHSA Colindale or other specialist laboratories. (N.B Laboratories can identify Salmonella spp. but due to S. Typhi and S. Paratyphi being HSE Category 3 pathogens, suspected food items need to clearly state if S. Typhi and S. Paratyphi infection is suspected.
Specific control measures	Standard control water measures apply.

Exclusions:	Cases: Exclusion and microbiological clearance is required for probable and confirmed cases in risk groups A to D. All other cases should be excluded whilst symptomatic and until 48 hours after last symptoms. See UKHSA Public Health Operational Guidelines for Typhoid and Paratyphoid (Enteric Fever), 2017 for further details. Contacts: Management of contacts will depend on type of case (travel or non-travel) and type of contact (household or co-traveller). See UKHSA Public Health Operational Guidelines for Typhoid and Paratyphoid (Enteric Fever), 2017 for further details.

Pathogen	**Non-typhoidal Salmonella species**
Microbiology	Gram negative, facultatively anaerobic rods. The most common serotypes are S. Enteritidis and S. Typhimurium.
Temperature range/pH	The reported temperature range for Salmonella enterica spp. is 5 – 46.2 C., with the optimal temperature for growth between 37 and 42 °C. Salmonella can survive freezing and long-term frozen storage. Salmonella spp. will grow in a broad pH range of 3.8–9.5, with an optimum pH range for growth of 7–7.5
Reservoir/source	Wide range of domestic and wild animals including poultry, cattle, pigs, reptiles and rodents. Also humans. Non-typhoidal Salmonella enterica species can also be present in the environment and internalised within plants/crops.
Mode of transmission and commonly associated foods	Foodborne transmission is predominant. Common sources of foodborne outbreaks include animal products, raw/undercooked meat, eggs, unpasteurised milk etc. Salmonella also survives well in high fat foods. A number of published outbreaks have also been linked to raw vegetables/fruit, nuts and nut butters and chocolate. Infected food handler linked outbreaks involving other food products have also been reported. Person-to-person transmission can also occur.
Infectious dose	As little as 100 - 1000 organisms. The infectious dose varies with the serotype, the immune-competence of the individual and the nature of the food.
Incubation period	Typically 6-72 hours but longer incubation periods have been documented.
Symptoms	Abdominal pain, diarrhoea (sometimes bloody), nausea, headache and fever are the most common symptoms. Vomiting also occurs occasionally. Is typically a self-limiting illness. Rare complications include reactive arthritis, osteomyelitis, cholecystitis, meningitis and septicaemia, particularly in immunocompromised individuals, young children and the elderly.
Duration of illness	Typically < 7 days but can be longer.
Infectious period	The period of communicability extends throughout the course of infection/carriage and is greatest when the case is symptomatic. Carriage can be prolonged, especially in young children; potentially lasting many months.
Laboratory diagnosis	Culture for Salmonella spp. is carried out on all stool samples submitted to diagnostic Microbiology laboratories. Some laboratories also offer stool PCR testing. Positive isolates are sent to the Scottish Salmonella, Shigella &. C. difficile Reference Laboratory (SSSCDRL) for further typing.
Food & water testing	Food and water samples can be tested for Salmonella spp. Samples should be submitted to one of the Public Analyst laboratories according with their sample submission requirements. Positive isolates are sent to the SSSCDRL for further typing.
Specific control measures	Standard control measures apply.
Exclusions:	Cases: Until 48 hours after diarrhoea and/or vomiting have ceased. Contacts: Not required.

Pathogen	Shiga toxin-producing Escherichia coli (STEC)
Microbiology	Gram negative facultatively anaerobic rods. STEC are a group of infectious E. coli strains capable of producing Shiga toxins. E. coli O157 is the serogroup most frequently associated with disease in the UK. There are over 100 serogroups associated with human disease. Common non-O157 serogroups include O26, O103, O111, O145 and O146.
Temperature range/pH	7 °C - 50 °C (optimum 37 °C), pH > 4.4.
Reservoir/source	Cattle (and other ruminants) are the most important reservoir. Various other animals may also be carriers. Humans can serve as a reservoir for person-to-person transmission.
Mode of transmission and commonly associated foods	Through ingestion of food/water contaminated with faeces or direct contact with animals or their environment. Person-to-person spread can also occur. Food items typically implicated in outbreaks include raw or undercooked meat (especially minced products e.g. burgers), unpasteurised dairy products, salad leaves, sprouted seeds and other raw vegetables. STEC infections typically show seasonality with cases higher in the summer months.
Infectious dose	Considered to be very low. Potentially as little as 10 bacteria.
Incubation period	Usually 3-4 days, with a range of 1-10 days, longer incubation periods (up to 14 days or more) have occasionally been reported.
Symptoms	Typically abdominal pain and diarrhoea (often bloody). Occasionally fever. Complications include haemolytic uraemic syndrome (HUS) and cerebral involvement, particularly in children and the elderly. Asymptomatic carriage can also occur.
Duration of illness	Typically between 4-10 days but can be longer, especially with complications e.g. HUS.
Infectious period	Cases (including asymptomatic cases) are infectious until the organism is no longer detected from stool samples, but are considerably more infectious whilst symptomatic. STEC may be shed in the stool for several weeks or months following resolution of diarrhoea. Children tend to continue to shed for longer than adults.
Laboratory diagnosis	Culture for E. coli O157 is carried out on stool samples submitted to diagnostic Microbiology laboratories. Some laboratories also offer stool PCR testing. Stool samples from patients with suspected STEC infection which test negative (as well as positives) at the diagnostic lab should be submitted to the Scottish E. coli reference laboratory (SERL) for further testing (including for non-O157 STEC), in line with SHPN Guidance for the public health management of Escherichia coli O157 and other Shiga toxin-producing (STEC) infections.
Food & water testing	Food and water samples can be tested for STEC using PCR or tested specifically for E.coli O157 using culture + immunomagnetic separation (IMS) or PCR. The sample volume for water samples should be a minimum of 1L, food samples should be a minimum of 100g. Samples should be submitted to one of the Public Analyst laboratories. Positive isolates will be sent to SERL for confirmation and typing.
Specific control measures	Standard control measures apply.

Pathogen	Shiga toxin-producing Escherichia coli (STEC)
Exclusions:	Cases: Cases who fall into one or more of risk groups A to D (see Table 1) should be formally excluded or restricted from work or school/nursery until microbiological clearance has been achieved. All other cases should be advised to refrain from attending work or educational establishment until 48 hours after diarrhoea and / or vomiting have ceased. This exclusion should also extend to other group settings such as playgroups and sports clubs. See SHPN Guidance for the public health management of Escherichia coli O157 and other Shiga toxin-producing (STEC) infections for further details. Contacts: Asymptomatic close contacts who fall into one or more of the risk groups A to D should be formally excluded or restricted from work or school until microbiological clearance has been achieved. Those not in risk groups do not require to be excluded. See SHPN Guidance for the public health management of Escherichia coli O157 and other Shiga toxin-producing (STEC) infections for further details.

Pathogen	Shigella species
Microbiology	Gram negative, facultatively anaerobic, non-motile rods. S. dysenteriae, S. flexneri, S. boydii and S. sonnei.
Temperature range/pH	Shigella spp. grow at temperatures between 6 °C and 48 °C and at a pH of between 4.8 and 9.3. Optimal temperature for growth is 37°C. Shigella spp. can survive at room temperature for up to 50 days in certain food products.
Reservoir/source	The gastrointestinal tracts of humans and some primates.
Mode of transmission and commonly associated foods	Person-to-person transmission through the faecal-oral route and through consumption of water or food contaminated with faeces from infected individuals. Foodborne outbreaks due to Shigella species often do not follow the same pattern; they can be small/localised or affect thousands of individuals in multiple countries. Foods implicated in Shigella outbreaks have included cheese/bean dip, sugar peas, uncooked tofu salad as well as secondary spread by food handlers. Outbreaks have also been associated with holidaymakers staying in all-inclusive resorts and thought to be transmitted by infected food handlers.
Infectious dose	Reported to be very low, between 10-100 organisms.
Incubation period	Ranges of 6 hours to 4 days but may be up to one week for S. dysenteriae type 1.
Symptoms	Typically diarrhoea (or bloody diarrhoea), fever and abdominal pain. Infection with S. sonnei generally results in mild symptoms. Toxic megacolon and haemolytic uraemic syndrome are occasionally seen complications in disease caused by S. dysenteriae. Infection with S. flexneri can lead to Reiter's Syndrome. Immunocompromised individuals, children (under 5 years of age) and the elderly are more vulnerable to severe infection.
Duration of illness	Typically 4-10 days but may last up to one month.
Infectious period	The period of communicability continues during acute infection and until organism is no longer being excreted in faeces, although cases are most infectious when diarrhoea is present.
Laboratory diagnosis	Culture for Shigella spp. is carried out on all stool samples submitted to diagnostic Microbiology laboratories. Some laboratories also offer stool PCR. Positive isolates are sent to the Scottish Salmonella, Shigella &. C. difficile Reference Laboratory (SSSCDRL) for confirmation and further typing.
Food & water testing	Testing is not currently carried out by Public Analyst Laboratories in Scotland. Please discuss with local Public Analyst laboratory as testing may be carried out at UKHSA Colindale or other specialist laboratories.
Specific control measures	Standard control measures apply.
Exclusions:	Cases: S. dysenteriae, S. flexneri and S. boydii cases in risk groups A to D - exclude until microbiological clearance is achieved* *Microbiological clearance - 2 consecutive negative samples taken at least 24 hours apart Cases not in a risk group AND all cases of S. sonnei- exclude until 48 hours after diarrhoea and / or vomiting have ceased. At advice from HPT/IMT; Groups A & B for S. sonnei may require more prolonged exclusion periods. Contacts: No exclusion of contacts required.

Pathogen	**Staphylococcus aureus**
Microbiology	Gram-positive, non-motile, non-spore-forming, facultatively anaerobic coccus able to produce enterotoxins.
Temperature range/pH	Able to grow at 7–48 °C (optimum 37 °C), pH 4.0-9.3 (optimum 7.0–7.5). Toxin production occurs within the temperature range 10-48 °C, and once produced, toxins are heat stable below 80°C.
Reservoir/source	Humans are the main reservoir, typically from infected, exposed skin lesions. S. aureus can also be carried in nostrils and on healthy skin, between 25-50% of people are colonised by S. aureus. Occasionally, infected animals can act as a reservoir/source.
Mode of transmission and commonly associated foods	Through ingestion of food containing staphylococcal enterotoxins. Food handlers who carry the bacteria on their skin may contaminate food by direct contact. Inadequate heating or refrigeration allows the bacteria to multiply and produce toxins. Published outbreaks have also been associated with unpasteurised milk/milk products. The remainder of outbreaks involved various foods due to contamination by food-handlers.
Infectious dose	Not well established but considered to be very low; possibly as little as 20-100ng of enterotoxin in food.
Incubation period	30 minutes to 8 hours (usually 2-4 hours).
Symptoms	Rapid onset, severe abdominal cramps, nausea and vomiting. Diarrhoea and hypotension sometimes occur. Mortality is rare.
Duration of illness	Typically 1-2 days.
Infectious period	N/A- not communicable from person-to-person.
Laboratory diagnosis	In an outbreak situation, quantitative culture from faeces and, where available, vomit may be attempted. This must be discussed with the local microbiology department in advance as S. aureus culture from these samples is not a routine investigation in most clinical diagnostic laboratories. Toxin testing by PCR can be carried out at the Glasgow Reference Laboratory.
Food & water testing	Food samples can be examined for presence of S. aureus, a minimum sample of 100g is required. Foods can also be tested for the presence of the enterotoxin. Samples should be submitted to one of the Public Analyst laboratories.
Specific control measures	Standard control measures apply. Key control measures include the following; Food handlers ensuring that cuts and other skin lesions are covered. Effective temperature control of food to prevent bacterial growth and toxin production (e.g. keeping food in the range of ≤ 5°C or ≥63°C). Toxin is heat-resistant and will not be inactivated by re-heating of food.
Exclusions:	Cases: Food handlers with visibly infected skin lesions (boils, cuts, etc.) that cannot be effectively covered should be excluded from work until the lesions are healed. Nasal carriers do not need to be excluded unless implicated as the source of an outbreak. Medical/ occupational health advice can be sought in complex cases. Contacts: Not required

Pathogen	Vibrio cholerae
Microbiology	Gram-negative, facultatively anaerobic, motile, non-spore-forming rods. Toxigenic V. cholerae serogroups O1 (further divided into “classical” and “El Tor”) and O139 can produce the cholera toxin and most commonly cause cholera. Infection with other serogroups may cause mild gastroenteritis.
Temperature range/pH	Considered to grow between 15- >40°C (optimum 37°C) and a pH range of 5.0-9.6. V. cholerae has survival mechanisms in response to non-optimal, colder temperatures. It is reported that in adaptation to cold temperatures (4 °C) V. cholerae enters viable, but non-culturable state. This allows its survival in an unfavourable environment.
Reservoir/source	V. cholerae can be found in fresh water as free living, forming biofilms or in association with plankton (recognized environmental reservoir). V. cholerae is the only Vibrio spp. that has both human and environmental stages in its life cycle. Humans are the only host.
Mode of transmission and commonly associated foods	Primary: Ingestion of water or food contaminated with human sewage (e.g. raw or undercooked shellfish, foods washed in contaminated water), is the predominant method of transmission of V. cholerae. Secondary: Secondary transmission is unlikely in the UK due to good sanitation. Infected food handlers have been implicated in a small number of published outbreaks worldwide.
Infectious dose	A large infectious dose (> 1 x 104 organisms) is required.
Incubation period	Few hours - 5 days (usually 2-3 days).
Symptoms	Most cases are asymptomatic. When symptomatic, onset is sudden, with profuse, painless watery diarrhoea. Nausea and vomiting occur early in the course of illness. If untreated can cause death due to rapid dehydration and circulatory collapse.
Duration of illness	Up to 7 days.
Infectious period	Cases are considered infectious whilst diarrhoea is present and for approximately 1 week after resolution of symptoms. While intermittent shedding occasionally persists for several months, chronic carriage is rare (but when present can persist for years).
Laboratory diagnosis	Cultured from stool samples if requested or if clinical details/history indicate e.g. foreign travel. Some laboratories offer stool testing by PCR. Isolates should be sent to the Gastrointestinal Bacteria Reference Unit (GBRU) at UKHSA Colindale for confirmation/ further typing.
Food & water testing	Testing is not currently carried out by Public Analyst Laboratories in Scotland. Please discuss with local Public Analyst laboratory as testing may be carried out at UKHSA Colindale or other specialist laboratories.
Specific control measures	Standard control measures apply.
Exclusions:	Cases: Serogroups O1 and O139 only: Cases in risk groups A to D – exclude until microbiological clearance achieved (2 consecutive negative stool samples taken a minimum of 48 hours after vomiting and/or diarrhoea have ceased and at least 24 hours apart). Cases not in risk groups A to D or other serogroups - exclude until 48 hours after vomiting and/or diarrhoea have ceased. Contacts: Serogroups O1 and O139 only- no action required for asymptomatic close contacts. Screen symptomatic co-travellers and household contacts.

Pathogen	Non-cholera Vibrios
Microbiology	Gram-negative, facultatively anaerobic, motile, non-spore-forming rods. More than 100 species of Vibrios have been identified, out of which approximately 12 are known as pathogenic species, including V. parahaemolyticus and V. vulnificus which are most commonly isolated.
Temperature range/pH	Ability to grow in food at 4-43°C has been experimentally demonstrated. Vibrio spp. are able to grow over a wide temperature range (20°C to >40°C) and grow preferably under alkaline conditions, although most species have been reported to grow between pH 6.5 and 9.0.
Reservoir/source	Marine environments, including fish and shellfish. Vibrio spp. can persist in a free-living state in water, colonise fish and marine invertebrates or be associated with plankton and algae.
Mode of transmission and commonly associated foods	By ingestion of raw or inadequately cooked contaminated seafood, especially oysters or other shellfish or through direct exposure to water.
Infectious dose	Not well established. Strain to strain variability have been noted, with 1 x 103 -104 bacteria suggested for V. parahaemolyticus.
Incubation period	May vary depending on species. Ranges from 4-96 hours but usually about 24 hours.
Symptoms	V. parahaemolyticus - Diarrhoea (sometimes bloody) and abdominal cramps in most cases, often with headache, nausea and vomiting. V. vulnificus-infection can present as sepsis or gastroenteritis.
Duration of illness	Usually 1-7 days (median 3 days).
Infectious period	N/A- not normally communicable from person-to-person.
Laboratory diagnosis	Cultured from stool samples if requested or clinical details/history indicate e.g. foreign travel. Some laboratories offer stool testing by PCR. Isolates can be sent to the Gastrointestinal Bacteria Reference Unit (GBRU) at UKHSA Colindale for confirmation/further typing if required.
Food & water testing	Testing is not currently carried out by Public Analyst Laboratories in Scotland, and it will be necessary to seek advice on testing services.
Specific control measures	Standard control measures apply.
Exclusions:	Cases: Until 48 hours after diarrhoea and/or vomiting have ceased. Contacts: Not required.

Pathogen	**Yersinia entercolitica**
Microbiology	Gram-negative, facultatively anaerobic, non-spore-forming rod. Y. entercolitica causes yersiniosis in humans; in rare instances yersiniosis can also be caused by Y. pseudotuberculosis.
Temperature range/pH	Cold tolerant. Temperatures for growth are estimated to range from below 0°C up to 44°C (optimum 25-37°C) and pH 4 - 10.
Reservoir/source	Many animals but pathogenic strains are most frequently isolated from pigs.
Mode of transmission and commonly associated foods	Faecal-oral transmission through consumption of contaminated food or water. Particular association with raw/undercooked pork or pork products.
Infectious dose	Estimated to be between 104 - 106
Incubation period	Ranges from 1-11 days but typically 3-7 days.
Symptoms	May be asymptomatic. Typical symptoms include acute diarrhoea with abdominal pain and fever, which are usually self-limiting. Nausea/vomiting and mesenteric adentitis can also occur. Occasionally, cases may present with pharyngitis, an appendicitis-like syndrome (pseudoapendicitis) typically in children or septicaemia, particularly in the elderly and immunosuppressed. Post infective syndromes with reactive arthritis or erythema nodosum can occur.
Duration of illness	Ranges from 1-3 weeks for acute infection. Post infective syndromes will last longer.
Infectious period	Secondary spread is uncommon. Excretion typically lasts for up to two weeks but can occur for extended periods (up to three months, particularly in children), especially if untreated.
Laboratory diagnosis	Usually only cultured from stool samples on request or if clinically suspected (e.g. enterocolitis or mesenteric adenitis). Some laboratories offer stool PCR. Can occasionally be isolated from blood or other normally sterile sites. Isolates can be sent to UKHSA Gastrointestinal bacteria reference unit (GBRU) for molecular typing.
Food & water testing	Testing is not currently carried out by Public Analyst Laboratories in Scotland. Please discuss with local Public Analyst laboratory as testing may be carried out at UKHSA Colindale or other specialist laboratories.
Specific control measures	Standard control measures apply.
Exclusions:	Cases: Until 48 hours after diarrhoea and/or vomiting have ceased. Contacts: Not required.

6.2 Supporting information for toxin and chemical incidents

6.2.1 Background

Due to the variable nature of contamination risks associated with chemicals and toxins, it is not possible to define a set of standard control measures, as has been presented for foodborne pathogens. However, specific control measures for each chemical or toxin are listed in the relevant tables. Causative agents were selected based on the potential to cause acute toxicity and hence could present as a chemical or toxin related foodborne outbreak.

The causative agent specific tables in Section 6.2.2 can be used to support investigation and management of foodborne incidents involving toxins or chemicals. It should be noted that information on toxin-producing bacteria is included in the pathogen tables in Section 6.1.3.

See Appendix 4 for details of guidance development methodology, and key references used.

6.2.2 Information on specific chemicals/toxins

General toxicological risk guidance

Chemical contaminants in food may present a wide range of acute or chronic risks. While incidents caused by acute chemical risks are rarer than for microbiological risks, there may be occasional incidences of such cases.

Examples of specific known common chemical hazards which have been historically linked to incidents globally and which may be relevant to the UK are listed below. However, this list is not exhaustive of the many additional chemical hazards which may be present in food.

Toxbase may be used to provide further information in the case of suspected chemical poisoning incidents.

Chemical/ Toxin	**Amatoxins (Mushroom poisoning)** **Approximately 90% of deaths associated with mushroom poisoning are due to amatoxins**
Source	Amatoxins largely arise in the Amanita mushroom species; most commonly A. phalloides and A. virosa, which grow in the UK. A number of species of the genera Galerina and Lepiota also contain amatoxins, but are considered to be less common in the UK.
Associated foods	Poisonous mushrooms. 95% of mushroom deaths worldwide are due to amatoxin containing mushrooms. Amatoxin is heat stable and therefore it remains toxic whether mushrooms are eaten cooked or raw.
Incubation period	8 – 24 hours.
Symptoms	Abdominal pain, nausea, vomiting and diarrhoea, often followed by a period of convalescence (approximately 24 hours) where the case appears to improve. Central nervous system (CNS) symptoms, such as altered mental status or seizures, have been reported. Acute liver failure/fulminant hepatitis precede multi-organ failure, disseminated intravascular coagulation, seizures and death, which may occur 1-3 weeks after ingestion. Mortality is considered to range from 10-90%.
Duration of illness	Typically ranges from 1 – 30 days.
Clinical diagnosis	Diagnosis is typically based on onset of symptoms following ingestion of associated foods.
Food & water testing	Testing of remaining mushroom material or visual identification of toxic mushroom may provide further confirmation. There are currently no legal food safety limits for amatoxins. Public Analyst laboratories should be consulted when testing of food and water is required to support investigations.
Specific control measures	Nothing additional to providing advice on caution when foraging for mushrooms. Advice for foraging can be found on the FSA website.

Chemical/ Toxin	**Glycoalkaloids (Chaconine & Solanine)**
Source	Naturally found in plants of the Solanaceae (Nightshade) family. Can occur in any part of a plant including leaves, fruit and tubers.
Associated foods	High levels are most commonly associated with green or sprouting potatoes.
Incubation period	Approximately 30 minutes – 12 hours.
Symptoms	Low level intake may result in vomiting, diarrhoea, fatigue, muscle weakness, low blood pressure, drowsiness, confusion and headache. Ingestion of higher doses may lead to severe neurological symptoms, cardiac failure, coma and in extreme cases result in death.
Clinical diagnosis	Diagnosis is typically based on onset of symptoms following ingestion of associated foods.
Food & water testing	There are currently no legal food safety limits for glycoalkaloids. Public Analyst laboratories should be consulted when testing of food and water is required to support investigations
Specific control measures	Appropriate post-harvest techniques for limiting accumulation are necessary, particularly when potatoes are stored for extended periods of time under light and high temperature. When processing, the peel and green parts must be removed, as far as possible.

Chemical/ Toxin	**Mycotoxins**
Source	Naturally occurring chemicals produced by certain moulds, particularly Aspergillus and Fusarium species. Those considered to be of most concern from a food safety perspective include: Aflatoxins (B1, B2, G1, G and M1), Ochratoxin A, Patulin toxins including Fumonisins (B1, B2 and B3), Trichothecenes (principally nivalenol, deoxynivalenol, T-2 and HT-2 toxin), Zearalenone, Ergot Alkaloids, Citrinin, Sterigmatocystin and Alternaria toxins. N.B. Significant exposure to mycotoxins is considered to occur extremely rarely in the UK due to implementation of effective control measures.
Associated foods	Mycotoxin producing moulds can grow in a variety of foodstuffs including cereals, nuts, spices, dried fruits, fruit juice and coffee, which are typically subject to warm and humid conditions.
Incubation Period	Varies.
Symptoms	Symptoms vary depending on mycotoxin type and level/duration of exposure. In particular, acute exposure to high levels of aflatoxins can lead to aflatoxicosis (acute hepatic necrosis, bile duct proliferation, oedema, lethargy and rarely, death). Various long-term health problems are associated with chronic exposure, including the development of a number of cancers, kidney & liver damage, as well as digestive & reproductive system problems.
Clinical diagnosis	Diagnosis is typically based on onset of symptoms following ingestion of associated foods. However, diagnosis may be confirmed by identification of species in epidemiologically-linked foods (see below).
Food & water testing	Analysis of some mycotoxins in food can be commissioned through the Public Analyst laboratory. The legal food safety criteria for mycotoxins in food are described in Regulation 1881/2006. For sampling see FSA Mycotoxins Sampling Guidance, 2016
Specific control measures	Mycotoxins are naturally occurring; therefore presence in food cannot be completely avoided. Controls range from ensuring that good practice is undertaken during growing, harvesting and storage of foods, in addition to establishing maximum levels where necessary (there are strict limits in place for aflatoxins, ochratoxin A and patulin toxins in certain foodstuffs in the UK).

Chemical/ Toxin	**Shellfish poisoning (marine biotoxins): Okadaic Acid (Diarrhetic Shellfish Poisoning (DSP))**
Source	The above toxin is produced by phytoplankton (primarily dinoflagellates) and known to accumulate in certain shellfish.
Associated foods	Shellfish and occasionally fish.
Incubation period	Typically within 30 minutes to 12 hours.
Symptoms	Symptoms vary depending on which biotoxin has been ingested. All shellfish poisoning may cause abdominal pain, diarrhoea, nausea and vomiting. In addition, DSP may cause headache and fever,
Clinical diagnosis	Diagnosis is typically based on onset of symptoms following ingestion of associated foods.
Food & water testing	There is a legal requirement for food business operators (FBOs) to ensure that shellfish are harvested from classified waters and comply with the biotoxin standards in Annex III of Regulation 853/2004 before being placed on the market. The FSS Official Control Monitoring Programme samples shellfish flesh from fixed monitoring points within inshore classified harvesting areas and additional sampling is conducted at commercial processors of wild pectinidae (scallops), which have been harvested from unclassified offshore waters, for toxins responsible for shellfish poisoning. FSS also carry out a programme of phytoplankton sampling in a selection of classified areas over the summer months. This is used as an indicator test for biotoxin levels. Flesh samples are sent to the Centre for Environment, Fisheries and Aquaculture Science (Cefas) for biotoxin testing. Phytoplankton samples are analysed by Scottish Association for Marine Science (SAMS). FSS can provide advice on the provision of testing services for the investigation of outbreaks involving shellfish biotoxins.
Specific control measures	When legal regulatory limits of toxins in shellfish are breached, FSS and LA take action to ensure the affected areas are closed to harvesting and any affected product is recalled from the market, as necessary. Shellfish can only be placed on the market if appropriate food safety controls have been applied. For the majority of shellfish including mussels and oysters, this means that they must be sourced from a classified production area which has been monitored for marine biotoxins. Scallops (which are harvested outwith classified areas) are either placed on the market whole or shucked (to remove the digestive tissues which are known to accumulate the toxins). Both whole and shucked scallops are also subjected to checks to ensure their safety before placing on the market. Gathering of shellfish by consumers can present an increased risk as none of the above controls will have been applied.

Chemical/ Toxin	**Shellfish poisoning (marine biotoxins): Saxitoxin (Paralytic Shellfish Poisoning (PSP))**
Source	The above toxin is produced by phytoplankton (primarily dinoflagellates) and are known to accumulate in certain shellfish.
Associated foods	Shellfish and occasionally fish.
Incubation period	Typically within 30 minutes but can be up to 4 hours.
Symptoms	Symptoms vary depending on which biotoxin has been ingested. All shellfish poisoning may cause abdominal pain, diarrhoea, nausea and vomiting. In addition, PSP may cause headache, tingling of face, tongue and lips, numbness of extremities, weakness and dizziness. In severe cases PSP may result in death.
Clinical diagnosis	Diagnosis is typically based on onset of symptoms following ingestion of associated foods.
Food & water testing	There is a legal requirement for food business operators (FBOs) to ensure that shellfish are harvested from classified waters and comply with the biotoxin standards in Annex III of Regulation 853/2004 before being placed on the market. The FSS Official Control Monitoring Programme samples shellfish flesh from fixed monitoring points within inshore classified harvesting areas and additional sampling is conducted at commercial processors of wild pectinidae (scallops), which have been harvested from unclassified offshore waters, for toxins responsible for shellfish poisoning. FSS also carry out a programme of phytoplankton sampling in a selection of classified areas over the summer months. This is used as an indicator test for biotoxin levels. Flesh samples are sent to the Centre for Environment, Fisheries and Aquaculture Science (Cefas) for biotoxin testing. Phytoplankton samples are analysed by Scottish Association for Marine Science (SAMS). FSS can provide advice on the provision of testing services for the investigation of outbreaks involving shellfish biotoxins.
Specific control measures	When legal regulatory limits of toxins in shellfish are breached, FSS and LA take action to ensure the affected areas are closed to harvesting and any affected product is recalled from the market, as necessary. Shellfish can only be placed on the market if appropriate food safety controls have been applied. For the majority of shellfish including mussels and oysters, this means that they must be sourced from a classified production area which has been monitored for marine biotoxins. Scallops (which are harvested outwith classified areas) are either placed on the market whole or shucked (to remove the digestive tissues which are known to accumulate the toxins). Both whole and shucked scallops are also subjected to checks to ensure their safety before placing on the market. Gathering of shellfish by consumers can present an increased risk as none of the above controls will have been applied.

Chemical/ Toxin	**Shellfish poisoning (marine biotoxins)** **Azaspiracids (Azaspiracid Shellfish Poisoning (AZP))**
Source	The above toxins are produced by phytoplankton (primarily dinoflagellates) and are known to accumulate in certain shellfish.
Associated foods	Shellfish and occasionally fish.
Incubation period	AZP - Typically within a few hours.
Symptoms	Shellfish poisoning may cause abdominal pain, diarrhoea, nausea and vomiting.
Clinical diagnosis	Diagnosis is typically based on onset of symptoms following ingestion of associated foods.
Food & water testing	There is a legal requirement for food business operators (FBOs) to ensure that shellfish are harvested from classified waters and comply with the biotoxin standards in Annex III of Regulation 853/2004 before being placed on the market The FSS Official Control Monitoring Programme samples shellfish flesh from fixed monitoring points within inshore classified harvesting areas and additional sampling is conducted at commercial processors of wild pectinidae (scallops), which have been harvested from unclassified offshore waters, for toxins responsible for shellfish poisoning. FSS also carry out a programme of phytoplankton sampling in a selection of classified areas over the summer months. This is used as an indicator test for biotoxin levels. Flesh samples are sent to the Centre for Environment, Fisheries and Aquaculture Science (Cefas) for biotoxin testing. Phytoplankton samples are analysed by Scottish Association for Marine Science (SAMS). FSS can provide advice on the provision of testing services for the investigation of outbreaks involving shellfish biotoxins.
Specific control measures	When legal regulatory limits of toxins in shellfish are breached, FSS and LA take action to ensure the affected areas are closed to harvesting and any affected product is recalled from the market, as necessary. Shellfish can only be placed on the market if appropriate food safety controls have been applied. For the majority of shellfish including mussels and oysters, this means that they must be sourced from a classified production area which has been monitored for marine biotoxins. Scallops (which are harvested outwith classified areas) are either placed on the market whole or shucked (to remove the digestive tissues which are known to accumulate the toxins). Both whole and shucked scallops are also subjected to checks to ensure their safety before placing on the market. Gathering of shellfish by consumers can present an increased risk as none of the above controls will have been applied.

6.3 FSS & LA responsibilities, legal obligations, and powers

6.3.1 Responsibilities

Food Standards Scotland (FSS) is responsible for policy development and advice to support the implementation legal food safety requirements and any additional national measures that are appropriate for the protection of public health or other consumer interests.

These requirements are laid down by Regulation (EU) 2017/625 which requires Competent Authorities (FSS and LAs) to have a framework for effective delivery of official controls to ensure compliance with food law. This includes requirements for the following:

- The designation of competent authorities and laboratories.
- Arrangements for coordination of control activities and audit functions.
- The training and qualification of authorised officers

These provisions are given effect in Scotland by The Official Feed and Food Control (Scotland) Regulations 2009 (as amended) and The Food Hygiene (Scotland) Regulations 2006 (as amended). Local Authority EH Professionals have responsibility for the delivery of 'official controls' at retailers, caterers, manufacturers, takeaways, butchers and stand-alone approved meat establishments (including cold stores, businesses involved in the re-wrapping of meat, and those which produce minced meat, meat preparations or mechanically separated meat). Official controls undertaken by FSS at abattoirs, cutting plants, and game handling establishments require specified inspections of all animals, carcasses and offal through risk-based audits to verify compliance with food law, and are aimed at safeguarding the health of the public, and the health and welfare of animals at slaughter.

FSS has issued a Code of Practice on behalf of Scottish Ministers which provides directions to Food Authorities on the execution and enforcement of Food Law, including the investigation of incidents and outbreaks of foodborne illness.

FSS has also produced a guide to Scottish Food and Feed Law which details all of the current food and feed law applicable in Scotland. This includes references to overarching UK Food Hygiene legislation and supporting guidance that is relevant to the investigation and enforcement action that is relevant to foodborne outbreaks.

6.3.2 Legal obligations and powers

Informing the general public of the nature of health risks

Article 10 of Regulation (EC) 178/2002 provides that where there are reasonable grounds to suspect that food may present a risk for public health, depending on the nature seriousness and extent of that risk, public authorities shall take steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible, the food, the risk it may present and the measures taken to prevent, reduce or eliminate that risk.

Section 3(1)(c) of the Food Scotland Act 2015 provides a general function that Food Standards Scotland keep the public adequately informed about and advised in relation to matters which significantly affect their capacity to make informed decisions about food matters.

Ensuring unsafe products are restricted or withdrawn from the market/ ensuring compliance with Food Hygiene Regulations

Article 14 (8) of Regulation (EC) 178/2002 provides that the competent authorities can take appropriate measures to impose restrictions on food being placed on the market or to require its withdrawal where there are reasons to suspect that the food is unsafe even if it is considered to comply with specific Community provisions governing food safety. The competent authorities for article 14 (8) are the Local Authority and Food Standards Scotland.

Article 14(6) provides that where any food which is unsafe is part of a batch, lot or consignment of food in the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe unless following detailed assessment of the rest of the batch etc. there is no evidence. The terms “batch, lot or consignment” are not defined in the Regulation so the normal rules of construction would apply and the words would be given their ordinary meaning. However, guidance can be found by referring to Article 2(e) of Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs, which defines batch as meaning:

> **“a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period”.**

Section 9 of the Food Safety Act 1990 provides that an authorised officer of a Food Authority may, by notice, detain and/or seize food which on inspection appears to fail to comply with food safety requirements. If not satisfied on receipt of additional information such as the results of microbiological samples, the officer shall seize the food and remove it to have it dealt with by a sheriff or a justice of the peace.

Similar powers of seizure and detention apply by virtue of Regulation 23 of The Food Hygiene (Scotland) Regulations 2006. Regulation 27 specifies that food which has not been produced, processed or distributed in accordance with the hygiene regulations shall be treated as failing to comply with food safety requirements. The relevant hygiene regulations are these domestic provisions plus EU Regulations 852,853, 854/2004 and 2073/2005.

Article 5 of Regulation (EC) No. 852/2004 provides that food business operators shall put in place, implement and maintain a permanent procedure based on HACCP principles including identifying hazards that must be prevented, eliminated or reduced to acceptable levels, identifying critical control points at the steps essential to prevent or eliminate these hazards and establish corrective actions and verify and document these controls. Regulation (EC) 2073/2005 provides that food business operators shall ensure compliance with relevant microbiological criteria set out in the Regulation throughout their shelf-life. Similar legislative end product standards exist for chemical contaminants in Regulation (EC) 1881/2006.

Article 5(4) of Regulation (EC) No. 852/2004 specifies that food business operators must provide the competent authorities with evidence of their compliance in a manner that the competent authority requires and must ensure that any documentation is kept up to date.

The LA is designated as the competent authority for verifying compliance with the relevant UK and Scottish Hygiene Regulations and powers (including the issuing of enforcement notices) and offences are contained within the Scottish Regulations for the majority of food businesses in Scotland, whilst FSS are so designated in some premises principally in the meat production sector. This includes approval of certain manufacturing establishments handling foods of animal origin.

Responsibility for coordinating and auditing implementation and enforcement of official controls in Scotland

The Food Scotland Act 2015 provides a general function that Food Standards Scotland (FSS) should monitor the performance of and promote best practice by enforcement authorities in enforcing food legislation. (Section 3(1)(e)).

The 2015 Act also provides that FSS may do anything it considers necessary or expedient for the purpose of its functions. (Section 16).

The 2015 Act also provides that FSS may determine standards of performance for enforcement authorities (section 23).

The 2015 Act also provides that FSS may issue guidance on control of food-borne disease to Scottish Ministers or other public bodies and office holders and to publish that guidance as it sees fit. Persons in receipt of such guidance must have due regard to it (section 30).

FSS is also responsible for monitoring the performance of enforcement authorities in enforcing relevant audit legislation which includes enforcement by LA of all food law by virtue of Regulation 7 of The Official Feed and Food Controls (Scotland) Regulations 2009. The function includes setting standards of performance in relation to the enforcement of relevant legislation. Scottish Ministers have powers to issue Codes of Practice to food authorities by virtue of both Regulation 6 of The Official Feed and Food Control (Scotland) Regulations 2009 and Section 40 of the Food Safety Act 1990. In both circumstances FSS may give a Food Authority a direction requiring them to take steps to comply with a Code and every Food Authority must have regard to the Code and comply with any direction given to them under the Code.

Appendix 1: Key contact details

NHS Health Boards
NHS Board Health Protection Team contact details can be found on the Public Health Scotland website:
https://publichealthscotland.scot/contact-us/general-enquiries/health-protection-team-contacts/

Public Health Scotland
Contact details for Public Health Scotland can be found at:
https://publichealthscotland.scot/contact-us/contacting-public-health-scotland/

Food Standards Scotland (FSS)
Contact details for FSS can be found at:
http://www.foodstandards.gov.scot/contact-us

FSS Food Incidents
Food incident management at Food Standards Scotland

Local Authorities
Contact details for Scottish Local Authorities can be found at:
http://www.foodstandards.gov.scot/contact-us/local-authorities

Public Analyst Laboratories

- Aberdeen Scientific Services Laboratory - Aberdeen City Council
- Edinburgh Scientific services - The City of Edinburgh Council
- Glasgow Scientific Services - Glasgow City Council
- Tayside Scientific Services - Dundee City Council

Clinical Microbiology and Reference Laboratories
Scottish Salmonella, Shigella and Clostridium difficile reference laboratory (SSSCDRL)

Scottish E. coli O157/STEC Reference Laboratory (SERL)

Gastrointestinal Bacteria Reference Unit (GBRU) is part of UKHSA labs, Colindale, London

Appendix 2: Contributors

Membership of the Guidance Development Group

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Appendix 3: Guidance consultation list

Public Health Scotland

Scottish Health Protection Network Guidance Group

Scottish Health Protection Network Gastrointestinal and Zoonoses Group

Scottish Health Protection Consultants

Health Protection Nurses Network

Scottish Microbiology and Virology Network

Scottish Public Analysts / Food Examiners

Society of Chief Officers of Environmental Health

Royal Environmental Health Institute for Scotland (REHIS)

Public Health England (UKHSA) National Infections Service

Public Health England (UKHSA) Food, Water & Environmental Laboratory services

Food Standards Agency

Food Standards Scotland

Scottish Food Enforcement Liaison Committee (SFELC)

Lead Food Officers, Scottish Local Authorities

Scottish Government, Food and Drink Policy team

Scottish Government, Health Protection Team

Scottish Government Resilience Room, Support Team

Appendix 4: Methods used for guidance development

Initial development of this document commenced in 2017 and was interrupted in 2020 due to the COVID-19 pandemic. During this initial period, the Guidance Development Group (GDG) met on a regular basis to discuss and draft relevant content. Any disagreement on content was approached by group discussion and informal consensus, with ultimate decision making by the co-chairs.

Foodborne pathogen tables

The GDG reviewed the following documents in 2017 to agree a list of pathogens for inclusion in this guidance.

- Investigation and Control of Outbreaks of Foodborne Disease in Scotland, 2006.
- Preventing person-to-person spread following GI infections: guidelines for public health physicians and environmental health officers, Health Protection Agency/Public Health Laboratory Service Advisory Committee, 2004.
- Management of outbreaks of foodborne illness in England & Wales, Food Standards Agency, 2008.
- Foodborne disease outbreaks guidance, World Health Organization, 2008.
- Infectious Intestinal Disease: Public Health & Clinical Guidance, Health Protection Surveillance Centre, 2012
- Communicable Diseases Manual, 20th Edition, 2014

The Information Tables for each of the selected pathogens are based on the aforementioned guidance documents, pathogen-specific guidance where available, and evidence gathered from targeted searches for relevant published literature.

In relation to peer reviewed published literature, in brief; Medline/Embase searches for ‘foodborne outbreak.mp’, 2006-December 2016, English Language, Human only, were undertaken as well as organism specific searches using the same methodology e.g. Bacillus cereus’ AND ‘outbreak’, filtered by English Language and Human. Where insufficient documents where identified, literature published prior to 2006 was reviewed and included. Review level literature was used where possible. Evidence tables for foodborne outbreak literature for each pathogen are not included in this guidance, but can be requested by contacting phs.shpn-admin@phs.scot.

In 2023, a rapid review of key guidance and literature from 2017 onwards was undertaken for each organism, using key word searches on Pubmed/Google.

Chemical contaminant/toxin tables

The GDG reviewed previous guidance along with available published literature to develop information tables on chemicals and toxins which have been associated with foodborne illness for inclusion in this guidance. Due to limited information published on these topics, the literature searched focussed on key word searches for identification of relevant guidance and peer reviewed published literature, spanning 2005 to 2023.

Additional references

The sections below provide lists of the key references used to develop the pathogen and toxin/chemical tables in sections 6.1.3 and 6.2.2.

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