Food Safety
AUTHORITY OF IRELAND

In collaboration with:

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hpsc

Management of Outbreaks of Foodborne Illness

(Revision 1)

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(Revision 1)

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Foreword

The *E. coli* O104 outbreak identified in Germany in May 2011 resulted in a total of 852 hemolytic-uremic syndrome (HUS) cases and 54 deaths. It was a stark reminder of the potential severity of disease associated with Verotoxigenic *E. coli* (VTEC) infections and the magnitude of outbreaks that can result from contamination of food produced and distributed on a large scale. As part of improving its response to dealing with the consequences of a microbiological hazard contaminating the food chain, a draft working document 'Management of Outbreaks of Foodborne Illness' was produced by a cross-agency, multidisciplinary steering group (facilitated jointly by the Food Safety Authority of Ireland (FSAI) and the Health Service Executive (HSE)) to provide guidance for the way outbreaks are managed in Ireland. A list of steering group members is included in **Appendix 1**.

The procedures in the protocol are intended to ensure prompt action to: recognise an outbreak of communicable disease, eliminate the source and stop further spread, prevent recurrence and ensure satisfactory communications between all concerned. In tandem with the launch of the protocol, the FSAI and the HSE organised an outbreak simulation exercise (Exercise Clea) to test it. The report following the exercise provided recommendations to better prepare Ireland's response to foodborne outbreaks and these recommendations were taken on board in the Outbreak Protocol.

The management of foodborne outbreaks demand a considerable amount of public resource and effort. We are always looking to improve the way we operate in order to better protect the consumer and deliver public value. This revision is designed to ensure that feedback from further training on the protocol in the form of regional training workshops is reflected and to ensure the protocol replicates best practice.

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Abbreviations

CIDR	Computerised Infectious Disease Reporting
DAFM	Department of Agriculture, Food and the Marine
EHO	Environmental Health Officer
FSAI	Food Safety Authority of Ireland
HACCP	Hazard Analysis Critical Control Point
HPSC	Health Protection Surveillance Centre
HSE	Health Service Executive
HUS	Hemolytic-uremic syndrome
IID	Infectious Intestinal Disease
OCT	Outbreak Control Team
PEHO	Principal Environmental Health Officer
PFGE	Pulse Field Gel Electrophoresis
SFPA	Sea-Fisheries Protection Authority
SPHM	Specialist in Public Health Medicine
VTEC	Verotoxigenic *E. coli*

Introduction

Food represents an important vehicle for pathogens of substantial public health significance. The investigation and control of foodborne illness outbreaks are multi-disciplinary tasks requiring skills in the area of public health, environmental health, clinical microbiology, food and veterinary microbiology, food safety, food control, risk assessment and management. The aim of this document is to describe the management of an outbreak of suspected foodborne illness and to provide a protocol for best practice for official agencies to manage outbreaks of infectious intestinal disease (IID) caused by ingestion of contaminated food[1].

The objectives of this guidance are to:

- Provide a practical resource for professionals involved in foodborne illness outbreak management
- Provide a standardised approach to the management of foodborne outbreaks in Ireland
- Provide a structure for outbreak preparedness at a local and national level
- Define the roles of those involved in an outbreak control team
- Provide a format for dissemination of lessons learned

Responsibility for the investigation of foodborne outbreaks follows from:

- Infectious Diseases Regulations, 1981 (S.I. No. 390 of 1981), as amended. An amendment to the Infectious Diseases Regulations 1981 (*Infectious Diseases (Amendment) (No. 3) Regulations, 2003 S.I. No. 707 of 2003*) established a revised list of notifiable diseases and introduced a requirement for laboratory directors to report infectious diseases
- Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents, to investigate foodborne outbreaks, transposed by European Communities (Monitoring of Zoonoses) Regulations, 2004 (S.I. No. 154 of 2004)
- Food Safety Authority of Ireland Act, 1998 as amended[2]

At national and regional levels, the document will assist decision-makers in identifying and coordinating resources and in creating an environment appropriate for the successful management of foodborne illness outbreaks.

[1] There are separate procedures in place for managing waterborne outbreaks and chemical contamination of food

[2] For list of food legislation see www.fsai.ie

Chapter 1. Surveillance

Foodborne illness is usually either infectious or toxic in nature, caused by agents that have been, or are likely to have been, transmitted by food. Foodborne illness may occur when a person consumes food contaminated with particular types of bacteria, viruses, parasites or toxins.

An essential part of any programme for the control of outbreaks of illness is the requirement for systematic surveillance, i.e. the collection, collation, analysis and dissemination of information, of indicator pathogens and diseases. Surveillance can be carried out at local, national and international level. Three sources of data are important in the surveillance of foodborne illness:

- The clinical and laboratory notification system of sporadic cases of IID
- The national outbreak notification system of IID and
- Food and human reference laboratory services

Detecting outbreaks requires efficient surveillance systems to capture and respond to information and data from a variety of sources. The primary goal of surveillance for foodborne illness outbreaks should be the prompt identification of clusters of disease potentially transmitted through food, which might require an investigation or response.

In circumstances where food might be a vehicle of disease transmission, a number of agencies will be involved. Most outbreaks are local and will be led by the Health Service Executive (HSE) in the location that identified the outbreak. Occasionally, in outbreaks that extend beyond more than one region, the Health Protection Surveillance Centre (HPSC) may be invited to lead the investigation. The HPSC will take the lead in national and international outbreaks.

The following is a brief *aide memoire* in determining, under varying circumstances, which agency among main agencies should adopt the lead role in infectious disease incidents involving food:

- The HSE will take the lead role in local outbreaks of foodborne illness (in the event of a cluster of confirmed or suspected human cases of illness)
- The HPSC will take the lead role in national or international outbreaks of foodborne illness, in the event of a cluster of confirmed or suspected human cases of illness)
- If the HPSC/HSE becomes aware of cases of human illness that may have been transmitted by food, it will liaise with the Food Safety Authority of Ireland (FSAI) (rapidalert@fsai.ie) at the earliest opportunity
- If the FSAI becomes aware of a food incident that may lead to human cases of illness, it will liaise with the HPSC/HSE at the earliest opportunity
- The FSAI will take the lead role in a large scale food incident inside or outside Ireland, where no human illness has been reported
- The FSAI will initially take the lead role in a food incident outside Ireland in which there are human cases of foodborne illness abroad, in liaison with the HPSC and/or the HSE

In the event of a national outbreak, the '*Inter-agency Protocol for the Management of a Food Crisis*' may also be relevant.

1.1 Definitions[3]

The terms "cluster" and "outbreak" are often used interchangeably despite the fact that they have very specific meanings.

A "**sporadic**" case is one that cannot be linked epidemiologically to other cases of the same illness.

A "**cluster**" is used to describe a group of cases linked by time or place, but with no identified common exposure or a series of isolates that appear to be linked based on a similarity on strain typing.

In the context of foodborne illness, "**outbreak**" refers to two or more linked cases of the same illness. Outbreaks have certain unique features: they may constitute a public health emergency; they are unpredictable; they can be alarming to the public; and they can be socially and economically disruptive. The importance of the concept of an outbreak having a common source is that this immediately suggests the potential for control.

[3] World Health Organization, 2008. Foodborne disease outbreaks: Guidelines for investigation and control.

Chapter 1. Surveillance

1.2 Outbreak Surveillance

Outbreaks of foodborne illness generally come to the attention of public health agencies in one of the following ways:

- Report of a cluster of illness among persons linked to an event or location, and/or clustered according to time, place, person:
  - Cluster of people of a similar age, e.g. group of elderly patients
  - Cluster of people exposed at a common location, e.g. wedding guests
  - Cluster of individuals dispersed geographically with similar symptoms, e.g. ate same food item produced by a single company
- Review of notification data shows an excess of cases of a particular illness clustered according to time, place, person, or sub-type of pathogen, e.g. a cluster of *S. Umbilo* in Galway, a cluster of *Shigella dysenteriae* in Dundalk
- Discovery of additional cases during routine investigation of an apparently sporadic case. This happens with a significant degree of regularity in the investigation of Verotoxigenic *E. coli* (VTEC) cases
- Report of an excess of human isolates of a particular sub-type of a pathogen by a clinical or human reference laboratory
- Report by clinicians of an increase in clinical cases

1.2.1 Notification process

S.I. No. 707 of 2003 lists the gastrointestinal/foodborne diseases which are considered of public health importance and which are required to be legally notified both by clinicians and laboratory directors (see **Appendix 2**). Relevant legislation stipulates that notification should be made by a medical practitioner "as soon as he/she becomes aware or suspects that a person on whom he is in professional attendance is suffering from or is the carrier of an infectious disease" (Infectious Diseases Regulations, 1981). Notification should be made by a clinical director of a diagnostic laboratory "as soon as an infectious disease is identified in that laboratory" (Infectious Diseases (Amendment) Regulations, 2003. S.I. No. 707 of 2003). Timely notification is required to ensure timely public health action.

In addition to the above, there is a requirement to give "immediate preliminary notification" to a medical officer of health in the case of certain specified notifiable diseases, e.g. VTEC, Cholera, Typhoid/Paratyphoid, Legionellosis and Meningococcal disease, or if there is a serious outbreak of infectious disease in the locality.

Individual notifications are assessed on receipt by appropriate staff in departments of public health to determine the clinical and public health significance of each notification, to determine what immediate investigative/control measures are required and to determine if the case (or cases) could be part of an outbreak that would require immediate public health action. Anonymised surveillance data are provided to the HPSC by the departments of public health for collation nationally.

COMPUTERISED INFECTIOUS DISEASE REPORTING (CIDR)

In all HSE-areas, data are maintained in the Computerised Infectious Disease Reporting (CIDR) database, a secure national integrated web-based real-time surveillance system accessible only to authorised public health personnel. Hospital laboratories are linked directly to the CIDR system and report their notifications electronically, while clinicians notify cases by conventional methods, e.g. post, fax, phone. An episode of disease for which there are one or more clinical and/or laboratory notifications for the patient, is recorded as an 'event' on CIDR, with the clinical and laboratory notification data electronically filed together for that event.

Where potentially linked events are identified, an outbreak is recorded on CIDR by public health personnel and the event-based information electronically linked on CIDR with aggregate information on the outbreak as a whole.

Chapter 1. Surveillance

Further laboratory typing may be sought to verify that the isolates for cases within a cluster are indistinguishable, supporting the likelihood that the cases are linked epidemiologically. Reference services provide crucial data for surveillance by confirming the isolate and by further characterisation of pathogens. Timely referral of human isolates of foodborne pathogens is essential to optimise the value of reference services in outbreak detection. For more details on both human and food reference laboratories, see **Appendix 3**.

1.2.2 Outbreak/Cluster reporting

Outbreaks generally come to attention when cases of illness are linked epidemiologically or microbiologically (see Section 1.2).

Under S.I. No. 707, *all outbreaks of disease are notifiable* regardless of whether the specific pathogen implicated is notifiable or not. Moreover, unusual clusters or changing patterns of illness are also notifiable. It is not necessary for a pathogen to have been identified before an outbreak is notified.

A protocol for the routine and rapid relay of complaints of gastroenteritis between the principal environmental health officer (PEHO) and specialist in public health medicine (SPHM) should be in place locally.

Each sporadic notification of a confirmed or presumptive case is investigated further, using a HPSC designated form/questionnaire (a-f below) as appropriate (see **Appendix 4**), by departments of public health/environmental health service.

(a) Generic IID

(b) Cryptosporidium (same form also used for Giardia)

(c) VTEC

(d) *Listeria*

(e) Typhoid

(f) Botulism

The HSPC intends to develop a full library of forms. In the meantime, locally developed forms are used for the following sporadic infections:

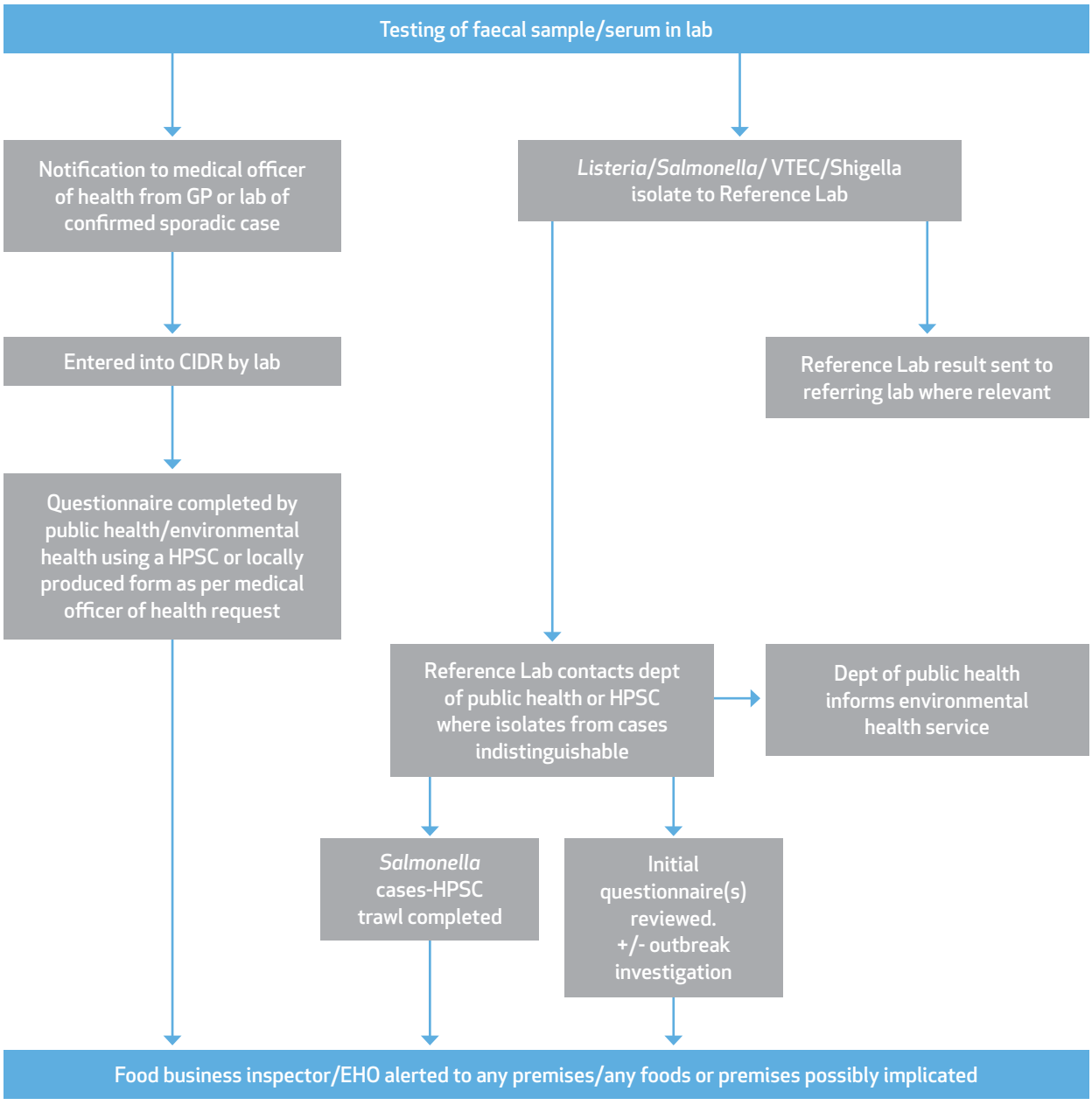
- *Bacillus cereus*
- *Campylobacter* (where relevant, as most *Campylobacter* are not followed by departments of public health/environmental health service up any longer)
- *Clostridium perfringens*
- Shigella
- *Staphylococcus aureus*
- Yersinia

Extensive trawling questionnaires have been developed for use in the case of *Salmonella*.

If reference laboratories (or laboratories carrying out reference function) identify clusters of pathogens, they will alert the relevant department of public health and, if more than one HSE region is involved, the HPSC will be alerted for further investigation. The department of public health will alert the environmental health service and, if more than one HSE region is involved, the HPSC will alert the Assistant National Director for Environmental Health.

Chapter 1. Surveillance

FIGURE 1: INFORMATION FLOW OF SPORADIC POSITIVE SAMPLE



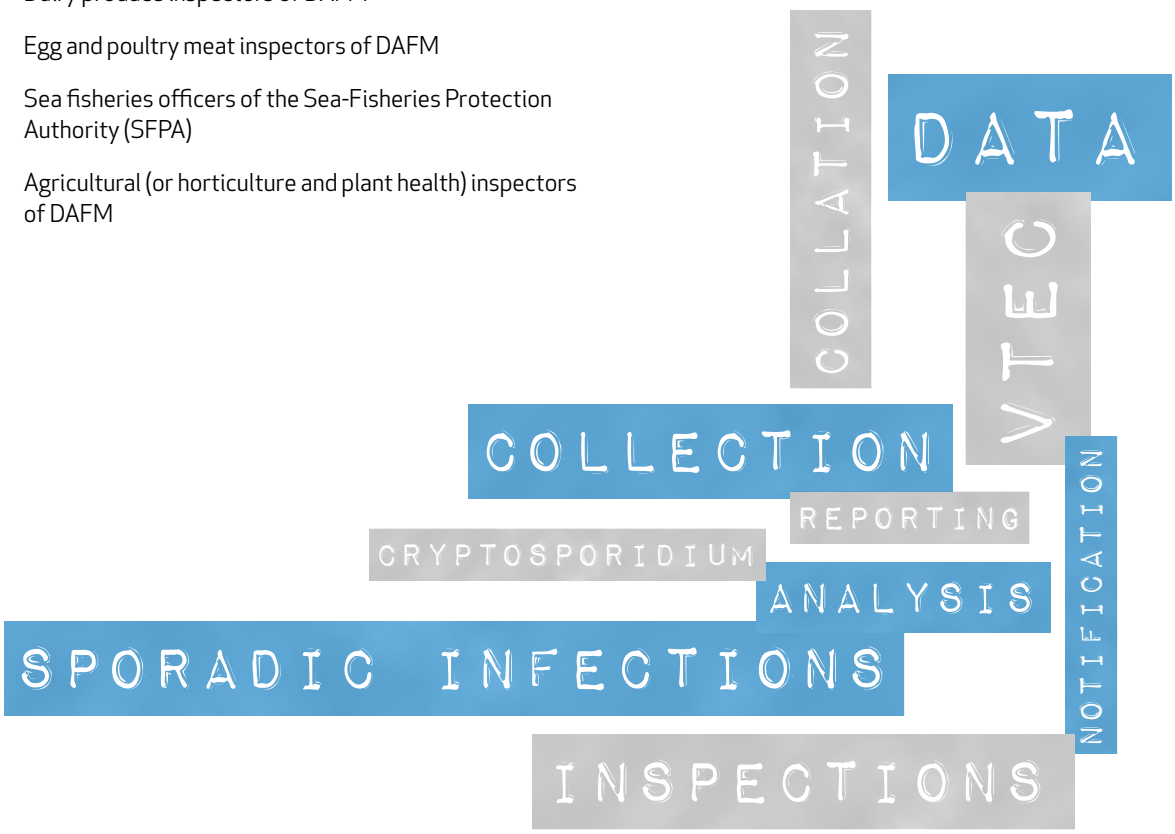
Chapter 1. Surveillance

1.3 Food and Animal Surveillance Data

Food control systems are designed to focus on preventative strategies, whereby food contamination is minimised or eliminated during production or preparation rather than trying to control the hazard when it has reached the market. Animal health surveillance provides early warning/ prompt detection of animal health and welfare problems, together with tracking and analysis of the way diseases spread. Communication between animal, food and clinical laboratories is essential to enable the detection of hazards so that systematic control and intervention strategies can be adopted quickly.

Official controls are organised along the food chain to assess compliance by food business operators with food law. Samples taken by enforcement officers are tested for microbiological parameters in official laboratories to determine compliance. In Ireland, a range of official agencies carry out official controls at different points along the food chain. Food samples are taken by:

- Environmental health service of the HSE
- Veterinary inspectors of the Department of Agriculture, Food and the Marine (DAFM) and the local authorities
- Dairy produce inspectors of DAFM
- Egg and poultry meat inspectors of DAFM
- Sea fisheries officers of the Sea-Fisheries Protection Authority (SFPA)
- Agricultural (or horticulture and plant health) inspectors of DAFM



Chapter 2. Organisational Arrangements

2.1 Introduction

Statutory responsibilities for identifying, managing and controlling outbreaks rest with a number of official agencies. The roles and responsibilities of these agencies and Government departments are outlined in **Appendix 5**.

2.2 Outbreak Control Arrangements

The purpose of an outbreak investigation is to stop the current outbreak, to determine how food contamination occurred, and to implement prevention–based approaches to minimise the risk for future outbreaks.

The objectives of a foodborne outbreak investigation are to:

- Determine that an outbreak actually exists
- Identify cases and population at risk
- Agree the types of investigations that need to take place and which agency is responsible
- Coordinate case finding and interviews
- Identify the aetiological agent and the implicated food(s)
- Identify the source of the contamination
- Implement necessary control measures
- Act as a central point of contact for collating and issuing information
- Inform and update official agencies
- Provide necessary briefing to official agencies, Governments departments, other professionals, media etc. as necessary
- Produce interim and final outbreak reports, incorporating lessons learned

2.2.1 Outbreak control plan

A local outbreak control plan based on this document should be drawn up if one does not already exist. It should be drawn up by a specialist in public health medicine, principal environmental health officer, consultant microbiologist and other key stakeholders. It should include:

- Key aspects of this document
- List of contact points within the HSE and with relevant official agencies, Government departments etc. This contact list should be reviewed annually
- A protocol for the routine and rapid relay of alleged food poisoning complaints between departments of public health and environmental health departments locally
- The Generic IID Investigation Form and other questionnaires as appropriate (see Section 1.2.2 & **Appendix 4**) http://www.hpsc.ie/A-Z/Gastroenteric/GastroenteritisorIID/InvestigationForm/
- Protocols for clinical sample taking, screening of food handlers etc (see www.hpsc.ie)

Chapter 2. Organisational Arrangements

2.2.2 Criteria for convening an outbreak control team

Once there is a **suspicion** that an outbreak may be occurring, a **scoping meeting** or teleconference should be convened to determine if there is a need to trigger an outbreak control team (OCT). In some cases where enough evidence is available, the scoping meeting may be a conversation or a telephone call prior to an OCT being convened. It is the responsibility of the medical officer of health, or a health officer on the advice of a medical officer of health, to call the scoping meeting which will involve at least some of the core members of an OCT outlined in Section 2.2.3 below. The responsibility for investigating foodborne illness outbreaks falls to a multidisciplinary OCT[4].

The criteria for convening an OCT will vary. An OCT may be considered when some or all of the following arise:

- Disease is important in terms of severity or propensity to spread
- Immediate health risk to the public
- There is the potential for an identifiable point source
- Widespread distribution of cases without obvious point source
- Public or political concerns

Usually, the HSE region that first identified the outbreak initiates the establishment of an OCT. A medical officer of health or a health officer, on the advice of a medical officer of health, shall agree to convene an OCT. A record should be made of the decision to convene an OCT. The specialist in public health medicine should inform the HPSC. The PEHO should contact the FSAI in respect of any foodborne or suspected foodborne outbreaks.

The **role of the OCT** is to agree and coordinate the activities of the agencies involved in the investigation and control of the outbreak.

2.2.3 Membership of the OCT

Each member of an OCT will contribute complementary and specific skills. The success of the OCT will depend on a strong working relationship and on-going, effective communication between its members. Membership of the OCT should be agreed and recorded at the first meeting. Additional team members may be needed subsequently depending on the scale/unique features of the outbreak (see Table 1). The OCT may invite colleagues and experts to join OCT meetings to advise on the investigation but the responsibility for decisions and actions rests with the core OCT. Any changes to the membership should be recorded. Core members and any other attendees should be clearly identified as such in all meeting minutes (other attendees should be recorded as being 'in attendance'). The core composition of the OCT investigating an outbreak will normally include:

- Specialist in public health medicine
- Principal environmental health officer
- Consultant clinical microbiologist
- Administrative support

A list of key contact points in the official agencies is provided in **Appendix 6**.

[4] In certain situations in health care facilities, the OCT will need to liaise with an infection control team.

Chapter 2. Organisational Arrangements

TABLE 1: LIST OF POTENTIAL ADDITIONAL OCT MEMBERS (NOT EXHAUSTIVE)

Medical officers
Environmental health officer
Microbiologist
HPSC representative
FSAI representative
Surveillance scientist
Toxicologist/Virologist
Legal adviser
Director of public health
Regional chief environmental health officer
Hospital clinician
General practitioner
Occupational health physician/Nurse
Public analyst
Press officer
Local authority veterinary inspector
DAFM veterinary or agriculture inspector
DAFM representative for food of non-animal origin
SFPA representative
Water authority representative
National Reference Laboratory representative
Representatives from other authorities/agencies, other technical experts, co-terminus areas etc. as necessary

2.2.4 OCT meetings

At its first meeting the team should agree the medical officer of health or a health officer on the advice of the medical officer of health, who will act as chairperson. In an outbreak that crosses administrative boundaries, the team should determine, at its first meeting, who is represented and who will act as chairperson. At the outset, the terms of reference and the members of the OCT should be clarified by the chair. Other attendees should also be recorded as being 'in attendance'. Sample terms of reference and a list of possible agenda items for the first outbreak control meeting are provided in **Appendix 7a**. Following introductions, urgent information should be requested by the chair. An agenda should be agreed and complied with. Only urgent information that could affect the direction of the OCT should interrupt the agenda of the meeting. All decisions and actions should be discussed, documented and circulated to OCT members.

For OCTs held by teleconference, there should be strict adherence to teleconference etiquette (see **Appendix 7b**). Consideration should also be given to:

- holding OCT meetings face-to-face and /or
- using a matrix/spreadsheet to collate and compare case details (**Appendix 7c**) and circulate this to attendees in advance of OCT meetings

2.2.5 Resources for the OCT

Part of preparing for an investigation of a foodborne illness outbreak is assembling the necessary people, resources/supplies and equipment to support the outbreak investigation. Sufficient resources will allow for more efficient progress. Having support personnel available ensures that phone calls can be answered and data can be entered quickly into databases etc. It is important that the HSE and other official agencies at regional level have procedures in place for routinely reviewing and replacing missing or outdated supplies and equipment. A list of the recommended resources that should be readily available is included in **Appendix 8**.

Chapter 2. Organisational Arrangements

2.2.6 OCT up-scaling

An apparently local outbreak may be the first indication of a much larger incident. If an outbreak affects multiple regions or is likely to exceed the resources or expertise of a particular agency, the local OCT should escalate the investigation and involve other agencies as soon as the need is suspected. This may require the establishment of a more extensive OCT. Among the circumstances in which the local OCT may require scaling up, are:

- Scale or complexity of outbreak seems likely to overwhelm agency resources
- Specific technical support is needed that requires expertise not available locally
- Investigation points to a commercially distributed product
- Outbreak is known or suspected to affect multiple regions
- Incidents with a potential international dimension

A larger scale OCT should include, as a core member, a specialist in public health medicine from the HPSC. In the case of national and international foodborne illness outbreaks, responsibility to chair the OCT falls to the HPSC. In addition, if the large scale outbreak has (or is suspected of having) food as a vehicle of transmission, a nominated representative from the FSAI should be included as a core member of the OCT.

Chapter 3. The Investigation and Control of an Outbreak

3.1 Overview

No one set of steps is appropriate for all outbreak investigations. The response varies with the outbreak and surrounding circumstances, e.g. aetiologic agent, number of cases and likely source of exposure. The response also varies depending on the agencies involved, available resources and the expertise of investigators. Where a decision is made to carry out a full investigation of an outbreak, irrespective of the scale, it will normally include epidemiological, environmental and laboratory investigations. This chapter considers the activities involved in investigating an outbreak of foodborne illness. The source of an infectious disease may not be apparent at first - it is essential to keep an open mind as to attribution from the outset. The possibility of waterborne, direct animal contact or person-to-person spread may require consideration, until the evidence supporting foodborne origin is clear.

3.2 Principles of Outbreak Management

(i) Communication

Effective communication is critical throughout the investigation of a foodborne illness outbreak. The OCT should develop a list of key personnel that may need to be contacted in the event of an outbreak (suggested list of stakeholders in **Appendix 9**). Together with cases and family/relatives/guardians, this should include:

- The OCT and involved agencies
- Relevant local and national agencies
- Relevant professionals
- The public
- The media
- Food industry representatives

Processes for communication should include the maintenance of routinely updated stakeholder lists and standard channels of communication so that each knows who to communicate with and where the information will come from during an outbreak. The specialist in public health medicine should inform the HPSC of any foodborne or suspected foodborne outbreaks and similarly, the environmental health service should inform the FSAI. The FSAI should contact other agencies including DAFM, local authorities or the SFPA as appropriate. Relevant contacts in Government departments should be kept informed by the HSE/HPSC and the FSAI as appropriate. The press offices of the HSE, FSAI and DAFM should be alerted by the relevant OCT representative as soon as possible. If it is decided that an advice-line is to be put in place, careful selection and full briefing of advice-line staff for dealing with calls from the public or food business operators of food outlets is important.

In addition, while a transparent public information strategy is recommended, unconfirmed information should not enter the public domain. The release of information identifying a particular suspect product or premises should be undertaken only when the benefit to public health justifies this action.

(ii) Records

The chairperson and secretariat of the OCT should create a log of daily actions including telephone conversations, emails, faxes, meetings etc. From the outset, all information received and all processes whereby any decisions were taken should be recorded reliably and appropriately and maintained in a master file by the chairperson. This means that:

- Individual members of the OCT keep records of all activities performed during the outbreak investigation
- Minutes, including most up-to-date decisions and actions, are kept and distributed
- Notes and other records collected during all environmental, epidemiological and laboratory investigations are maintained locally
- Copies are kept of all communications with the public (including letters, fact sheets, public notices and media reports)

Consideration should be given to potential 'Freedom of Information' requests.

Chapter 3. The Investigation and Control of an Outbreak

(iii) Confidentiality within the OCT

All OCT members must treat information relating to outbreaks with an appropriate level of confidentiality and should be allowed to have access to any information of potential relevance to the outbreak under investigation. Although priority is given to efficient communication and the sharing of relevant information during outbreaks, patient confidentiality must be safeguarded.

3.3 Outbreak Management

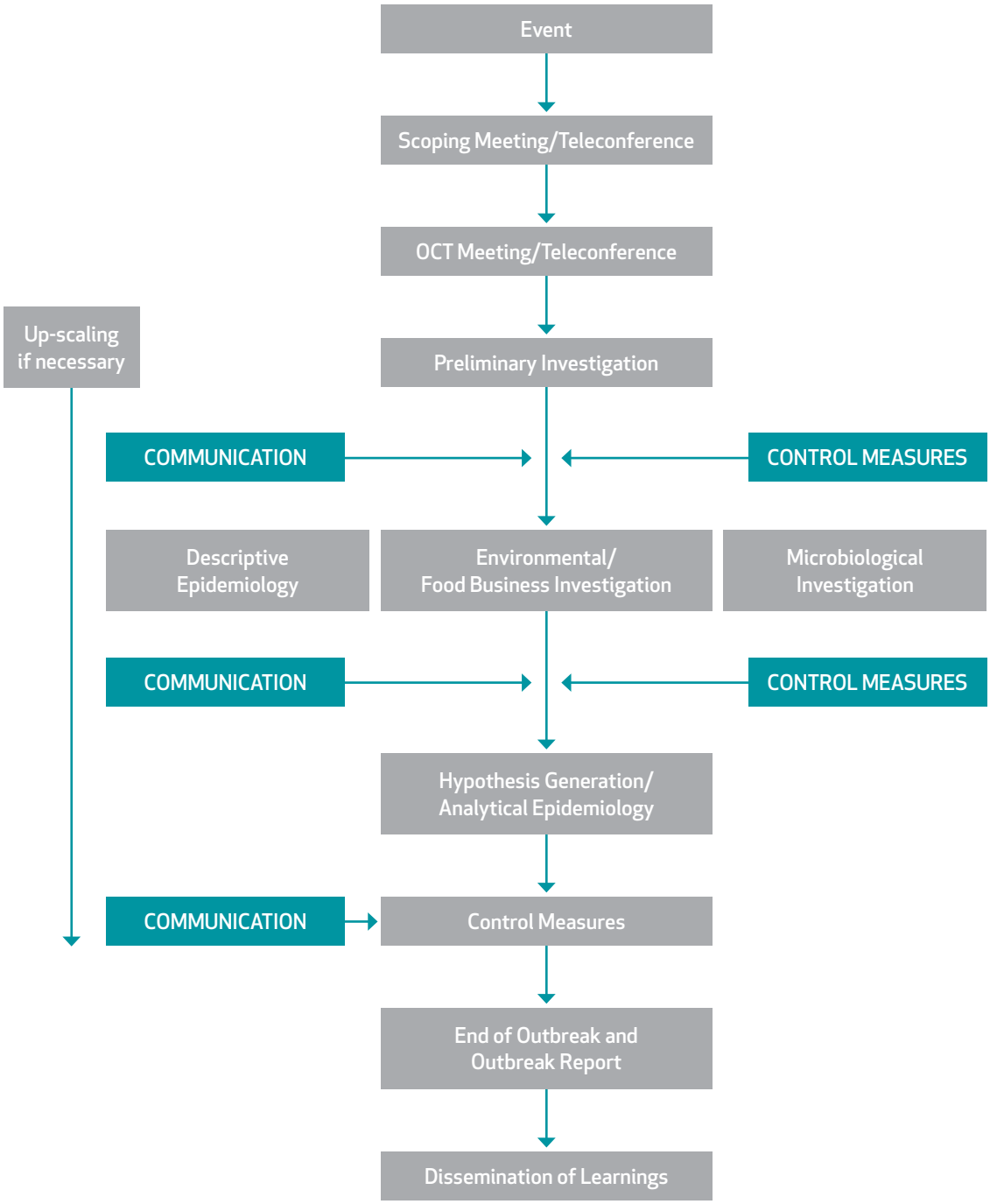
While the approach to the investigation and control of an outbreak is likely to vary depending on the circumstances, the following approach is designed to assist in systematically managing the outbreak. Some activities can take place concurrently, while others must wait for the results of earlier activities. Furthermore, some activities such as communication or implementation of control measures may often occur repeatedly throughout the investigation.

Most/all of the following activities may be included in outbreak management (see Figure 2):

1. Preliminary investigation
2. Descriptive epidemiology
3. Food business investigation
4. Microbiological investigation
5. Hypothesis generation (analytical epidemiology)
6. Implementation of control measures
7. Communication
8. End of outbreak and report
9. Dissemination of learning

Chapter 3. The Investigation and Control of an Outbreak

FIGURE 2: MANAGEMENT OF OUTBREAKS OF FOODBORNE ILLNESS



Chapter 3. The Investigation and Control of an Outbreak

1. Preliminary Investigation

The preliminary investigation has one overriding aim, i.e. to determine "*Does this event constitute an outbreak?*" This will be done by determining if:

- The number of cases is higher than expected
- The cases that have been initially uncovered are epidemiologically linked, e.g. did they attend the same wedding/restaurant, did they eat the same food, are they clustered in time, place and person? Are there initial pointers that these individuals may have undergone a common experience or exposure?
- Outbreak is still on-going

This assessment must be initiated quickly and completed promptly in order to try to prevent further illnesses. It should include:

- Checking the validity of the information
- Obtaining reports of relevant laboratory tests if available
- Identifying cases and obtaining relevant information
- Ensuring the collection of appropriate clinical specimens and food samples

Outbreak title and code

The title of an outbreak and an outbreak code for specimens should be agreed by public health, environmental health and the relevant laboratories. Both should be included in the headings on all correspondence.

Initial case interviews

An initial trawl of a small number of cases (perhaps as few as 5-10 cases) should be undertaken using the relevant questionnaire to generate a hypothesis as soon as possible.

The official agency should commence interviews with a generic questionnaire if the agent is unknown, then a specific questionnaire for the organism if it is known, then use an IID or more tailored questionnaire after that (see **Appendix 4**). Basic information can be gathered on all cases and then an outbreak specific questionnaire can be applied once a hypothesis is developed, rather than taking detailed histories pre-hypothesis. This critical step helps to provide a clearer picture of the clinical and epidemiological features of the affected cases. The interviews should include the completion of the IID Investigation Form which incorporates:

- Demographic details, including occupation and contact telephone number
- Clinical details, including date of onset, duration and severity of symptoms
- Visits to health care providers/hospitals
- Laboratory test results
- Contact with other ill persons
- Food consumption history over previous five days[5]
- Knowledge of others with the same or a similar illness
- Potential common exposures among those who have the same/similar illness
- Date of exposure to suspected foods

http://www.hpsc.ie/A-Z/Gastroenteric/GastroenteritisorIID/InvestigationForm/

Case definition

The function of a case definition is to determine which ill individuals are cases and which are not. A case definition is a set of criteria for determining whether a person should be classified as being affected by the outbreak illness under investigation and whether they are part of the outbreak. It is an epidemiological tool intended for correctly including and counting cases. A case definition should be simple and its development based on three core components:

- **Clinical and laboratory criteria** to assess whether a person has the illness in question; the clinical features chosen should be characteristic of the illness
- **A defined period of time** during which cases of illness are considered to have been exposed to and to have become ill with, the outbreak pathogen
- **Restriction by 'place'** to determine where possible exposure occurred, e.g. limiting to those who ate in a particular restaurant, attended a particular wedding, work in a particular factory or who reside in a particular town

  or

  Restriction by 'person' characteristics to determine which group or population of people were exposed to the pathogen in question, e.g. limiting the group to those over 65 years if the source of the outbreak might be a food supplier of nursing homes; limiting to babies in the case of suspected infant formula contamination

[5] For certain pathogens with longer incubation periods, it may be necessary to go back further than five days.

Chapter 3. The Investigation and Control of an Outbreak

CASE DEFINITION EXAMPLE

A case is defined as any person:

- Having diarrhoea*
- With a date of onset on or after Sat 1st Jan, 2014
- Who ate at Restaurant X between 09.00hrs on Mon 27th Dec 2013 and 24.00hrs on Friday 31st Dec 2013

**Three or more loose bowel motions/24hrs and of such consistency that they would take up the shape of any container into which they were poured.*

The initial case definition should be designed to include all those who could reasonably be expected to have been exposed to the pathogen or source in question and hence to be part of the outbreak. It may be based on clinical symptoms or laboratory results or both. Case definitions are not fixed and may be amended as further information comes to hand about the mechanism, transmission routes and exposures associated with the outbreak.

Definitions can be categorised as being 'confirmed', 'probable' and 'possible' cases. 'Confirmed' cases have a positive laboratory result; 'probable' cases have the typical clinical features of the illness but without laboratory confirmation and/or an epidemiological link to 'confirmed' cases; 'possible' cases have fewer or atypical clinical features.

When an OCT is preparing briefing papers or press releases, particular care should be taken in determining what is referred to as a 'case'. The press and public are likely to assume that all cases are confirmed cases. The refinement of unconfirmed cases into 'probable' and 'possible' may be of value to the OCT, but such specificity is seldom of help in briefing papers and press releases.

Questionnaires

Questionnaires (see **Appendix 4**) should be completed by environmental health service staff or department of public health staff as agreed within the HSE. Where a pathogen is known and a specific questionnaire is available, then this should be used.

Systematic case interviews

Once the case definition has been applied and the outbreak cases are identified, information about them should be obtained in a systematic way by use of standard questionnaires. If the pathogen is identified during the early stage of the investigation, a pathogen-specific questionnaire should be completed. If the pathogen has not been identified, then the IID Investigation Form should be completed (see **Appendix 4**). Alternatively, it is often possible to design an outbreak-specific questionnaire depending on the circumstance of the outbreak, e.g. guests at a wedding who may have had their food consumption dictated by a specific menu.

The use of standardised forms for collecting exposure histories ensures that pertinent information is collected in a systematic and uniform way from all cases. In addition, use of standardised "core" questions, i.e. questions that use the same wording for collecting information about certain exposures, and data elements, e.g. same variable names and attributes, will enhance data sharing and comparisons of exposures across regions. A detailed history of the illness and the time and place of all food and drink consumed over at least the preceding five days should be taken from cases and suspected cases in an effort to identify possible common factors.

Probing questions should be used to try to ensure the fullest information. Interviewees can be encouraged to remember information by asking them to elaborate on where they ate, with whom they ate and events associated with the meals. Referring to a calendar from the appropriate time periods might help to jog memories. Occasionally, two food items confound a foodborne outbreak when only one is truly a source of infection, e.g. ham and turkey served at the same meal. One way of getting around this is to try to calculate a dose response. This will require questions that are designed to capture the actual amount of a food item eaten, i.e. half a serving or a double-serving or went up for 'seconds'. This should be considered at an early stage in questionnaire

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development as it is very difficult to go back and re-interview cases and non-cases at a later stage. The quality of information gained is of utmost importance. Information about suspected food items or working hypotheses must not be shared with interviewees.

It should be agreed between the relevant services at local level whose responsibility it is to complete this questionnaire and this should be incorporated into the local plan. In addition, if an investigation into a premises or event, e.g. a wedding meal, has commenced in an area but an ill person has returned home to another HSE region, questionnaires should be completed by the region where the investigation is on-going (unless otherwise agreed). The area investigating should agree with the area in which the ill person resides if any sampling needs to be completed and whose role it is.

Specimen collection

Prior to any specimen collection, communication with the relevant laboratory should occur to agree: the urgency of the samples; the expected sample number; the expected delivery time; the test scope; the appropriate sample size; and containers and the outbreak code. Arrangements should be made locally to obtain appropriate specimens from the cases if this has not already been done (see Section 4 Microbiological Investigation). It should be agreed between the relevant services at local level whose responsibility it is to collect samples. This should be carried out in conjunction with the case interviews if possible. In investigating foodborne outbreaks, it is rarely necessary to microbiologically confirm every case; probable cases (those with a consistent clinical picture and an epidemiological link) can provide sufficient information for analysis purposes. If an outbreak pathogen is identified, subsequent cases for which microbiological confirmation is sought will generally only be tested for the outbreak pathogen and not the full suite of pathogens that would be sought in the case of a sporadic case.

Food premises

As soon as there is reasonable suspicion that a food premises is involved in an outbreak, then an inspection of the suspect premises should be made as soon as possible. Details of the investigation at the food business are outlined in Section 3 Food Business Investigation.

Preliminary hypothesis

From the information gathered from case interviews, the laboratory results and the initial inspection of the suspected premises, it may be possible to form a working hypothesis about the contributing factors and the source of the outbreak and the degree of risk to public health.

Early control measures

The purpose of putting in place early control measures is to reduce the risk of further cases. In addition, they can help to identify possible sources of infection and to stop distribution of suspected food or vehicle (see Section 6 Implementation of Control Measures).

2. Descriptive Epidemiology

The main purpose of the initial epidemiological investigation is to describe the situation in terms of person, place and time. The function of descriptive epidemiology is two-fold: (1) to begin the process of determining if the known cases had a common exposure and (2) to provide a hypothesis which will form the basis of continuing investigation and also to provide a hypothesis to examine using an analytical design if this approach is felt to be necessary. Often, descriptive epidemiology in combination with the results of microbiological and environmental investigations, will be sufficient to find the source of an outbreak. However, if such support is lacking, or important questions remain unanswered, further studies may be needed. Analytical epidemiological studies are then used to test the hypothesis. When considering analytical studies, epidemiological advice is available from the HPSC.

The steps of descriptive epidemiology include:

(a) Case definition

The case definition should be reviewed and should include time, place and person (see Section 1 Preliminary Investigation).

(b) Identify population at risk

Obtain records, e.g. list of guests at a function, employees in a workplace, residents in an institution or school register.

- Ask cases about any other persons whom they know may have been exposed to the same risk factor.
- Assess the geographical spread of the suspected exposure factor, e.g. distribution of food.

(c) Case finding

Examine routine surveillance data (notifications and laboratory reports). Consideration may need to be given to one or more of the following:

- Contact GPs, laboratories, clinicians, hospitals, e.g. casualty, pharmacies
- Contact guests from lists at functions, weddings, christenings etc.
- Other records, e.g. school registers or record or absence from work due to sickness
- Media alert to the public - helpline

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- National/International alert (if suspected contaminated product was distributed elsewhere and determine if cases have arisen in the distribution catchment; this may well be outside a region or even outside Ireland)

(d) Descriptive data collection

- Results of general questionnaire should be collated.
- Once the isolate is typed, a more detailed microorganism specific questionnaire may be designed and utilised.
- Use either direct or telephone interview (or self-administered questionnaire, if appropriate).

(e) Descriptive data analysis

Information from individual cases should be collated either manually or using a computer software package. The main outputs from the data collected are that the outbreak can be described in terms of age, symptoms, severity and other descriptive variables.

TIME

- Epidemic curve is drawn – the shape of the curve can indicate the magnitude of the outbreak, whether it is a point source or if there is on-going exposure.

PLACE

- If a common event or function is not involved, plot cases on a map. A GIS system is useful for this.
- Refine and develop the hypothesis to be tested.

PERSON

- Refine the case definition.
- Describe cases by time, place and person.
- The range of incubation periods and symptoms may indicate which pathogen is involved (see **Appendix 10**).

(f) Describe outbreak

- How many cases, how many hospitalised, how many deaths?
- Is the illness serious or life-threatening?
- Are cases still occurring?
- Is more than one location involved?
- Are there any secondary cases?
- Is there a potential for recurrence of the problem?

It is crucial that all clinical and public health information relevant to the outbreak investigation is shared fully among OCT members.

3. Food Business Investigation

The primary objective of the environmental investigation is to determine what specific factors may have contributed to the outbreak, whether related to structural/operational hygiene, foodstuffs, water supply or staff illness. This investigation is undertaken by the agency responsible for the supervision of the premises and appropriate controls applied as required.

As soon as a premises is suspected to be implicated in an outbreak situation, it is important that a site visit is made unannounced. This may have to be done outside office hours. It is recommended that more than one authorised officer should be involved in the inspection. A review of the food business file should take place prior to the inspection. If necessary, make appropriate arrangements with laboratories so that food/water and/or environmental samples can be taken. It is important that any evidence is secured and that foods which may be implicated are not destroyed or discarded. It is important that the food business operator (the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business) is briefed on the investigation and his/her co-operation is elicited. It is important that all food handlers on the premises are interviewed in detail and contact details of all staff obtained to ensure that all can be contacted if necessary. Emphasise to staff the importance of giving honest information especially in relation to illness and symptoms that they or their colleagues may have experienced. It may be necessary to further verify this information. Clear communication with the food business operators/managers of food businesses suspected of being implicated in an outbreak is essential. Any control measures that are to be immediately initiated should be clearly outlined where possible verbally and then in writing to the food business operator. It is also crucial that the investigating officers be fully updated on all available information concerning the outbreak. Contact with OCT members should be maintained during the inspection as additional information may come to light. In particular, the identification of suspect foods based on information from case histories can be very useful.

Foods associated with a processor/producer

Implication of multiple food establishments in an outbreak or receipt of multiple, seemingly unrelated reports of illness from consumers eating the same type of food, suggests an outbreak caused by food contaminated at the processor/producer-level. Traceback investigations can help identify the point in the production and distribution process at which the implicated food most likely became contaminated and allow for targeted environmental health assessments to determine how the food became contaminated and to recommend specific interventions.

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In the course of an outbreak investigation, evidence may emerge to implicate a food premises or farm supervised by inspectors in either DAFM or local authorities or the SFPA. A representative from the relevant agency should be notified immediately and requested to provide representation to the outbreak control team. This agency should immediately arrange for a detailed investigation to include inspection of the implicated premises/product. The representative from this agency should keep the outbreak control team briefed on a timely basis on the progress of this investigation.

It is important that agencies that do not deal with outbreaks on a routine basis, review this document to ensure that inspectors are familiar with best practices in the event of an outbreak investigation. An investigation in a food business at the time of an outbreak will require inspectors to look at different aspects of a food business.

Focus on a food business establishment

A full inspection may be necessary or it may be more appropriate to concentrate on specific areas. The exact activities included in an environmental investigation will differ on the basis of the causative agent, the suspected vehicle, the at-risk population and the setting but usually involves some of the following:

MANAGEMENT

- Identify and obtain up-to-date contact details for the food business operator. This may be a company. It may also be important to establish the most appropriate other person to whom communication is sent to ensure prompt action
- Identify the person in charge of the food business (if different from food business operator) through whom all communications will be channelled. A copy of all written communications to be sent to the food business operator at a minimum and whoever else is appropriate
- Establish nature and extent of food business
- Establish the risk status of customers
- Identify sources of water supply, i.e. local authority mains supply, private well supply, group scheme or combination of these
- Review pre-requisite programme including:
  - Premises and structure
  - Plant and equipment
  - Services – ventilation, ice, water etc.
  - Storage distributions and transport of food
  - Zoning
  - Cleaning and sanitation
  - Maintenance and calibration
  - Personal hygiene
  - Pest control
  - Waste management – solid waste/refuse/drainage
- Examine the Hazard Analysis Critical Control Point (HACCP) system or the food safety management system. If possible, compare any written documentation with the actual process on the ground throughout the inspection. In particular, it is important to review food business operator sampling and analysis results where available.

FOOD HANDLERS

- Review absenteeism records and question them thoroughly.
- Pose questions about staff physically getting sick on premises.
- Interview each food handler.
- Make enquiries about illness policy with staff and management separately.
- Provide advice on exclusion of ill food handlers. Liaise with the public health department about any staff illness.
- Medical officer to liaise with occupational health department if required.
- Consider need for clinical samples from food handlers (this should be in conjunction with the public health department/OCT as appropriate).
- Assessment of food handlers' knowledge of food hygiene training and food safety management system.
- Observe food handlers' hygiene practices.
- Reinforce good hygiene and food handling practices.

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CONDITIONS AT TIME OF INCIDENT

- Obtain verified menus for the meal/event that took place.
- Obtain information on any other recent complaints of illness.
- Pose questions about customers physically getting sick on the premises.
- Obtain information on functions and people who ate in the premises around the time of the incident.
- Identify actual staff on duty at the time of the incident, e.g. staff rosters.
- Question if any changes to staff rosters/menus/water supply/power supply/suppliers.
- Review all relevant food safety and cleaning records and relevant documentation.

SUSPECT FOOD

- Apply hazard assessment and risk analysis of operational/structural measures.
- Develop a food flow (flow chart/process description) for the suspected food items or ingredients implicated to get detailed information on each step of process:
  - Transport
  - Delivery
  - Storage
  - Preparation
  - Cooking
  - Cooling
  - Reheating
  - Service
  - Any other relevant process step, e.g. vacuum packing, packaging etc.
- Compare actual practices to food safety management system.
- Observe operational hygiene.
- Observe cross contamination/handling/segregation practices.
- Review temperature control records and monitor temperatures.
- Examine cleaning programmes and techniques, including the sanitising of implicated work surfaces and equipment.
- Investigate control of raw materials and suppliers, including examination and copying of invoices, delivery dockets and raw materials specifications.
- Obtain labelling information including batch and date of minimum durability.
- Take samples of water.
- Take samples of suspect foods and ingredients.
- Conduct traceback and trace forward of food items under investigation, including taking copies of appropriate documentation.
- Review food business operator's procedure for recalling suspect food from the market.

Enforcement action

The authorised officer shall apply whatever enforcement action is necessary.

At the time of inspection, the food business operator should be informed of any infringements noted that will require immediate action. A report should be issued to the food business operator following the inspection indicating corrective actions and the time scale for the required corrective actions to be completed.

It is recommended that an *aide-memoire* is used to assist in the inspection in order to facilitate a structured approach to the inspection process. An *aide-memoire*, which may be used or adapted for use, is included in **Appendix 11**.

Food, water and environmental sampling

Official samples must be submitted to an official food control laboratory accredited against ISO 17025, who has had prior communication that such samples are to be delivered. All samples[6] should be in sterile containers/pouches, well recorded and labelled, and continuity of handling from sampling to report stage should be recorded. It is critical that the outbreak code, date and time are recorded on both the sample submission form and the sample container. The sampling officer should keep a record of as much detail as possible about where the food was found and its storage conditions so that the significance of the microbiological results can be assessed. Sample temperatures should not be substantially altered during handling. Sample procurement should be conducted to ensure that cross contamination does not occur. Cold and frozen food should be kept as close to its original temperature as possible during transit, although hot food need not necessarily be kept hot.

[6] FSAI/HSE Guidance on Sampling of Food for Microbiological Testing

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Foods taken from establishments during 'out of hours' can be stored overnight at appropriate temperatures in the office fridge/freezer.

Smaller 'left over' samples, even if retrieved from dustbins, may be useful in certain circumstances, e.g. the investigation of a case of botulism. Any samples not sent for examination should be retained until after investigations have been completed.

Consideration should be given to sampling raw foods traditionally linked to the type of outbreak being investigated. Samples of raw foods, e.g. chicken or pork, may indicate the source of a suspect organism. Such food may not have been consumed but may have been prepared during the suspect period and have been a source of contamination.

Water samples may be taken from the kitchen tap and any other taps deemed necessary. Consideration should be given to taking samples for 'Total' and 'Free' chlorine levels, as well as bacteriological analysis.

Environmental samples may be used to determine the nature and the extent of any contamination. Samples may be taken from working surfaces, food equipment and containers. Surfaces which food handlers may have touched such as door handles, refrigerators, and switches may also be swabbed, as may cleaning and other equipment such as sinks, nail brushes and wiping cloths. It should be noted that, even though superficial cleaning may have been carried out, the organism may still be present in numbers sufficient to be identified in sampling. Drain or sewer swabs may occasionally, be useful for investigating a contaminated area.

In accordance with the laboratories quality system for release of results, the laboratory will communicate preliminary results to the relevant environmental health officer. All validated final results should be communicated as soon as possible by an agreed mode, e.g. phone, encrypted email, fax etc.

Traceback

While effective control of many outbreaks may be achieved by the identification of the implicated product and perhaps the identification of poor hygiene practices at a retail or catering establishment, it will always be desirable to carry out a traceback investigation to follow the supply chain of the implicated food back to primary production. Relevant official agencies should be requested to assist in this traceback. The FSAI will facilitate this process (see FSAI *Guidance Note 10 Product Recall and Traceability, Revision 3*[7]).

The use of schematics to visually portray the supply chain as it unfolds should be provided by the environmental health service, the FSAI or other investigating agency as appropriate and then circulated to all relevant agencies as a snapshot of investigations to-date. This could take the form of a simple flow chart, mapping the various food business operators and their contact with suspect food.

1. **Identification of the ingredients used**
   Traceback is an important aspect of investigating a suspect food vehicle. If more than one food vehicle is implicated, cross contamination may be involved, e.g. mousse, hollandaise sauce.

2. **Tracing and sampling of ingredients**
   Samples of raw products (if possible from the same batch used to make the food vehicle) should be tested, e.g. sample of raw milk implicated in a *Salmonella* outbreak or the base raw egg used to make egg fried rice.

3. **Post treatment contamination investigation**

4. **Other sampling (foods/food handlers and environmental)**
   The pathogen may also be identified from environmental samples, water or other foods, or from food handlers (worker involved in production, cooked food, serving salad, mixing juice).

5. **Traceback in distribution chain**
   Origin of suspect food – veterinary traceback, invoices, suppliers, intermediate suppliers.

6. **Investigation of primary produce/animals/birds**
   - Meat and meat products: may involve investigation of the meat processing plants, abattoirs and the supply farms.
   - Milk and milk products: may involve investigation of production facilities and supply farms.
   - Eggs and egg products: may involve investigation of processing plants, packing stations and supply farms.
   - Fresh fruit and vegetables: may involve investigation through the whole supply chain to the farms.
   - Fish and fishery products: may involve investigation of processing plants and aquaculture sites.
   - Animal derived products: may include animal feeds, feed raw ingredients and feed supply mills.

It is crucial that all environmental health information is shared fully among OCT members to ensure that each member has full access to all relevant information.

[7] http://www.fsai.ie/publications_guidancenote10_recall

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4. Microbiological Investigation

The aims of the microbiological investigation are:

1. To determine if a pathogen can be detected in clinical specimens and in food, environmental and animal samples, where appropriate
2. Where appropriate, to guide targeted therapy of the infection
3. To formulate or refine hypotheses on likely source of infection based on historical data on associations between pathogen subtypes and particular foods, regions or animal species
4. To characterise clinical and non-clinical isolates, possibly related to the outbreak
5. To determine the extent to which isolates from different sources and times are likely to be related epidemiologically to one other

Clinical samples

Depending on the size of the outbreak and time elapsed since it was detected, a decision should be made on persons from whom specimens are to be collected: whether all cases or only those that remain symptomatic. The OCT (or authorised officer in the event of no OCT) should arrange to have clinical samples taken when food handlers or a specific group, e.g. wedding guests, may be considered a risk. Sample submission forms should include full patient identification details (full name, date of birth and address), relevant clinical details, outbreak code and possible incubation period. Specimen containers must have identification details, e.g. full name and date of birth, that correspond to the details on the request form. This information will assist the laboratory in decisions concerning appropriate processing of clinical samples. The range of analysis performed should be based on an assessment of likely causes of the outbreak, but may include analysis for bacteria, virus and or protozoa. The following arrangements will be made in discussion with the consultant microbiologist/virologist:

- Persons from whom clinical specimens are to be collected
- Medical personnel to whom results are to be reported
- Which are the appropriate clinical specimens
- Provision of sterile containers, laboratory request forms and plastic transport bags
- Collection points and storage of specimens
- Method and time of transport to laboratory
- Method and times of communication between laboratory and senior medical officer/specialist in public health medicine/environmental health officer

Patients should be provided with clear and straightforward written instructions on specimen collection and arrangements for safe and prompt transportation to the laboratory should be agreed.

In so far as possible, clinical specimens should be submitted to a laboratory accredited to the ISO 15189 standard or equivalent.

Food, water and environmental sampling

Refer to Section 3 Food Business Investigation.

Processing of clinical samples and identification and typing of isolates

Detailed discussion of laboratory methods is beyond the scope of this document.

Clinical samples should be processed promptly and stored appropriately and for a reasonable duration of time to ensure that it is possible to perform repeat or extended analysis if required for the purposes of investigation of the outbreak.

Where a laboratory does not have the capacity to perform the required analyses, samples should be referred to a microbiology laboratory with the appropriate competence as soon as possible.

In accordance with the laboratories quality system for the release of clinical results, the consultant microbiologist/chief medical scientist of the laboratory will communicate results to the relevant clinician and/or other agreed persons such as public health doctors/environmental health officer. All validated final results will be communicated as soon as possible by an agreed mode, e.g. phone, encrypted email, fax etc., to the OCT/requestor.

The laboratory should work as quickly as possible to confirm the isolate as a pathogen and to ensure that the isolates are sent to an appropriate reference laboratory service for detailed characterisation. In the context of a major outbreak, confirmed or highly suspect isolates should normally be dispatched to the reference laboratory on the next working day. The reference laboratory should be informed that the isolate has been dispatched.

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In the context of an outbreak, the reference laboratory should aim to confirm the identity of most isolates associated with the outbreak as soon as possible of receipt and attempt to provide such additional typing as may be required to assess the likelihood of a link between cases as soon as possible with regard to resources available.

When pathogenic bacteria are isolated from samples, their presence alone may be insufficient to support a presumptive association. Some organisms are very common and their presence in related specimens may be coincidental. Further subdivision into types/subtypes (or genetic sequencing if/when available) may show them to be distinct and therefore unrelated, or still indistinguishable, thus increasing the significance of their isolation.

5. Hypothesis Generation

As more information becomes available from case interviews, the laboratory and the visit to the suspect premises, data need to be summarised and a hypothesis formulated to explain the outbreak. The hypothesis should address the source of the agent, the mode of and vehicle of transmission, and the specific exposure that caused the disease. Hypotheses should be plausible, supported by the facts established during the epidemiological/laboratory/food investigations, and should be able to explain most of the cases.

Formal testing of a hypothesis may be unnecessary if it is strongly supported by epidemiological, laboratory data, food data or other strong circumstantial evidence.

Analytical epidemiology

Under certain circumstances, it may be necessary to investigate using an analytical approach (a case control or cohort study). This becomes necessary when:

- The descriptive results are felt to be insufficiently strong to back up the necessary control measures
- There is pressure to provide evidence of additional strength, e.g. when there is resistance to undertaking control measures, or when there is legal pressure to bolster the strength of evidence

Analytical epidemiological studies involve comparisons of the characteristics of a group of well persons with those of ill persons in order to quantify the relationship between specific exposures and the disease under investigation. The two types of analytical studies most commonly used in outbreak investigations are cohort studies and case control studies.

Cohort studies

Cohort studies are used when the population at risk can be identified, e.g. guests at wedding, attendees at school etc.

Case control studies

Case control studies are used when it is not possible to define the group exposed or when the population at risk is so large in relation to the number ill that it is not practical or cost-effective to include them all in the study. This is often the case in an outbreak in a restaurant where it is not possible to identify all diners who might have been exposed to a contaminated food item; in this instance a representative sample of cases and controls is obtained and a case control design adopted.

An example of a cohort study and a case control study is shown in **Appendix 12**.

Interpretation of results

The results of the epidemiological, microbiological and food business investigations must be considered together. Examples from the literature and previous outbreaks may suggest possible contributory factors. Environmental inspections may identify factors that could have contributed to the outbreak such as inadequate structural or operational hygiene. Microbiological evidence could indicate contaminated food, equipment or an animal/poultry reservoir. Definitive typing may demonstrate that isolates from food or animals/poultry are similar to human isolates providing further evidence of an association.

6. Implementation of Control Measures

Control measures should be initiated as soon as possible, documented and dated. These will often be concurrent with ongoing investigations. Control measures can be categorised as those that control the source, i.e. prevent continued exposure to original source, and those that prevent secondary transmission, i.e. transmission from those originally infected to others through food, water or person-to-person spread. Additional measures might be necessary to prevent future outbreaks.

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(a) Control of source

Once investigations have identified an association between a particular food or food premises and the transmission of the suspected pathogen, measures should be taken to control the source.

Ideally, the OCT should agree by consensus or majority, on how to proceed with actions. However, decisions of the OCT cannot supersede the individual statutory responsibility of an authorised officer. Any discussion/decision of the OCT that involves the use of statutory powers must clearly identify the statutory basis for same and cannot circumscribe the prescribed statutory responsibilities of those charged with enforcement of such statutory provision.

Facility implicated: Where a food business has been implicated, control measures can be implemented even though a specific food has not yet been identified.

Food implicated: Where a specific food(s) has been implicated, targeted control measures can be implemented. These will vary depending on whether the implicated food is associated with food-service establishments (single or multiple facilities), with home processing or with a processor/producer (see Table 2).

TABLE 2: CONTROL OF SOURCE (EXAMPLES ARE NOT EXHAUSTIVE)

Facility Implicated (but specific food not identified) ↓ **NON-SPECIFIC MEASURES**	Good practice regardless of the disease: • Stopping potential high-risk food production if required • Applying enforcement action as necessary • Holding of leftovers for further analysis if warranted • Emphasising hand-washing • Excluding ill employees with gastro-intestinal illness symptoms
Food Implicated ↓ **SPECIFIC MEASURES**	Food service establishment: • Removal of implicated food • Eliminating implicated food from menu until control measures in place • Cleaning and sanitising implicated facility and equipment • Modifying food production or preparation at the facility to prevent further contamination • Staff training • Modifying menu • Exclusion of infected food handlers • Apply enforcement action if necessary Food associated with a processor/producer: • Many of above may be appropriate once point of contamination identified • Removal of product from market • Product recall

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(b) Control of (secondary) transmission

Public Advice: If a contaminated food product cannot be controlled at its source, steps need to be taken to eliminate or minimise further transmission of the pathogen.

Appropriate public advice may be necessary e.g.:

- Advice on proper preparation of foods
- Advice on disposal of foods
- Advice on personal hygiene measures
- Boiling of microbiologically contaminated water

The HPSC has information available online relating to gastrointestinal illness and personal hygiene. Such information could be speedily modified as necessary by the agencies involved and circulated to the public as necessary. http://www.hpsc.ie/hpsc/TopicsA-Z/

Exclusion of infected persons from settings where transmission can occur (including food-preparation, health-care and child-care settings) may be necessary. The risk of infection being spread by infected individuals depends on their clinical status and their standards of hygiene. People with diarrhoea are far more likely to spread infection than asymptomatic individuals with subclinical illness. Infected skin lesions can be a reservoir for pathogens which can be transmitted to food.

Food handlers at the implicated facility should be educated about the disease (symptoms, mode of transmission, prevention), advised about general infection control precautions and about not working when ill. Temporary restriction, exclusion and - for certain pathogens - microbiological clearance, may be necessary (see www.hpsc.ie for *Food Handler Guidelines/Pathogen Specific Guidelines*). All cases of gastroenteritis should be regarded as potentially infectious and should normally be excluded at least until 48 hours after the person's diarrhoea and/or vomiting have resolved.

Food handlers whose work involves preparing or serving unwrapped foods not subjected to further heating pose an increased risk of spreading infection if infected.

Advice on personal hygiene should be given to all individuals with gastrointestinal disease, including:

- Avoid food preparation for others until free of diarrhoea or vomiting
- Thorough hand-washing after toileting and before meals
- Environmental cleaning instructions where household member has diarrhoea or vomiting (toilet seats, flush handles, hand-basin taps and toilet door handles after use)

Infection control precautions for hospitalised and institutionalised individuals with infectious diarrhoea include standard precautions and:

- Isolation of patients, e.g. private room with separate toilet if possible
- Additional contact precautions as may be required
- Strict control of disposal or decontamination of contaminated clothing/bedding
- Strict observation of personal hygiene measures

PROTECTING RISK GROUPS

- Certain groups are at higher risk of severe illness and poor outcomes after exposure to a foodborne disease (including infants, pregnant women and the immuno-compromised). Safe food preparation practices and thorough hand-washing should be particularly emphasised to these groups.
- Specific advice for certain groups may need to be considered in some circumstances, such as advising pregnant women against consumption of unpasteurised milk products or other products potentially containing *Listeria*.

Control of distant cases

National alerts to public health authorities and other interested parties may be appropriate. In some cases, international alerts may be indicated. Collaboration with and between national bodies such as the FSAI, the HSE, the HPSC, Department of Health (DoH) and DAFM is important in this regard.

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7. Communication

Good communication is one of the most important factors in successful outbreak control. Without it, investigations and responses can be delayed, uncoordinated and ineffective. Good communication can help allay public concerns and improve industry support for actions to control the outbreak. To promote better outcomes, agencies should use the time before and between outbreaks to lay the groundwork for good communication - including developing and updating contact lists, defining communication processes and establishing relationships with individuals and organisations key to an investigation. Official agencies of the FSAI have access to contact details of all agency staff in the FSAI extranet facility known as *Safetynet*. If requested by the OCT, relevant cross agency contact details, either regional or national, can be emailed as a directory to the OCT and relevant officials.

TABLE 3: OUTBREAK INVESTIGATION: COMMUNICATION ISSUES

Key Individuals/ Organisations	Communication Issues
OCT	• Ensure all members know each other. • Develop a consistent approach to internal communications. • Sidebar/offline discussions between certain members of the OCT to the exclusion of other core members/chair of the OCT is not conducive to good communications and should be discouraged. • Identify who will be responsible for communication on behalf of their organisational unit and for the OCT. • Communicate actions taken and outbreak status information to all involved in the outbreak investigation. • Information provided to the public or industry by the FSAI or the HPSC should be pre-shared with all OCT members.
Affected Cases	• Good communication with affected cases is essential so as to assess the progress of the outbreak. • Ensure all information provided to the general public and the media is passed to the affected cases and their families in the first instance if possible. • It may be appropriate to set up a designated helpline for affected cases.
Agencies/ Professional Groups	• Ensure each agency/professional grouping involved is fully informed about the outbreak investigation status as early as possible. • Other professional groups with no direct part in the investigation may still be affected by the outbreak, e.g. local hospitals/GPs. Good communication with them should be maintained. • Colleagues in other geographical areas may be able to provide additional insight.

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Chapter 3. The Investigation and Control of an Outbreak

Key Individuals/ Organisations	Communication Issues
Public	Public concern can become an important feature of an outbreak investigation. To achieve a proper balance between the scientific requirements of an investigation and responsiveness to public concern, public health authorities must deal actively with the need for public information. The OCT should be seen as, and should act as, the most reliable source of information. • Adopt a standardised format for reporting risk information (helps make the process more familiar and reduces concerns about the message). Information should be timely, accurate and consistent. – Acknowledge problem – What is being done – Who is doing it – Risk +/- advice on measures to reduce risk – Keep updating • Consider methods (print media, radio, TV, internet, public meeting, social media, leaflets, face-to-face advice, consumer group messages, telephone helpline, …). • In some outbreaks, communication with the public will also help in identifying additional cases. • In the event of several public advice-lines, it is imperative there is clarity between the HSE, the HPSC and the FSAI on advice issued to the public.
Media	It is critical that all agencies involved in the response to a food outbreak adopt a common approach to managing the release of information to the media. If agencies act individually, there is a danger that the message will get confused and that the crisis will be exacerbated as a result. A member of the OCT should ensure that information is released to the media in a coordinated manner and that this information is accurate and timely. It may be necessary to appoint a media liaison officer to coordinate the messages. This will ensure that all have an appropriate input to any press releases issued on behalf of the OCT. It is acknowledged that individual agencies may wish to release their own press statements during an outbreak. In this case, it is essential that copies of such statements are made available to the OCT as soon as is practicable. • All official information passed to the media should be cleared with the OCT. • The OCT should identify a media spokesperson and a media relations officer. • Communication should be maintained with all appropriate media outlets (including radio, television, internet, social media, newspapers and other publications). • Regular press briefings may need to be considered where there are multiple media demands for interviews with key investigators to avoid distracting the investigation.
Industry	• Keep owners/managers of the implicated establishment informed, telling them as much as possible about the significance of the findings. • Notify them that they must share any new reports of illness or other new information that could affect the investigation. • Advise about potential outbreak control measures.

Chapter 3. The Investigation and Control of an Outbreak

8. End of Outbreak and Outbreak Report

Most outbreaks can be considered over when two or more incubation periods have passed without new cases. Post-outbreak monitoring is necessary to ensure the outbreak has ended and the source has been eliminated. The OCT should decide and formally declare when an outbreak is over and when there is no longer a risk to the public health.

Review of outbreak

All members of the OCT should be informed by the chairperson about the results of the investigation. A formal debriefing meeting is appropriate for all large outbreaks involving multiple agencies and should:

- Identify measures to prevent further such outbreaks at this and other facilities
- Assess the effectiveness of outbreak control measures and difficulties in implementing them
- Identify the long-term and structural control measures
- Identify factors that compromised the investigation and seek solutions
- Discuss any communication issues that may have arisen
- Discuss any legal issues that may have arisen
- Clarify resource needs, structural changes or training needs
- Identify any necessary changes to current guidelines
- Assess whether further scientific studies should be conducted

Outbreak report

Reports should be prepared for all outbreak investigations and copied to the HPSC. This report should be drafted by the chairperson of the OCT and must be signed off by the members of the OCT before dissemination. The complexity will depend on the size of the outbreak. For small outbreaks, a simple summary (locally produced template) may be sufficient. Mindful of the increasing incidence of litigation, OCT members should be careful to address the probability of doubt that a particular vehicle was the source and take particular care in wording statements to that effect. Given that outbreak reports, especially reports for large outbreaks, are likely to be subject to Freedom of Information Act requests, they should be written with public disclosure in mind. In general, the most important output from such reports are the lessons learned and these can be outlined in a way that safeguards clinical and business confidentiality, unless it is felt necessary to name the food business operator.

An interim report should be made available by the OCT within a month of the end of the investigation. For small outbreaks, this may comprise a simple summary as above, and will suffice as the final report.

The final report, for large or complex outbreaks, should be comprehensive, protect confidentiality and be circulated to appropriate individuals and participating agencies. The report should follow the usual scientific format of an outbreak investigation report (see **Appendix 13**) and include a statement about the effectiveness of the investigation, the control measures taken and recommendations for the future.

Outbreak reports should be used as a continuous quality improvement opportunity

Chapter 3. The Investigation and Control of an Outbreak

9. Dissemination of Learning

Education and training needs should be identified for those involved in outbreak response.

- All **team investigators** need to be adequately prepared. Training is likely to be most effective when interesting and provided through team and interagency exercises, on-the-job training during real-life investigations, and debriefings after each outbreak investigation.
- An **annual training day** to share learning from outbreaks should be facilitated annually and co-hosted by the FSAI and the HPSC.
- For the **food industry**, outbreaks can present an opportunity for significant learning. When the media carries stories about an outbreak, communication within the industry is lively, often with misinformation. Food safety and public health agencies need to dispel misconceptions and explain their response to the outbreak. Collaboration with industry on long-term development of training materials, together with input at industry meetings, will also assist industry in future preventive efforts. A certain proportion of national and local conferences and seminars should seek to have a mix of regulatory and private sector participation to ensure that each is aware of the pressures and drivers on the other.

New policy needs may be identified from information gained during an outbreak. Reports of past outbreaks should be analysed to determine whether multiple outbreaks support the need for new public health or regulatory policy.

Publication: Outbreak details may be published in the international literature to inform the wider scientific community. Important lessons learned should be disseminated widely (mindful of confidentiality considerations).

Future studies and research: Economic evaluations of outbreaks and associated controls can be important in assessing the cost-effectiveness of outbreak investigations and food safety measures. Costs associated with outbreaks can be enormous. Quantifying them may help to increase the commitment of the food industry and other agencies to food safety. Identifying issues that need follow-up research is important to improving the practice of responses to outbreaks. Further studies may be conducted where a new/unusual pathogen is involved, where additional information for risk assessment is required etc.

Appendices

Table of Contents

Appendix 1. Members of the Outbreak Control Steering Group

Prof. Patrick Wall (Chair)
Associate Professor of Public Health,
University College, Dublin

Mr Jim Buckley
Chief Veterinary Officer,
Cork County Council
(now retired)

Prof. Martin Cormican
Consultant Microbiologist,
University College Hospital, Galway

Ms Catherine Cosgrove
Principal Environmental Health Officer,
Health Service Executive

Ms Mary Falvey
Principal Environmental Health Officer,
Health Service Executive
(now retired)

Dr Cliodhna Foley Nolan
Specialist in Public Health Medicine,
*safe*food

Dr Monserrat Gutierriz
Senior Research Officer,
Central Veterinary Research Laboratory,
Dept of Agriculture, Food and the Marine

Mr Paddy Lynch
Agricultural Inspector,
Dept of Agriculture, Food and the Marine

Ms Gemma McGrane
Environmental Health Officer,
Health Service Executive

Dr Paul McKeown
Specialist in Public Health Medicine,
Health Protection Surveillance Centre

Mr David Nolan
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Ms Maureen O'Hara
Quality Manager,
Official Food Microbiology Laboratory,
Health Service Executive

Ms Eibhlin O'Leary
Audit and Investigations Manager,
Food Safety Authority of Ireland

Mr Micheál O'Mahony
Authority Member,
Sea-Fisheries Protection Authority

Dr Margaret O'Sullivan
Specialist in Public Health Medicine,
Health Service Executive

Ms Ann Marie Part
Regional Chief Environmental Health Officer,
Health Service Executive

Appendix 2. Notifiable Diseases (Republic of Ireland) Relevant to Foodborne Transmission

(Infectious Diseases under Infectious Diseases (Amendment) Regulations, 2016 (S.I. No. 276 of 2016) (May 2016))

- *Bacillus* cereus foodborne intoxication
- Botulism
- Brucellosis
- *Campylobacter* infection
- Cholera
- *C. difficile*
- *Clostridium perfringens* (type A)
- Cryptosporidiosis
- Echinococcosis
- Enterohaemorrhagic *Escherichia coli* (EHEC)
- Giardiasi
- Hepatitis A
- Listerosis
- Noroviral infection
- Paratyphoid
- Rotavirus infection
- Salmonellosis
- Shigellosis
- Staphylococcal food poisoning
- Tuberculosis due to *Mycobacterium bovis*
- Trichinosis
- Typhoid
- variant Creutzfeldt–Jakob disease (vCJD)
- Yersiniosis

Source: *Case definitions for Notifiable Diseases*. HSE/HPSC March 2012

www.hpsc.ie

Appendix 3. Human and Food Reference Laboratories

Human Reference Laboratories

The **National Salmonella, Shigella and Listeria Reference Laboratory (NSSLRL)**, in Galway accepts *Salmonella* isolates from all clinical laboratories, public health food laboratories, veterinary laboratories and research institutes in the Republic of Ireland. It undertakes serotyping, phage typing and antimicrobial sensitivity testing. In addition, the laboratory also applies molecular typing including Pulse-Net pulsed-field gel electrophoresis (PFGE) and multi-locus variable-number tandem repeat analysis (MLVA) on *S. Typhimurium* isolates. It has recently established capacity to perform Multi-Locus Sequence Typing (MLST). Molecular methods are applied selectively to facilitate detection of unrecognised clusters of cases and to confirm associations between isolates that are suspected on conventional epidemiological grounds and to identify episodes of laboratory cross contamination. In addition, around 60-80% of all human *Listeria* and Shigella isolates are referred to the laboratory annually, where serotyping and antimicrobial sensitivity are performed on all isolates received, with further molecular typing applied selectively.

The **HSE Public Health Laboratory at Cherry Orchard Hospital** in Dublin has established a VTEC (O157 and non-O157) national reference service for clinical food and water samples. It receives 100% of the clinical VTEC isolates and maintains the VTEC laboratory national database. The service includes high throughput DNA extraction and verotoxin detection. *E. coli* serotyping and verotoxin subtyping, along with VTEC virulence gene characterisation and VTEC molecular typing – utilising PFGE, is performed on all VTEC isolates. This is prioritised during outbreak investigations. For all cases, serotyping and verotoxin typing results from the HSE Public Health Laboratory Dublin, VTEC Reference Laboratory are currently circulated to public health departments for manual data entry on CIDR, where they are integrated with public health information. The HSE Public Health Laboratory Dublin VTEC Reference Laboratory, along with the HPSC, provides regular national enhanced VTEC data to the European Centre for Disease Control.

In relation to *Campylobacter*, there is currently no national service for speciation and typing of human isolates. The HSE Public Health Laboratory Dublin has the research capability to speciate such *campylobacter* isolates, but it is not currently in a position to provide a dedicated reference service. Where speciation is performed at the primary hospital laboratory, the results are reported through CIDR.

A number of primary hospital laboratories in the Republic of Ireland avail of the services of the **UK *Cryptosporidium* Reference Laboratory** in Swansea for genotyping of human specimens found positive for *Cryptosporidium*. Where typing information is available, the data are reported to CIDR by the referring primary hospital laboratory. To date, comprehensive human reference services are not available in the Republic of Ireland. For other pathogens where human reference services are not available in the Republic of Ireland, only a portion of those strains isolated are sent to the reference laboratory at the Centre for Infections (CfI), Colindale for confirmatory tests and detailed identification.

National Virus Reference Laboratory

The **National Virus Reference Laboratory**, located at the UCD Centre for Research in Infectious Diseases (CRID), provides a national diagnostic service for Ireland in relation to virus detection and epidemiology using a wide range of methods to identify viral infections in humans.

UCD Centre for Food Safety

The UCD Centre for Food Safety similarly provides pheno- and genotype based typing support when requested. The UCD Centre for Food Safety can provide identification services for several foodborne zoonotic pathogens in addition to antimicrobial susceptibility testing and genetic characterisation. The centre is also designated as the World Health Organization (WHO) Collaborating Centre for *Cronobacter* (formerly *Enterobacter sakazakii*) – a pathogen associated with powdered infant formula.

Food National Reference Laboratories

All isolates from positive food samples should be tested and typed in the National Reference Laboratory, other official food control laboratory or the NSSRL as appropriate'. The National Reference Laboratories were designated by the Department of Health following consultation with DAFM and the FSAI. All of the National Reference Laboratories for food in the Republic of Ireland for microbiological parameters (*Salmonella*, *Listeria*, *E. coli*, *Campylobacter*, *Staphylococci*), TSEs, parasites and antimicrobial resistance are located on the Backweston Complex under the remit of DAFM.

In addition to the National Reference Laboratories, there is a network of official food control laboratories, designated by the competent authorities (DAFM and Department of Health) for the purposes of official food and feed controls.

Appendix 4. HPSC Questionnaires

Infectious Intestinal Disease (IID) Investigation Form (Generic IID):
http://www.hpsc.ie/hpsc/A-Z/Gastroenteric/GastroenteritisorIID/InvestigationForm/

Cryptosporidiosis Enhanced Surveillance Form:
http://www.hpsc.ie/hpsc/A-Z/Gastroenteric/Cryptosporidiosis/SurveillanceForms/

Listeriosis Surveillance Forms:
http://www.hpsc.ie/hpsc/A-Z/Gastroenteric/Listeriosis/SurveillanceForms/

VTEC Enhanced Surveillance Report Form and Questionnaires:
http://www.hpsc.ie/hpsc/A-Z/Gastroenteric/VTEC/SurveillanceInvestigativeForms/

Salmonellosis Enhanced Surveillance Form and Questionnaire:
http://www.hpsc.ie/hpsc/A-Z/Gastroenteric/Salmonellosis/SurveillanceInvestigativeForms/

Botulism Investigative Form:
http://www.hpsc.ie/A-Z/Gastroenteric/Botulism/InvestigativeForms/

Enhanced Typhoid & Paratyphoid Investigative Form:
http://www.hpsc.ie/hpsc/A-Z/Gastroenteric/Typhoid/InvestigativeForms/

Appendix 5. Official Agencies and Government Departments

1. Department of Health

The Department of Health's statutory role is to support the Minister in the formulation and evaluation of policies for the health services. It also has a role in the strategic planning of health services. This is carried out in conjunction with the Health Services Executive, voluntary service providers, Government departments and other interested parties.

The department supports the Minister and the Government by:

- Advising on the strategic development of the health system including policy and legislation
- Supporting their parliamentary, statutory and international functions
- Evaluating the performance of the health and social services; and
- Working with other sectors to enhance people's health and well-being

2. Health Service Executive

The Medical Officer of Health role is defined by legislation. The main Acts and Regulations which govern the role in relation to infectious diseases are:

- **Health Act 1947 Part IV** in relation to infectious diseases and infestation and the amendment of Section 48 of this Act by Article 35 of the 1953 Health Act
- **Health (Duties of Officers) Order, 1949** where the operation of the relevant part of the 1947 Act is specifically referred to
- **Food Hygiene Regulations, 1950 S.I. No. 205 of 1990 Part III, Section 33**, which gives the Medical Officer of Health specific authority in relation to the prohibition of infected persons from working in food outlets
- **Infectious Disease Regulations, 1981 S.I. No. 390 of 1981** which declare certain infectious diseases notifiable, and which give specific functions and responsibilities to the Medical Officer of Health in relation to the surveillance, prevention and investigation and control of infectious diseases

On becoming aware, whether from a notification or intimation under these Regulations or otherwise, of a case or a suspected case of an infectious disease or of a probable source of infection with such disease, a Medical Officer of Health, or a Health Officer on the advice of a Medical Officer of Health, shall make such enquiries and take such steps as are necessary or desirable for investigating the nature and source of such infection, for preventing the spread of such infection and for removing conditions favourable to such infection. The list of diseases (and their respective causative pathogens) that is notifiable is contained in the Infectious Diseases Regulations, 1981 and subsequent amendments.

- **Infectious Diseases (Amendment) (No.3) Regulations, 2003 (S.I. No. 707 of 2003)** which require, in addition to medical practitioners, clinical directors of diagnostic laboratories to notify infectious diseases to a Medical Officer of Health. New case definitions were included, and infectious disease outbreaks were also made notifiable.
- **Infectious Diseases (Amendment) Regulations, 2016 (S.I. No. 276 of 2016)** contain the most recent amendment to the Regulations.

All functions related to the area of infectious diseases and the Chief Medical Officer/ Medical Officer of Health functions have been sub-delegated by the Assistant National Director/Health Protection to each director of public health. The latter have also assigned/designated the Medical Officer of Health functions to specialists in public health medicine. All medical practitioners, including clinical directors of diagnostic laboratories, are required to notify the medical officer of health of certain (notifiable) diseases.

Departments of Public Health

Through the responsibility vested in the role of the medical officer of health, the eight departments of public health have a key role in the management of outbreaks of foodborne disease. The Director of Public Health heads the Public Health Department and is the designated Medical Officer of Health for the public health service region. The Medical Officer of Health function has also been designated to specialists in public health medicine. Senior medical officers play integral roles in foodborne outbreak investigation. Surveillance scientists and communicable disease control/ Surveillance nurses also partake.

In relation to infectious diseases, the work of public health departments includes on-going surveillance and control, enhanced surveillance of specific illnesses and outbreak identification. Core functions in outbreak investigations include: epidemiological investigation, public health risk assessment, identification of vulnerable groups and the provision of public health medical advice to other health professionals, to other agencies and to the public.

Appendix 5. Official Agencies and Government Departments

The public health medical service participates in multidisciplinary teams in the investigation management and control of outbreaks of foodborne illnesses. The public health medical service links closely with the environmental health service clinical laboratories, the food safety laboratory service and with the HPSC during these investigations.

Health Protection Surveillance Centre

The HPSC has responsibility to protect and improve the health of the Irish population by collating, interpreting and disseminating data to provide the best possible information on infectious disease. This is achieved through surveillance, independent advice, epidemiological investigation, research and training. The HPSC works in partnership with health service providers and sister organisations around the world to provide up-to-date information for the effective control of infectious diseases.

The HPSC undertakes surveillance of outbreaks of infectious disease and produces regular reports on the level of illness caused by outbreaks and their causative pathogens. A national outbreak case definition (available at http://www.hpsc.ie/hpsc/NotifiableDiseases/CaseDefinitions) determines what constitutes an outbreak. The HPSC collates and analyses statutory weekly notifications of infectious diseases that have been provided by medical practitioners and clinical directors of diagnostic laboratories. Data are collected nationally using Computerised Infectious Disease Reporting (CIDR) as discussed in Chapter 1. The HPSC has a central role in the investigation of outbreaks. It takes the lead in the investigation of national and international communicable disease outbreaks and can become involved in the investigation of regional outbreaks at the invitation of the outbreak control team.

Environmental Health

The environmental health service investigates, manages and controls in multi-disciplinary teams, outbreaks of foodborne illnesses. It is responsible for the environmental and premises investigation. The environmental health service is responsible for a range of food safety/food control services in over 45,000 food businesses which includes the determination of compliance with food legislation by means of:

(i) The inspection, approval, licensing and/or registration of premises and equipment, including premises or equipment used in connection with the manufacture, processing, disposal, transport and storage of food including formal enforcement action to ensure compliance

(ii) The inspection, sampling and analysis of food, including food ingredients

(iii) Sampling of water

(iv) The inspection and analysis of food labelling

so as to ensure that food produced in the State (whether or not distributed or marketed in the State) and food distributed or marketed in the State complies with any relevant food legislation.

The legislation enforced by this service includes infectious disease and zoonoses legislation, general food law, official controls, food hygiene, labelling, presentation and advertising of foodstuffs, additives and flavourings, contaminants, microbiological criteria, specified risk material in retail butchers and materials in contact with foodstuffs. The environmental health service is responsible for import controls on products of non-animal origin. The environmental health service participates in multi-disciplinary teams investigating, managing and controlling outbreaks of foodborne illness. It is managed nationally by the Assistant National Director of Environmental Health and Emergency Management and is divided into four geographical regions: HSE South Region, HSE West Region, HSE Dublin Mid-Leinster Region and HSE Dublin North East Region. Each region is managed by a Regional Chief Environmental Health Officer, with the environmental health services delivered locally under the supervision of a principal environmental health officer.

Food Safety Laboratory Service

The HSE operates the food safety laboratory service. This network of laboratories comprises of three regional public analyst laboratories responsible for physical/chemical analysis of food and food related samples and seven official food microbiology laboratories responsible for the microbiological testing of foodstuffs. All of these laboratories are accredited to ISO 17025. The official food microbiology laboratories generally operate on a local basis, receiving samples from a number of neighbouring environmental health offices. For certain specialist parameters, a single official food microbiology laboratory provides analytical services on a national basis.

These laboratories analyse samples taken during official controls by environmental health officers. These samples are taken to support inspection, as part of monitoring and surveillance programmes or as part of the investigation of an outbreak, incident, food alert or consumer complaint. The environmental health service and the food safety laboratory service maintain close linkages, meeting frequently to discuss food monitoring and surveillance programmes.

Appendix 5. Official Agencies and Government Departments

The Public Analyst Laboratories generally operate on a regional basis, i.e. Dublin public analyst laboratory serves HSE Dublin Mid-Leinster and Dublin North Eastern Regions, Galway Public Analyst Laboratory serves the HSE Western Region and Cork Public Analyst Laboratories serves the HSE Southern Region. For certain specialist parameters, a single public analyst laboratory provides analytical services on a national basis. The public analyst laboratories are national reference laboratories for certain parameters.

3. Department of Agriculture, Food and the Marine

The **State Veterinary Service** of DAFM advises the Minister on matters of animal health and disease, zoonoses, and public health in so far as it relates to food and products of animal origin. It assists in the preparation; implementation and enforcement of European Union and national legislation, implements control measures to protect the health of the animal and human populations, and provides certification for animals and animal products intended for export.

Veterinary officers are authorised under the relevant legislation to enforce EU and national measures relating to animal health and welfare, including legislation concerning the control of animal disease, veterinary medicines, and the hygienic production of foods of animal origin, by routine inspection and sampling, by investigation and the acquisition of evidence, and by legal process in the courts, often in co-operation with the Gardaí (police) and customs officers.

The specific objectives of the **agricultural inspectorate** are to ensure compliance by food producers in relation to:

- Use of plant protection and biocidal products
- Pesticide residues in food of plant and animals origin
- Feeding stuffs requirements
- In the eggs and poultry meat and honey, dairy products sectors
- Plant health and horticultural produce

DAFM Laboratories

A key objective of the Central Veterinary Research Laboratory is to provide comprehensive diagnostic, surveillance and research service to the livestock and poultry industries by carrying out analysis and investigations. The Central Veterinary Research Laboratory plays an important statutory role in supporting the implementation of EU and national legislation. It has central and supporting roles in relation to national diseases surveillance and control schemes, providing laboratory services, including diagnosis, examinations and research, to the livestock and poultry industry. In this regard, it provides highly specialised veterinary expertise in support of the formulation and operation of DAFM's animal health policy.

Regional veterinary laboratories have been established across the country to serve the needs of the local livestock, poultry and feed industries. The six regional veterinary laboratories are located in Dublin, Kilkenny, Athlone, Sligo, Limerick and Cork. They provide a specialist diagnostic pathology service in support of DAFM's animal disease surveillance functions. In addition, they provide laboratory services on a regional basis, carrying out clinical diagnosis testing and examinations (such as post-mortem).

Dairy Science Laboratories

There are three dairy science laboratories, based in Backweston, Co Kildare; Model Farm Rd., Cork and Killeely Rd., Limerick. These laboratories are responsible for the analysis of milk and milk product samples, including drinking milk taken during official controls to ensure the verification of compliance with food law in milk processing establishments located across the country.

The dairy science laboratory in Backweston, Co Kildare is the national reference laboratory for *Listeria monocytogenes*, coagulase positive staphylococci, total bacterial count in raw milk, somatic cell count in raw milk and phosphatase activity in milk.

Organisational structure of the dairy science laboratories

Overall responsibility for the dairy science laboratories is with the Director of Laboratories. The dairy science laboratories are individually managed by agricultural inspectors, who report directly to a senior inspector who is head of the dairy laboratories division.

Appendix 5. Official Agencies and Government Departments

4. Local Authorities

The local authorities are responsible for official controls in low throughput slaughterhouses; establishments producing small quantities of fresh meat, minced meat, meat preparations or meat products; cold stores/distribution centres subject to Regulation 853/2004 and meat transport vehicles at, or associated with, inspected establishments.

The legislation enforced by these agencies includes general food law, official controls, food hygiene, labelling, presentation and advertising of foodstuffs, additives and flavourings, contaminants, residues of veterinary medicines, microbiological criteria, specified risk material, zoonoses, materials in contact with foodstuff, slaughter of animals and animal remedies. The local authority veterinary service participates as required in multi-disciplinary teams investigating, managing and controlling outbreaks of foodborne illnesses.

5. Sea-Fisheries Protection Authority

The SFPA is responsible for the implementation and enforcement of national and EU legislation which deal with health conditions for the production and placing on the market of fish, shellfish and fisheries products.

The SFPA carries out official controls on fish, shellfish and products thereof from harvesting, movement, processing, wholesale and distribution. The SFPA is responsible for official controls on imported fish and shellfish. The legislation enforced by this agency includes general food law, official controls, food hygiene, import control, labelling, presentation and advertising of foodstuffs, additives and flavourings, contaminants, residues of veterinary medicines, microbiological criteria, marine biotoxins, zoonoses, materials in contact with foodstuff, animal remedies and organic food.

6. Marine Institute

The role of the Marine Institute (MI), as defined by Marine Institute Act, 1991, is to undertake, to co-ordinate, to promote and to assist in marine research and development and to provide such services related to marine research and development, that in the opinion of the Institute will promote economic development and create employment and protect the environment.

The MI provides services to the SFPA and the FSAI, i.e. scientific advice, carries out risk assessments, carries out analyses and monitors analyses from other laboratories.

The MI carries out analyses to ensure compliance with legislative requirements with respect to general food law, official controls, food hygiene, contaminants, residues of veterinary medicines, microbiological criteria and marine biotoxins.

The MI acts as an NRL for certain parameters (further information on the analytical role of the MI is available on the FSAI website (http://www.fsai.ie/enforcement_audit/laboratories/labs.html).

Further information on the MI food control activities can be found in the FSAI MI Service Contract.

7. Food Safety Authority of Ireland

The FSAI is the competent authority with overall responsibility for the enforcement of food legislation in Ireland. The responsibility for enforcement of food legislation is managed through contractual arrangements (service contracts) between the FSAI and the competent authorities (official agencies) involved in the enforcement of food legislation (official agencies are listed in the Second Schedule of the FSAI Act, 1998), i.e.

- Department of Agriculture, Food and the Marine
- Health Service Executive
- Local authorities
- Sea-Fisheries Protection Authority
- Marine Institute
- National Standards Authority of Ireland

The FSAI crisis management plan will link to contingency plans in the relevant competent authorities (official agencies). It is a requirement in the service contracts for the official agency, in conjunction with the FSAI, to ensure that there are contingency plans in place at central and regional level for dealing with crisis incidents, large scale food safety incidents and outbreaks of food related disease.

8. Safefood

Safefood is a North-South body, responsible for the promotion of food safety on the island of Ireland. It was established in 1999 under the terms of the British-Irish Agreement Act 1999 and the North-South Co-operation (Implementation Bodies) Northern Ireland Order 1999.

It has legislative responsibility for overseeing the surveillance of foodborne disease on the Island of Ireland.

- **Information/Communication:** *Safe*food should be kept informed and updated on large outbreaks where food is a suspect vehicle to enable it to assist in the dissemination of information through the many channels it has developed. In order to clarify roles and responsibilities in specific outbreaks, it may be appropriate that a professional from *Safe*food is a member of the OCT or a subgroup of same. In this way, *safe*food can support the OCT, as appropriate.
- **Dissemination of learning:** via the *Safe*food networks/ other mechanisms can assist in this function.

Appendix 6. Agency Contact Details
(personal details omitted for online version)

Agency	Representatives	Job Title	Telephone/ Mobile	Email
Food Safety Authority of Ireland	Dr Pamela Byrne	Chief Executive Officer		
Department of Health – Food Unit	Audrey Hagerty Tommy Wilson	Principal Officer Assistant Principal		
Health Service Executive – Environmental Health	David Molloy *See list of EHS staff below*	Assistant National Director, Environmental Health Service		
Health Service Executive – Public Health	Dr Kevin Kelleher *See list of PH staff below*	Assistant National Director, Health & Wellbeing – Public Health and Child Health		
Health Service Executive – Health Protection Surveillance Centre	Dr Paul McKeown *Post vacant*	Specialist in Public Health Medicine Director		
Department of Agriculture, Food and the Marine	Aidan O'Driscoll Brendan Gleeson Martin Blake Donal Sammin Paula Barry Walsh	Secretary General Assistant Secretary Chief Veterinary Officer Director of Laboratories Deputy Chief Veterinary Officer		
Local authorities	*See list of LA staff below*	Country Veterinary Officers		

continued on next page

Appendix 6. Agency Contact Details
(personal details omitted for online version)

Agency	Representatives	Job Title	Telephone/ Mobile	Email
Sea-Fisheries Protection Authority	Daniel O Callaghan Aileen O'Sullivan	Director, Food Safety Unit Sea-Fisheries Protection Officer, Food Safety Unit		
Marine Institute	Jeffrey Fisher Joe Silke	Director, Marine Environment and Food Safety Shellfish Safety Section Manager		
Safefood	Dr Cliodhna Foley-Nolan	Director, Human Health and Nutrition		

DEPARTMENTS OF PUBLIC HEALTH, HSE – CONTACT DETAILS

Agency	Representatives	Job Title	Telephone/ Mobile	Email
HSE North East (Cavan, Louth, Meath, Monaghan)	Dr Bernadette O'Keefe Dr Paul Kavanagh Dr Peter Finnegan	Director of Public Health (DPH) Specialist in Public Health Medicine (SPHM) SPHM		
HSE East (Dublin, Kildare, Wicklow)	Dr Margaret Fitzgerald Dr Mary Ward	DPH SPHM		

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Appendix 6. Agency Contact Details
(personal details omitted for online version)

Agency	Representatives	Job Title	Telephone/ Mobile	Email
HSE South East (Carlow, Kilkenny, South Tipperary, Waterford, Wexford)	Dr John Cuddihy Dr Sarah Doyle	DPH SPHM		
HSE South (Cork, Kerry)	Dr Mary O'Mahony Dr Margaret O'Sullivan	DPH SPHM		
HSE Mid-West (Limerick, Clare, North Tipperary)	Dr Mai Mannix Dr Rose Fitzgerald	DPH SPHM		
HSE West (Galway, Mayo, Roscommon)	Dr Diarmuid O'Donovan Dr Regina Kiernan	DPH SPHM		
HSE North West (Donegal, Sligo, Leitrim)	Dr Peter Wright Dr Anthony Breslin	DPH SPHM		

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Appendix 6. Agency Contact Details
(personal details omitted for online version)

Agency	Representatives	Job Title	Telephone/ Mobile	Email
HSE Midlands (Laois, Offaly, Longford, Westmeath)	Dr Phil Jennings	DPH		

Note:
For a newly arising Out of Hours emergency - if urgent advice is required on a Health Protection issue, call Ambulance Control and ask for the Public Health Doctor on-call for the relevant HSE area.

ENVIRONMENTAL HEALTH SERVICE, HSE – CONTACT DETAILS

Agency	Representatives	Job Title	Telephone/ Mobile	Email
HSE Dublin/ North East Region	Mary Keane	Regional Chief Environmental Health Officer		
Food Hygiene Dublin City North East	Derek Bauer	Principal Environmental Health Officer		
Food Hygiene Dublin City North West	Jackie Kelly	Principal Environmental Health Officer		
Fingal Food Control	Noel Donnelly	Principal Environmental Health Officer		
Specialist Section	Deirdre O'Brien	Principal Environmental Health Officer		
Cavan/ Monaghan	Claire O'Dwyer	Principal Environmental Health Officer		
Meath	Elish O'Reilly	Principal Environmental Health Officer		
Louth	Tara Woods	Principal Environmental Health Officer		

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Appendix 6. Agency Contact Details
(personal details omitted for online version)

Agency	Representatives	Job Title	Telephone/ Mobile	Email
HSE-Dublin/ Mid-Leinster Region	Ann Marie Part	Regional Chief Environmental Health Officer		
Food Hygiene South City West	Declan Roe	Principal Environmental Health Officer		
Food Control South East Area	Marie Ryan	Principal Environmental Health Officer		
Food Control South Dublin Tallaght	David O'Brien	Principal Environmental Health Officer		
Food Control South Dublin Clondalkin	Tom Prendergast	Principal Environmental Health Officer		
Food Hygiene Dun Laoghaire Rathdown	Chris Counihan	Principal Environmental Health Officer		
Wicklow	Niamh McGrath	Principal Environmental Health Officer		
Kildare	Catherine Foye	Principal Environmental Health Officer		
Laois/Offaly	Declan Mulhare	Principal Environmental Health Officer		
Longford/ Westmeath	Paul McGuinness	A/Principal Environmental Health Officer		

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Appendix 6. Agency Contact Details
(personal details omitted for online version)

Agency	Representatives	Job Title	Telephone/ Mobile	Email
HSE Environmental Health – Southern Region	Catherine Cosgrove	Regional Chief Environmental Health Officer		
Carlow/ Kilkenny	Richard McGrath	Principal Environmental Health Officer		
Wexford	Paul Harrington	Principal Environmental Health Officer		
Waterford	Siobhan Murphy	Principal Environmental Health Officer		
South Tipperary	Ray Parle	Principal Environmental Health Officer		
North Cork	Bernadine Scanlan	Principal Environmental Health Officer		
West Cork	Geraldine Faughnan	Principal Environmental Health Officer		
North Lee	Kathleen Clifford	Principal Environmental Health Officer		
South Lee	Declan Hamilton	Principal Environmental Health Officer		
Kerry	John Moynihan	Principal Environmental Health Officer		

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Appendix 6. Agency Contact Details
(personal details omitted for online version)

Agency	Representatives	Job Title	Telephone/ Mobile	Email
HSE Western Region	Maurice Mulcahy	Regional Chief Environmental Health Officer		
Donegal	Dan Crowley	Principal Environmental Health Officer		
Sligo/Leitrim	Rita O'Grady	Principal Environmental Health Officer		
Mayo	A/PEHO currently rotating, please contact main number for assistance	Principal Environmental Health Officer		
Roscommon	John Hanily	Principal Environmental Health Officer		
Galway	Shane Keane	Principal Environmental Health Officer		
North Tipperary	Anne Moriarty	Principal Environmental Health Officer		
Limerick	Andrew Curtin	Principal Environmental Health Officer		
Clare	Gerry Leen	Principal Environmental Health Officer		

Note:
Out of Hours: There is no official out of hour's service in the EHS. The Assistant National Director, EHS and the RCEHOs have however agreed to make themselves available as out of hours contact points for emergency matters in their regions.

Appendix 6. Agency Contact Details
(personal details omitted for online version)

HSE NATIONAL REFERENCE LABORATORIES AND FOOD SAFETY LABORATORIES – CONTACT DETAILS

Agency	Representatives	Job Title	Telephone/ Mobile	Email
Public Analyst's Laboratory and Official Food Microbiology Laboratory, Dublin	Vincent Young Rosemary Hayden	Acting Public Analyst & Deputy Public Analyst -Microbiology Deputy Public Analyst - Chemical & Quality Manager		
Public Analyst's Laboratory, Galway	Rory Mannion Padraig Burke	Public Analyst Deputy Public Analyst		
Public Analyst's Laboratory, Cork	Dr Fred Davidson	Public Analyst		
Public Health Laboratory, Cherry Orchard Hospital, and VTEC Clinical Reference Laboratory	Dr Eleanor McNamara	Consultant Microbiologist & Director		
Public Health Microbiology Laboratory, Cork	Dr Dan Corcoran	Consultant Microbiologist		
Public Health Microbiology Laboratory, Galway and National Salmonella Reference Laboratory	Prof Martin Cormican Consultant Microbiologist on call for GUH	Consultant Microbiologist Consultant Microbiologist		
Public Health Laboratory, Waterford	Dr Mary Margaret Hickey	Consultant Microbiologist		
Public Health Laboratory, Limerick	Maureen O'Hara	Chief Medical Scientist		
Public Health Laboratory, Sligo	Dr Fiona Kenny	Consultant Microbiologist		

Appendix 6. Agency Contact Details
(personal details omitted for online version)

LOCAL AUTHORITY COUNTY VETERINARY OFFICERS – CONTACT DETAILS

Agency	Representatives	Job Title	Telephone/ Mobile	Email
Carlow	Anne Maria Brennan	County Veterinary Officer		
Cavan	Michael O'Sullivan	County Veterinary Officer		
Clare	Padraic Flynn	County Veterinary Officer		
Cork	Dan Crowley	County Veterinary Officer		
Donegal	Charlie Kealey	County Veterinary Officer		
Galway	Rita Gately	County Veterinary Officer		
Kerry	Paddy Fenton	County Veterinary Officer		
Kildare	Alan Mooney	County Veterinary Officer		
Kilkenny	Anne Maria Brennan	County Veterinary Officer		
Laois	Ruth Barry	County Veterinary Officer		
Leitrim	James Madden	County Veterinary Officer		
Limerick (City and County)	John McCarthy	County Veterinary Officer		
Longford	Michael King	County Veterinary Officer		
Louth	Garrett Shine	County Veterinary Officer		
Mayo	Cathy Waddel Cathy Gallagher Paul McDermott	County Veterinary Officer County Veterinary Officer County Veterinary Officer		

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Appendix 6. Agency Contact Details
(personal details omitted for online version)

Agency	Representatives	Job Title	Telephone/ Mobile	Email
Meath	John Johnston	County Veterinary Officer		
Monaghan	Brendan Smyth	County Veterinary Officer		
Offaly	Aidan Grant	County Veterinary Officer		
Roscommon	Michael Leyden	County Veterinary Officer		
Sligo	Conall Calleary	County Veterinary Officer		
South Dublin	John Murphy	County Veterinary Officer		
Tipperary	Richard O'Regan	County Veterinary Officer		
Waterford (City and County)	Frances Connolly	County Veterinary Officer		
Westmeath	Sean O'Laoide	County Veterinary Officer		
Wexford	Larry Forristal	County Veterinary Officer		
Wicklow	Ruth Daunt	County Veterinary Officer		

Appendix 7a. OCT Meetings – Sample Terms of Reference, Information Management & Agenda for First Meeting

Sample Terms of Reference

1. Review the evidence and confirm or refute existence of an outbreak; decide whether further investigation is required.
2. Develop a strategy to investigate and control the outbreak, including allocation of tasks to outbreak team members.
3. Assess whether the agencies involved have sufficient local capacity to undertake the outbreak investigation and response, and arrange for additional resources if required.
4. Enhance case finding if necessary by communicating outbreak details to other individuals or agencies.
5. Conduct formal outbreak control meetings on a regular basis.
6. Circulate a meeting agenda. Document and circulate the minutes of each team meeting, agree on allocated tasks with corresponding timeframe.
7. Communicate information to relevant departments/ agencies and to the media and public via a single designated spokesperson if necessary.
8. At the conclusion of the investigation, document the investigation and control measures by way of a formal outbreak investigation report.
9. Declare the outbreak over.
10. Conduct a debrief, if required, to identify strengths and weaknesses of the outbreak investigation process and make recommendations to improve future investigations.

Information Management at OCT meetings

1. The evolving outbreak situation should be captured as the meeting progresses using white boards, flip charts or online meeting tools
2. One person should be assigned responsibility for capturing information as the meeting progresses
3. Information displayed should be clearly visible and legible to all OCT members

Possible Agenda Items for First Meeting of OCT

1. Introductions and teleconference etiquette
   - Assign outbreak control code
2. Urgent information
3. Outbreak update
   - General situation report
   - Case report
   - Epidemiological report
   - Microbiological report
   - Environmental report
   - Other relevant report (veterinarians, toxicologist etc.)
4. Management of outbreak
   - Investigation/Case definition
   - Control measures
   - Care of patients: hospital, community
   - Microbiological aspects: specimens and resources
5. Local or national OCT – scale up required?
6. Agree on content of press releases and press arrangements
7. Advice to public/other stakeholders (see **Appendix 9**)
8. Consider arrangements for enquiries from the public
9. Obtain contact details of all key personnel within and after hours
10. Agree on actions taken
11. Date and time of next meeting

Appendix 7b. OCT Teleconference Etiquette

Teleconference Chair

Ahead of the Teleconference:

- Determine what technology will be needed in the meeting room. The teleconference Chair should be familiar with the features of the system and common troubleshooting strategies
- If necessary, consideration can be given to using technology such as Adobe Connect or GoToWebinar (both of which must be purchased), which allows teleconference participants to participate in a more interactive manner
- In large conference rooms, select technology that has multiple speakers/microphones distributed around the table
- Circulate dial in details as far in advance as possible. Include 'OCT Teleconference Etiquette'
- Inform participants of how to mute/unmute their line
- Include protocol, i.e. email or mobile SMS, on how the teleconference participant should notify the chair if connection problems occur

During the Teleconference:

- Begin precisely on time
- Undertake a round table introduction to ensure that all present can introduce themselves and their affiliation (it is crucial that ALL participants on a teleconference have been identified)
- Run through the rules of engagement and etiquette:
  - Use mute/unmute – phones should only be unmuted when a participant is speaking; they should be muted at all other times
  - Ensure that anyone with urgent news/updates that may potentially influence course/actions of OCT or that, if delayed, may have serious potential clinical/public health implications, can interrupt whenever necessary
  - To remind participants to speak clearly (using the handset if necessary)
  - To ensure that each participant has an equal opportunity to contribute and query
  - To remind participants of the "one speaker at a time" rule and inform them that the Chair will interrupt the group with this reminder, if necessary
  - To introduce any guests
  - To remind participants to introduce themselves when they begin to speak
- It is important that the Chair should not allow:
  - Any group/member to dominate the conversation
  - the teleconference to become sidetracked
- Interruptions should be kept to a minimum; if there is external noise (unmuted mobile phone noise, heavy breathing, typing etc) the Chair should pause the meeting and request that all participants mute their phones

Teleconference Participants

Ahead of the Teleconference:

- Ensure you can mute/unmute phone
- Try to access the teleconference from a land line phone if possible
- Use the handset where possible phone, then mobile, with speaker phone as the least desirable. Speaker phones often produce echoing noise and can be distracting
- If you must access with a mobile phone, consider where you receive the best phone reception and try to be in that location during the call
- If you arrive late, wait for a lull in the conversation before announcing yourself and your affiliation

During the Teleconference:

- Mute your line unless speaking
- Follow the Chair's instructions
- To speak, interject by saying "Through the Chair", and then state your name (and affiliation if speaking for the first time)
- Interject with urgent news if you feel necessary
- Introduce yourself each time before speaking
- Contact the teleconference Chair with any problems beforehand

Appendix 7c. Matrix to Collate and Compare Case Details from Individual Questionnaires

	Case 1	Case 2	Case 3
Name			
DOB			
Address			
Contact No.			
Ill (Yes/No & No. of days)			
Date Onset			
Symptoms			
Stool Sample			
Food 1 (Yes/No)			
Food 2 (Yes/No)			
Food 3 (Yes/No)			
Food 4 (Yes/No)			
Food 5 (Yes/No)			

Appendix 8. Recommended OCT Resources

Confirm availability and access to Incident room if necessary.

Administrative Staff

- Support personnel to make phone calls, answer incoming calls from concerned members of the public, enter data into a database, copy paperwork and other administrative work.

Teleconference/Phones/IT

- Capabilities and equipment for conference calls, *Multiple* phone lines and
- Computers, laptops, software, e.g. data entry, statistical, portable printers, paper, graph paper, pens, clipboards.

Emergency Sampling Kit for Food Business Inspector

Establish, maintain and review or verify inventory regularly (at least twice a year and preferably quarterly), particularly during and after an incident. Replace missing and expired materials and re-sterilise existing equipment.

1. Dedicated insulated sealable cool boxes, Refrigerants, ice packs and segregators, numbered seal tags
2. Food and water sample submission forms
3. Protective clothing – disposable coats and hats
   Packs of sterile latex surgical gloves and masks
4. Swabs and sterile sampling templates
   Sterilisation equipment for sample collection tools and temperature probes
   Sterile sampling bags, wide mouth plastic and glass jars with screw lids, bottles.
   Sterile and wrapped sample–collection implements (spoons, scoops, spatulas, knives)
   Alco-wipes, hand sanitisers (95% ethyl alcohol)
   Numbered tags to tie bags/boxes.
5. Water sample bottles without sodium thiosulphate
   Water sample bottles with sodium thiosulphate
   Chemical sampling bottles – 1 gallon
6. Sample labels, fine point biro pen, roll of adhesive/ masking tape
7. Temperature-checking probes and backups
8. Equipment to determine food characteristics, e.g. pH, water content, sugar content
9. Camera

Clinical Sampling

1. Relevant Laboratory forms, i.e. Public Health Laboratory and Virus Reference Laboratory
2. Stool sampling containers
3. Sterile latex surgical gloves
4. Water resistant envelopes/posting boxes
5. Instructions for providing a stool sample and delivery to a laboratory

Legal Advice

- Legal advice to prepare for legal action and advice on control measures may be necessary

Appendix 9. Stakeholder List (Not Exhaustive)

Official Agencies

- Food and feed agencies (inspectorate/laboratories): Department of Agriculture, Food and the Marine; Health Service Executive; local authorities; Sea-Fisheries Protection Authority; Marine Institute; Customs; Radiological Protection Institute of Ireland; National Standards Authority of Ireland; Loughs Agency

Government Departments

- Department of Health; Department of Agriculture, Food and the Marine; Department of Environment, Community and Local Government

Clinical

- Medical professionals - GPs, hospital consultant microbiologists
- Private food laboratories, public hospital laboratories

Public/Consumer Groups

- National Consumer Agency; Consumer Association of Ireland
- Anaphylaxis Ireland

Media Outlets

- National, regional, trade
- Written, radio, TV, social media – Twitter, facebook etc.

Government Agencies

- *Safe*food; Bord Bia; Teagasc; Irish Medicines Board; Pharmacy regulator; Health Information and Quality Authority

Non-governmental Agencies

- European Food Safety Authority; Food Standards Agency Northern Ireland; Food Standards Agency UK; EU Commission; Universities; Research organisations

Food Industry

- Retail, catering (restaurant, hotel)
- Manufacturing, artisan producers, pharmacies
- IBEC (including Meat Industry Ireland); Associated Craft Butchers of Ireland; distributors; traders
- Small Firms Association

Agriculture

- Irish Farmers Association; Irish Co-operative Organisation Society; National Dairy Council; aquaculture/shellfish; organic certification bodies

Appendix 10. Onset, Duration, and Symptoms of Foodborne Illness and Associated Organism or Toxin*

Approximate onset time to symptoms	Predominant symptoms	Associated organism or toxin
Upper gastrointestinal tract symptoms (nausea, vomiting) occur first or predominate		
Less than 1 h	Nausea, vomiting, unusual taste, burning of mouth.	Metallic salts
1-2 h	Nausea, vomiting, cyanosis, headache, dizziness, dyspnea, trembling, weakness, loss of consciousness.	Nitrites
1-6 h mean 2-4 h	Nausea, vomiting, retching, diarrhea, abdominal pain, prostration.	*Staphylococcus aureus* and its enterotoxins
8-16 h (2-4 h emesis possible)	Vomiting, abdominal cramps, diarrhea, nausea.	*Bacillus cereus*
6-24 h	Nausea, vomiting, diarrhea, thirst, dilation of pupils, collapse, coma.	Amanita species mushrooms
Sore throat and respiratory symptoms occur		
12-72 h	Sore throat, fever, nausea, vomiting, rhinorrhea, sometimes a rash.	*Streptococcus pyogenes*
2-5 days	Inflamed throat and nose, spreading grayish exudate, fever, chills, sore throat, malaise, difficulty in swallowing, edema of cervical lymph node.	*Corynebacterium diphtheriae*
Lower gastrointestinal tract symptoms (abdominal cramps, diarrhea) occur first or predominate		
2-36 h, mean 6-12 h	Abdominal cramps, diarrhea, putrefactive diarrhea associated with *C. perfringens*, sometimes nausea and vomiting.	*Clostridium perfringens, Bacillus cereus, Streptococcus faecalis, S. faecium*
12-74 h, mean 18-36 h	Abdominal cramps, diarrhea, vomiting, fever, chills, malaise, nausea, headache, possible. Sometimes bloody or mucoid diarrhea, cutaneous lesions associated with V. vulnificus. Yersinia enterocolitica mimics flu and acute appendicitis.	*Salmonella* species (including *S. arizonae*), *Shigella*, enteropathogenic *Escherichia coli*, other *Enterobacteriacae*, *Vibrio parahaemolyticus*, *Yersinia enterocolitica*, *Aeromonas hydrophila*, *Plesiomonas shigelloides*, *Campylobacter jejuni*, *Vibrio cholerae* (01 and non-01) *V.vulnificus*, *V. fluvialis*
3-5 days	Diarrhea, fever, vomiting abdominal pain, respiratory symptoms.	Enteric viruses
1-6 weeks	Mucoid diarrhea (fatty stools) abdominal pain, weight loss.	*Giardia lamblia*
1 to several weeks	Abdominal pain, diarrhea, constipation, headache, drowsiness, ulcers, variable -- often asymptomatic.	*Entamoeba histolytica*
3-6 months	Nervousness, insomnia, hunger pains, anorexia, weight loss, abdominal pain, sometimes gastroenteritis.	*Taenia saginata, T. solium*

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Appendix 10. Onset, Duration, and Symptoms of Foodborne Illness and Associated Organism or Toxin*

Approximate onset time to symptoms	Predominant symptoms	Associated organism or toxin
Neurological symptoms (visual disturbances, vertigo, tingling, paralysis) occur		
Less than 1 h	*** SEE GASTROINTESTINAL AND/OR NEUROLOGIC SYMPTOMS (Shellfish Toxins) (this Appendix)	Shellfish toxin
	Gastroenteritis, nervousness, blurred vision, chest pain, cyanosis, twitching, convulsions.	Organic phosphate
	Excessive salivation, perspiration, gastroenteritis, irregular pulse, pupils constricted, asthmatic breathing.	Muscaria-type mushrooms
	Tingling and numbness, dizziness, pallor, gastro-hemmorrhage, and desquamation of skin, fixed eyes, loss of reflexes, twitching, paralysis.	Tetradon (tetrodotoxin) toxins
1-6 h	Tingling and numbness, gastroenteritis, dizziness, dry mouth, muscular aches, dilated pupils, blurred vision, paralysis.	Ciguatera toxin
	Nausea, vomiting, tingling, dizziness, weakness, anorexia, weight loss, confusion.	Chlorinated hydrocarbons
2 h to 6 days, usually 12-36 h	Vertigo, double or blurred vision, loss of reflex to light, difficulty in swallowing. speaking, and breathing, dry mouth, weakness, respiratory paralysis.	*Clostridium botulinum* and its neurotoxins
More than 72 h	Numbness, weakness of legs, spastic paralysis, impairment of vision, blindness, coma.	Organic mercury
	Gastroenteritis, leg pain, ungainly high-stepping gait, foot and wrist drop.	Triorthocresyl phosphate
Allergic symptoms (facial flushing, itching) occur		
Less than 1 h	Headache, dizziness, nausea, vomiting, peppery taste, burning of throat, facial swelling and flushing, stomach pain, itching of skin.	Histamine (scombroid)
	Numbness around mouth, tingling sensation, flushing, dizziness, headache, nausea.	Monosodium glutamate
	Flushing, sensation of warmth, itching, abdominal pain, puffing of face and knees.	Nicotinic acid

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Appendix 10. Onset, Duration, and Symptoms of Foodborne Illness and Associated Organism or Toxin*

Approximate onset time to symptoms	Predominant symptoms	Associated organism or toxin
Generalized infection symptoms (fever, chills, malaise, prostration, aches, swollen lymph nodes) occur		
4-28 days, mean 9 days	Gastroenteritis, fever, edema about eyes, perspiration, muscular pain, chills, prostration, labored breathing.	*Trichinella spiralis*
7-28 days, mean 14 days	Malaise, headache, fever, cough, nausea, vomiting, constipation, abdominal pain, chills, rose spots, bloody stools.	*Salmonella typhi*
10-13 days	Fever, headache, myalgia, rash.	*Toxoplasma gondii*
10-50 days, mean 25-30 days	Fever, malaise, lassitude, anorexia, nausea, abdominal pain, jaundice.	Etiological agent not yet isolated -- probably viral
Varying periods (depends on specific illness)	Fever, chills, head- or joint ache, prostration, malaise, swollen lymph nodes, and other specific symptoms of disease in question.	*Bacillus anthracis, Brucella melitensis, B. abortus, B. suis, Coxiella burnetii, Francisella tularensis, Listeria monocytogenes, Mycobacterium tuberculosis, Mycobacterium species, Pasteurella multocida, Streptobacillus moniliformis, Campylobacter jejuni, Leptospira species.*
Gastrointestinal and/or Neurologic Symptoms - (Shellfish Toxins)		
0.5 to 2 h	Tingling, burning, numbness, drowsiness, incoherent speech, respiratory paralysis	Paralytic Shellfish Poisoning (PSP) (saxitoxins)
2-5 min to 3-4 h	Reversal of hot and cold sensation, tingling; numbness of lips, tongue & throat; muscle aches, dizziness, diarrhea, vomiting	Neurotoxic Shellfish Poisoning (NSP) (brevetoxins)
30 min to 2-3 h	Nausea, vomiting, diarrhea, abdominal pain, chills, fever	Diarrheic Shellfish Poisoning (DSP) (dinophysis toxin, okadaic acid, pectenotoxin, yessotoxin)
24 h (gastrointestinal) to 48 h (neurologic)	Vomiting, diarrhea, abdominal pain, confusion, memory loss, disorientation, seizure, coma	Amnesic Shellfish Poisoning (ASP) (domoic acid)

* From FDA. Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook. January 1992. Available at http://www.fda.gov/downloads/food/foodborneillnesscontaminants/ucm297627.pdf. Accessed November 28, 2008.

Appendix 11. An Aide Memoire for the Inspection of Food Business and Traceback Exercise in an Outbreak

Pre-inspection: File review, prepare equipment: sample kit, camera, enforcement forms, designated officer informed.

Inspection: Two authorised officers to investigate conditions prevailing at and prior to the period when suspect food was produced. All interviews to be carried out in a non-judgmental and non-directive manner to elicit accurate information with use of open questions.

It may be necessary to carry out a full inspection or it may be more appropriate to concentrate on particular areas. The specific activities included in an environmental investigation will differ on the basis of the causative agent, the suspected vehicle, the at-risk population and the setting but usually involves some of the following

Focus on management	✓	Focus on food handlers	✓	Focus on conditions-time of incident	✓	Focus on suspect food	✓
Establish person in charge		Establish language. Interpreter needed?		Other recent complaints		Food flow	
Details of food business operator and business		Contact details of food handlers		Other customers/ functions		Ingredients and suppliers	
Nature and extent of business		Any recent illness? If yes: Recent contact with a sick person, travel abroad, ate suspect food, non-treated water, and contact with pet/ animal.		Diaries, logs: check for: • Change of suppliers • Change from frozen to fresh ingredients • Equipment failures • Water supply failures hot/cold • Change of water supply • Changes to staff roster • New food handlers • Menu changes • Addition of high risk dishes • Power failures • Unusually busy		Records: Transport Delivery Storage Preparation Cooking Cooling procedure Reheating Any other relevant process step Cleaning records	
Layout of premises		Interview food handlers who were on duty at time of incident		Actual staff on duty-not roster		Internal stock control procedures/ traceability	
System of production		Exclusion of ill food handlers		Full menu including specials		Compare actual practices to food safety management system	

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Appendix 11. An Aide Memoire for the Inspection of Food Business and Traceback Exercise in an Outbreak

Focus on management	✓	Focus on food handlers	✓	Focus on conditions-time of incident	✓	Focus on suspect food	✓
Work flow		Any unusual occurrences				Try to obtain samples of actual food implicated	
Pre-requisite programme		Extent of food safety management system training				Review food business operator product recall procedures	
Details of connected premises. Satellite kitchens/ serveries		Extent of food handler training/ evidence of training					
Internal and external deliveries		Observe hand washing, use of gloves, food handling, potential for cross contamination, appearance, cuts and sores					
Water supply-samples?		Knowledge of cleaning procedures					
Drainage							

Now that you have considered all of the above, do you need to take further action?

- Do you need to take food samples (including raw food), swabs, environmental samples?
- Do you need to arrange clinical sampling of food handlers?
- Do you need to take any immediate enforcement action?

Appendix 12. Examples of Cohort and Case Control Studies

Reproduced with the permission of the publisher, from the *Foodborne disease outbreaks: Guidelines for investigation and control*, World Health Organization, 2008. (4.2 Epidemiological Investigations on Analytical epidemiological investigations (pages 28-36)

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Analytical Epidemiological Investigations

Analytical epidemiological studies frequently involve comparisons of the characteristics of a group of well persons with those of ill persons in order to quantify the relationship between specific exposures and the disease under investigation. The two types of analytical studies most commonly used in outbreak investigations are **cohort studies** and **case–control studies**. When investigating outbreaks, a rapid result may be required to assist in control efforts, and it may be advisable to conduct a limited analytical study initially. More thorough investigations can be conducted later, for example, to increase the knowledge of a particular food pathogen.

The value of a comparison group for identifying specific exposures is illustrated by the example of a school outbreak of gastroenteritis, in which 30 cases are identified. Interviewing all 30 cases about their food consumption shows that all ate vanilla ice-cream purchased from a street-vendor one day before illness. Enquiries about consumption of other foods show that no other food item was consumed by as many cases as vanilla ice cream.

Comparing the 30 cases with a group of 60 healthy students from the same school reveals that all the healthy students also ate vanilla ice-cream purchased from the same street-vendor. Comparison of other exposures, however, reveals that most of the 30 cases had lunch in the school canteen the day before illness while most of the healthy students did not. This difference indicates that food from the school canteen is the more likely vehicle for the outbreak than vanilla ice-cream: the finding that all cases had eaten vanilla ice-cream merely reflects its popularity among the students.

Retrospective cohort studies

Retrospective cohort studies are feasible for outbreaks in small, well-defined populations in which all exposed and all non-exposed persons are identifiable. These studies compare the occurrence of disease among those who were exposed to a suspected risk factor with occurrence among those who were not (Box 2, below). For example, all persons attending a wedding reception (the "cohort") may be interviewed to determine whether they became ill after the reception, and to identify what foods and drinks they had consumed. After collecting information from each attendee, attack rates for illness are calculated for those who ate a particular food and for those who did not eat that food (see Table 4).

TABLE 4. COHORT STUDY

Exposure	Ill	Not Ill	Total	Attack rate
Ate food "A"	48	20	68	71%
Did not eat food "A"	2	100	102	2%
Total	50	120	170	29%

In this example, of a total of 68 persons who ate food "A", 48 fell ill (attack rate 48/68 or 71%). The attack rate for those who did not eat food "A" was 2/102 or 2%. Food "A" is a likely risk factor for illness because:

- The attack rate is high among those exposed to food "A" (71%)
- The attack rate is low among those not exposed to food "A" (2%), so the difference (risk difference) between the two attack rates is high (69%);
- Most cases (48/50 or 96%) were exposed to food "A"

Appendix 12. Examples of Cohort and Case Control Studies

In addition, a ratio of the two attack rates, known as the *relative risk* (RR), can be calculated in the following way:

$$\text{Relative risk (RR)} = \frac{\text{Attack rate for those who ate food "A"}}{\text{Attack rate for those who did not eat food "A"}} = \frac{71\%}{2\%} = 35.5$$

A relative risk has no units and is a measure of the strength of association between the exposure and the disease. In the above example, the relative risk associated with eating food "A" is 35.5. This means that persons who ate food "A" were 35.5 times more likely to develop disease than those who did not. Statistical significance tests are used to determine the probability that this relative risk could have occurred by chance alone. For information about statistical significance testing, see Annex 7.

Case–control study

In many circumstances, no clearly defined "cohort" of all exposed and non-exposed persons can be identified or interviewed. In such situations – when cases have already been identified during a descriptive study and information has been gathered from them in a systematic way – a case–control study can be an efficient study design (Box 3, below).

In a case–control study, the distribution of exposures among cases and a group of healthy persons ("controls") are compared with each other (see Table 5). The questionnaire used for the controls is identical to that administered to the cases, except that questions about the details of clinical illness my not pertain to the controls.

TABLE 5. CASE-CONTROL STUDY

Exposure	Cases	Controls	Total
Ate food "A"	48	20	68
Did not eat food "A"	2	100	102
	50	120	170
Percentage exposed	96%	17%	40%

In this example, 96% of all cases had consumed food "A" compared with only 17% of the controls. This suggests that consumption of food "A" is associated with illness in one way or another. In contrast to a cohort study, attack rates (and therefore relative risk) cannot be calculated since the total number of persons at risk is unknown. Instead, a different measure of association – *odds ratio* (OR) – is used in case-control studies. The odds ratio is calculated as the "cross-product" of a two-by-two table (see Table 6).

TABLE 6. EXAMPLE OF A TWO-BY-TWO-TABLE FROM A CASE-CONTROL STUDY

Exposure	Cases	Controls	Total
Ate food "A"	48 X	20	54
Did not eat food "A"	2	100	21
Total	46	29	75

$$\text{Odds ratio} = \frac{(48 \times 100)}{(20 \times 2)} = 120$$

Chi-square 92.6, *p*-value $<\tilde{6}10^{-22}$

The odds ratio is calculated as the cross-product from a two-by-two table (the number of cases exposed times the number of controls not exposed, divided by the number of controls exposed times the number of cases not exposed). For rare conditions (i.e. less than 5% in the general population are affected), the odds ratio is a good estimate of the relative risk. Thus, in this example, an exposure odds ratio of 120 for food "A" can be interpreted as: the odds of having been exposed to the contaminated food in those who developed the disease was 120 times that of people who did not eat food "A". This odds ratio means that there is a very strong association between being a case and consumption of food "A". As in a cohort study, statistical significance can be calculated to determine the probability that such an odds ratio could have occurred by chance alone. For the example above, this probability is extremely small ($1/\tilde{6}10^{22}$). Box 3 (below) gives a calculated example of a case-control study.

Appendix 12. Examples of Cohort and Case Control Studies

Choosing controls

An important decision in the design of a case-control study is defining who should be the controls. Conceptually, controls must not have the disease in question but should represent the population from which the cases come. In this way, controls provide the level of background exposure that might be expected among cases. If cases have a much higher exposure than controls, exposure may be associated with disease.

Often it is difficult to know who the controls should be. Practical matters need to be taken into consideration, such as how to contact potential controls rapidly, gain their permission, ensure that they are free of the disease under investigation (and not just asymptomatic), and get appropriate exposure data from them. In a community outbreak, a random sample of the healthy population may be the best control group. Sometimes such community controls are identified by visits to randomly selected homes in the community of interest or by telephone calls to randomly selected telephone numbers within the area.

Other common control groups consist of:

- neighbours of cases;
- patients from the same physician practice or hospital who do not have the disease in question;
- family members or friends of cases;
- people who attended an implicated event but did not become ill
- people who ate at an implicated food service facility during the time of exposure but did not become ill.

While controls from these groups may be more likely to participate in the study than randomly identified population-based controls, they may not be as representative of the population. This kind of bias in the control group can distort the data in either direction masking an association between the exposure and disease or producing a spurious association between an innocent exposure and disease. However a group of controls is chosen substantial efforts should be made to interview all those selected. Making only a single attempt to contact randomly selected controls, for example, could result in a biased sample of people who are most likely to be available at a certain time of the day rather than being representative of the entire population of interest.

When designing a case-control study, the number of controls must be considered. While the number of cases is limited by the size of the outbreak the number of potential controls will usually be greater than is needed. In general, the more subjects are included in a study, the easier it will be to find a statistical association between exposure and disease.

In an outbreak of 50 or more cases, one control per case will usually suffice. In smaller outbreaks, two, three or four controls per case can be used. Increasing the number of controls beyond four per case, however, will rarely be worth the effort.

Appendix 12. Examples of Cohort and Case Control Studies

Box 2. Example of a cohort study[1]

Table A is based on an outbreak of gastroenteritis following a church supper. Of the 80 persons attending the supper, 75 were interviewed. Forty-six met the case definition. Attack rates were calculated for those who did and did not eat each of the 14 food items.

TABLE A. ATTACK RATES BY FOOD ITEMS SERVED AT CHURCH SUPPER, OSWEGO, NEW YORK, APRIL 1940

	Number of persons who ate food item			Number of persons who did not eat food item		
	Ill	**Total**	**Attack rate (%)**	**Ill**	**Total**	**Attack rate (%)**
Baked ham	29	46	63	17	29	59
Spinach	26	43	60	20	32	62
Mashed potatoes	23	37	62	23	37	62
Cabbage salad	18	28	64	28	47	60
Jello	16	23	70	30	52	58
Rolls	21	37	57	25	38	66
Brown bread	18	27	67	28	48	58
Milk	2	4	50	44	71	62
Coffee	19	31	61	27	44	61
Water	13	24	54	33	51	65
Cakes	27	40	67	19	35	54
Vanilla ice cream	43	54	80	3	21	14
Choc. ice cream*	25	47	53	20	27	74
Fruit salad	4	6	67	42	69	61

* Excludes one person who was unsure of consumption.

Looking at this table the most likely vehicle is vanilla ice cream. It has the highest attack rate (80%) for those who ate vanilla ice cream and the lowest for those who did not. Forty-three of the 47 cases can be "explained" by having eaten vanilla ice cream. The attack rates for the other 13 food items do not display the same characteristics.

Table B shows the same data for vanilla ice cream in the format of a two-by-two table which makes the calculation of attack rates, relative risks and statistical significance easier to visualize:

TABLE B. TWO-BY-TWO-TABLE FOR CONSUMPTION OF VANILLA ICE CREAM (COHORT STUDY)

Exposure	Ill	Well	Total	Attack rate
Ate Vanilla Ice cream	43	11	54	79.6%
Did not eat Vanilla Ice cream	3	18	21	14.3%
Total	46	29	75	61.3%

RR = 79.6/14.3 = 5.6

The relative risk (RR) for eating vanilla ice cream is 79.6/14.3 or 5.6. This means that persons who ate vanilla ice cream were 5.6 times more likely to become ill than those who did not.

To determine the probability that the relative risk of 5.6 could have occurred by chance alone a statistical significance test can be calculated. This shows that the probability of obtaining a relative risk of 5.6 or even higher is 1/5 000 000 and therefore very unlikely to have occurred by chance alone. For details of how this calculation was obtained see Annex 7. [WHO Guidelines]

[1] Source: Reproduced with permission of the publisher, from Goss, 1976.

Appendix 12. Examples of Cohort and Case Control Studies

Box 3. Example of a case-control study[1]

TABLE A. ODDS RATIOS FOR EXPOSURE TO FOODS SERVED IN HOSPITAL "X", DUBLIN, IRELAND, 1996[a]

	Number of persons who ate food item		Number of persons who did not eat food item		Odds ratio
	Ate	**Did not eat**	**Ate**	**Did not eat**	
French onion soup	8	51	15	45	0.47
Baked ham	21	37	18	42	1.32
Parsley sauce	18	40	15	45	1.35
Cold salads	5	54	8	52	0.60
Creamed potatoes	23	35	23	35	1.00
Turnips and cabbage	30	29	21	38	1.87
Chicken curry rice	15	44	7	53	2.58
Sandwiches	6	53	3	56	2.11
Danish pastries	1	58	6	53	0.15
Chocolate mousse cake	42	16	5	53	27.83
Ice cream	10	48	16	43	0.56
Scones	1	58	4	56	0.24

[a] Persons who were uncertain about consumption of a particular food item are excluded.

Table A is based on a salmonellosis outbreak in a hospital. Sixty-five patients and staff members met the case definition. Their exposures to specified foods were compared to those of 62 healthy patients and staff members. To determine the most likely vehicle of the outbreak, odds ratios were calculated for a total 56 food items served during breakfast, lunch and dinner over a three day period (Table A shows only food items served during one lunch). The highest odds ratio was found for consumption of chocolate mousse cake.

TABLE B. TWO-BY-TWO TABLE FOR CONSUMPTION OF CHOCOLATE MOUSSE CAKE (CASE CONTROL STUDY)

Exposure	Ill	Well	Total	Attack rate %
Ate chocolate mousse cake	42	5	47	47
Did not eat chocolate mousse cake	16	53	69	69
Total	58	58	115	115

$$\text{Odds ratio (OR)} = \frac{(42 \times 53)}{(5 \times 16)} = 27.8$$

The odds ratio for being exposed to chocolate mousse cake was 27.8. As salmonellosis is infrequent in the general population (and even in hospital) this odds ratio can be taken as a relative risk estimate, i.e. the risk of developing illness was much higher among persons who ate chocolate mousse cake than among those who did not.

[1] Source: Reproduced with permission of the publisher, from Grein et al., 1997.

Appendix 12. Examples of Cohort and Case Control Studies

Dose response

A dose response is present if the risk of illness increases with increasing amount or duration of exposure. For example, if individuals who ate two portions of a stew were more likely to become ill than people who ate only one portion, this would suggest a "dose response". Finding a dose response supports the hypothesis that a particular exposure caused illness.

Looking for a dose response is particularly important in outbreaks where cases and the comparison group (i.e. controls in case–control studies and unaffected persons in cohort studies) were exposed to the same risk factors. When the entire study population has been exposed to the same risk factors, demonstrating a dose response can be particularly helpful in assessing a situation.

Careful attention to study design is important to ensure that dose response can be evaluated. The first and most important step in looking for a dose response is to include questions about exposure levels in the questionnaire (e.g. how often or how much of a food was eaten). Once data on exposure levels have been collected, odds ratios (in case-control studies) or relative risks (in cohort studies) are calculated for each level of exposure and compared with the unexposed group or the group with the lowest exposure (the "reference" group). Statistical tests such as the chi-square test for trend can be employed to assess the statistical significance of the dose response. Table 7 gives an example of a dose-response calculation for a case control study, in which people eating more than 12 oysters were much more likely to become ill than people eating 7 to 12 oysters, who in turn were more likely to become ill than those eating fewer than 7 oysters.

TABLE 7. NUMBER OF OYSTERS EATEN AMONG OYSTER-EATING PATIENTS AND CONTROLS, HEPATITIS A OUTBREAK, FLORIDA, 1988

	Cases (*n* = 51)		Controls (*n* = 33)		Odds ratio
	Number	**Percentage**	**Number**	**Percentage**	
1 to 6	6	12	18	55	1.0 (reference)
7 to 12	20	39	11	33	5.5
>12	25	49	4	12	18.8

[a] Source: Reproduced with permission of the publisher, from Desenclos et al., 1991.

Chi-square for trend 20.0, $p < 0.001$

This chi-square value indicates that there is less than a 1 in 1000 chance that the increased odds of becoming ill after eating a larger quantity of oysters could be due to chance alone.

Table 8 gives an example of a similar calculation for a cohort study in which illness was increasingly likely among persons eating more éclairs.

TABLE 8. NUMBER OF ÉCLAIRS EATEN AMONG SPORT DAY ATTENDEES, THAILAND, 1995[a]

Pieces of éclair eaten	Number Ill	Total Number	Attack rate	Relative risk
0	15	285	5.3	1.0 (reference)
0.5 to 1	51	105	48.6	9.2
2 to 4	299	524	57.1	10.7
>4	105	171	61.4	11.6

[a] Source: Thaikruea et al., 1995.

Additional information on these and other topics pertaining to epidemiological and statistical aspects of investigating outbreaks is available free of charge on the internet (WHO, 2002; Dicker, 1992).

Appendix 13. A Template for an Outbreak Control Team Report

1. Introduction

A brief summary of the outbreak and setting the scene

2. Background

Optional section depending on the outbreak and implicated organism(s). If uncommon pathogen implicated, give brief description of clinical features, incubation period, infectious dose, source and modes of spread, diagnosis and treatment, etc. Also give background prevalence of the disease locally, nationally and globally if relevant.

3. Investigation of the Outbreak

3.1 Epidemiological

(i) Descriptive: description of initial cases, case definition and hypothesis generation, enhanced surveillance

(ii) Analytical: case control and/or cohort studies.

3.2 Environmental, e.g. food, water, risk assessment of production and distribution including food chain etc., staff interviews

3.3 Microbiological/Toxicological local labs, reference labs etc., clinical, food/water and environmental samples

4. Results

4.1 Epidemiological

4.2 Environmental

4.3 Microbiological

5. Control Measures

5.1 Overall co-ordination and management of the outbreak

5.2 Care of cases

5.3 Prevention of further cases (primary and secondary spread)

5.4 Public information

5.5 Information to professionals/businesses etc.

5.6 Outline of food safety enforcement action

6. Discussion and Conclusion

7. Lessons Learned and Recommendation

Bibliography and Acknowledgements

In this document extensive reference has been made to the following documents:

- Atlanta: Council of State and territorial Epidemiologists, 2009. Council to Improve Foodborne Outbreak Response.
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