

# **Manual for reporting on food-borne outbreaks in accordance with Directive 2003/99/EC for information deriving from the year 2015**

## **European Food Safety Authority**

### **Abstract**

This manual provides specific guidance for reporting on food-borne outbreaks under the framework of Directive 2003/99/EC. It is based on the reporting format described in the European Food Safety Authority (EFSA) report on 'Updated technical specifications for harmonised reporting of food-borne outbreaks through the European Union reporting system in accordance with Directive 2003/99/EC'. The objective is to harmonise and streamline the reporting to EFSA by the Member States (MSs). The manual includes the definitions used for reporting food-borne outbreaks data and the variables to be reported. It provides guidance with some examples on how to report and classify the causative agents, food vehicles implicated, places of exposure, places of origin of problem and the contributory factors.

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**Key words:** food-borne outbreak, reporting system, causative agent, food vehicle, strength of evidence

**Requestor:** European Food Safety Authority

**Question number:** EFSA-Q-2015-00660

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**Acknowledgements:** EFSA wishes to thank EFSA staff members: Giusi Amore, Valentina Rizzi, Doreen Dolores Russell and Anca-Violeta Stoicescu for the support provided to this output.

**Suggested citation:** EFSA (European Food Safety Authority), 2016. Manual for reporting on food-borne outbreaks in accordance with Directive 2003/99/EC for information deriving from the year 2015. EFSA supporting publication 2016:EN-989. 43 pp.

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## Summary

This manual provides specific guidance for reporting on food-borne outbreaks under the framework of Directive 2003/99/EC. It is based on the reporting format described in the report on 'Updated technical specifications for harmonised reporting of food-borne outbreaks through the European Union reporting system in accordance with Directive 2003/99/EC'. The manual is intended to be used when reporting data through the Data Collection Framework (DCF) run by the European Food Safety Authority (EFSA).

The manual includes the definitions used for reporting food-borne outbreaks data and the variables to be reported. It provides guidance with some examples on how to report and classify the causative agents, food vehicles, places of exposures, places of origin of problem and the contributory factors.

The distinction between food-borne outbreaks, based on the strength of evidence implicating a particular suspected food vehicle, is specifically addressed and the data to be reported for the two types of outbreaks (food-borne outbreaks supported by 'weak' evidence and food-borne outbreaks supported by 'strong' evidence) is explained.

In 2014, EFSA revised the European Union Food-borne Outbreak Reporting System (EU-FORS). In the updated EU-FORS, information from all food-borne outbreaks is collected and the same dataset is used for both strong- and weak-evidence outbreaks.

The same dataset is used for food-borne outbreaks in which no particular food vehicle is suspected and for food-borne outbreaks in which the evidence implicating a particular food vehicle is either weak or strong. This dataset includes the number of outbreaks, as well as the number of human cases, hospitalisations and deaths, per causative agent. In addition, other information can be reported, including data on causative agents, food vehicles and the factors in food preparation and handling that contributed to the food-borne outbreaks. Member States (MSs) can also report information on the nature of the evidence supporting the suspicion of the food vehicle. This evidence can be epidemiological, microbiological, descriptive environmental or based on product-tracing investigations.

Strong epidemiological evidence includes statistical associations in well-conducted analytical epidemiological studies or convincing descriptive evidence. Product-tracing includes investigating the movement of a food product and its constituents through the stages of production, processing and distribution. Microbiological evidence includes the detection of the causative agent in the food vehicle or its component and the detection of the causative agent in the food chain or from the preparation or processing environment. Microbiological evidence has to be combined with detection of the causative agent from the human cases or symptoms in the human cases that are pathognomonic to the causative agent. Descriptive environmental evidence alone is almost invariably weak.

This manual is specifically aimed at MSs data providers to guide the reporting of the information deriving from the year 2015.

## Table of contents

Abstract.....	1
Summary.....	3
Table of contents .....	4
1. Introduction .....	5
1.1. Background and Terms of Reference as provided by EFSA .....	5
1.2. Monitoring of zoonoses, antimicrobial resistance and food-borne outbreaks .....	6
2. Structure of the food-borne outbreak reporting .....	7
3. Outbreaks to be reported .....	7
4. Definitions.....	7
5. The nature and strength of evidence .....	9
6. Data reporting.....	9
6.1. National reporting system description (to be reported in the text form data model) .....	11
6.1.1. System in place for identification, epidemiological investigation and reporting of food-borne outbreaks .....	11
6.1.2. Description of the types of outbreaks covered by the reporting .....	11
6.2. National evaluation of the reported food-borne outbreaks (to be reported in the text form data model) .....	11
6.2.1. Trends in numbers of outbreaks and numbers of human cases involved .....	12
6.2.2. Relevance of the different causative agents, food categories and the agent/food category combinations .....	12
6.2.3. Relevance of the different types of places of food production and preparation in outbreaks ...	12
6.2.4. Evaluation of the severity and clinical picture of the human cases .....	12
6.2.5. Descriptions of single outbreaks of special interest.....	12
6.2.6. Control measures or other actions taken to improve the situation .....	12
6.2.7. Suggestions to the community for the actions to be taken .....	13
6.2.8. Additional information .....	13
6.3. Detailed dataset on food-borne outbreaks (to be reported in the food-borne outbreaks data model) .....	13
References.....	15
Abbreviations .....	16
Appendix A – Catalogues .....	17
Appendix B – Further guidance on the variables to be reported.....	20
Appendix C – Examples of convincing descriptive epidemiological evidence and evidence from product-tracing investigations .....	26
Appendix D – Explanation of the catalogues.....	29

## 1. Introduction

### 1.1. Background and Terms of Reference as provided by EFSA<sup>1</sup>

Directive 2003/99/EC<sup>2</sup> lays down the European Union (EU) system for monitoring and reporting of information on zoonoses, which obligates Member States (MSs) to collect data on zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks. EFSA is assigned the tasks of examining the data collected and preparing the EU Summary Reports in collaboration with the European Centre for Disease Prevention and Control (ECDC).

Based on the data reported each year, EFSA and ECDC will jointly produce an annual EU Summary Report (SR) on zoonoses, zoonotic agents and food-borne outbreaks. Similarly, the two agencies will produce a EUSR on antimicrobial resistance. To support the MSs in their reporting, the existing reporting manuals for zoonoses, antimicrobial resistance and food-borne outbreaks need to be updated to take into account the latest recommendations on reporting of antimicrobial resistance data and data on zoonoses and food-borne outbreaks. In addition, the manuals have to be revised as a result of changes in the relevant EU legislation.

The Data Collection Framework (DCF) is the only system for submitting data in XML/Excel format to EFSA. New XML reporting schemas are created before the start of the reporting period in April each year. This is supported by revised guidance documents.

The BIOCONTAM and DATA units are invited to:

- prepare and publish the EUSR on Zoonoses, Zoonotic agents and Food-borne Outbreaks in close collaboration with ECDC;
- prepare and publish the EU Summary Report on Antimicrobial Resistance in close collaboration with ECDC;
- revise the manual for reporting on zoonoses, zoonotic agents and antimicrobial resistance each year, and publish it as an EFSA technical report;
- revise the manual for reporting on food-borne outbreaks when appropriate, and publish it as an EFSA technical report;
- revise the guidelines (data dictionaries) for XML/Excel data reporting each year and publish them as an EFSA technical report.

This technical report specifically addresses the fourth term of reference above: revise the manual for reporting on food-borne outbreaks when appropriate, and publish it as an EFSA technical report.

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<sup>1</sup> Available online: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?mandate=M-2015-0231>

<sup>2</sup> Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. OJ L 325, 12.12.2003, p. 31–40.

## 1.2. Monitoring of zoonoses, antimicrobial resistance and food-borne outbreaks

Many MSs operate human communicable disease surveillance systems in the public health sector, which include food-borne diseases, whereas veterinary and food safety authorities have traditionally concentrated on food safety aspects.

Therefore, monitoring of food-borne outbreaks is of common interest to both food authorities and human health authorities in the MSs as well as to EFSA and ECDC at EU level.

Thus, the development of the food-borne outbreak reporting system should be undertaken in close collaboration between food authorities and human health authorities.

Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents (Zoonoses Directive) requires MSs to provide the European Commission (EC) with a report on the results of the investigations of food-borne outbreaks, which is sent to the EFSA. The Directive addresses the epidemiological investigation and reporting of food-borne outbreaks in the MSs of the EU. Thorough investigation of food-borne outbreaks aims to identify the causative agent, the implicated food and the factors in the food preparation and handling contributing to the outbreak.

Data on food-borne outbreaks to be collected through the EU reporting system include both mandatory and optional information. The mandatory information that MSs should submit annually on the results of investigations into food-borne outbreaks is laid down in Annex IV (E) to Directive 2003/99/EC as follows:

- total number of outbreaks over a year;
- number of human deaths and illnesses in these outbreaks;
- the causative agents of the outbreaks, including, where possible, serotype or other definitive description of the causative agents (where the identification of the agent is not possible, the reason for this should be stated);
- foods implicated in the outbreak;
- identification of the type of place where the incriminated foodstuff was produced/purchased/acquired/consumed;
- contributory factors, for example deficiencies in food processing hygiene.

In 2006, in order to provide harmonised reporting specifications for food-borne outbreaks in the EU, EFSA, in collaboration with ECDC, set up a shared working group to prepare a proposal for guidance in this regard.

The proposed harmonised reporting specifications were adopted on 8 November 2007 by the former Task Force on Zoonoses Data Collection and published as a report on harmonising the reporting of food-borne outbreaks through the Community reporting system in accordance with Directive 2003/99/EC (EFSA, 2007).

The reporting scheme was originally known as the Community Outbreak Reporting System (CORS) and was implemented for the first time in the reporting of data in 2007, and subsequently for the reporting of 2008 and 2009 data. From the experience gained during these reporting years, the need to make some adjustments to the reporting system has been identified. Updated technical specifications for harmonised reporting of food-borne outbreaks were published in 2011 (EFSA, 2011). The current system is now known as the European Union Food-borne Outbreak Reporting System (EU-FORS) and was implemented for the first time in the reporting of data in 2010, and subsequently for the reporting of 2011 and 2012 data.

With the EU-FORS, published in 2011, the distinction between 'verified' and 'possible' food-borne outbreaks was abandoned and outbreaks were classified as either strong- or weak-evidence outbreaks based on the evidence implicating a suspect food vehicle.

EU-FORS invited detailed reporting for strong-evidence food-borne outbreaks only, as only data from such outbreaks were intended to be analysed in detail and used in risk assessments. For weak-evidence food-borne outbreaks, only a limited dataset was requested.

Based on the experience gained, MSs identified further need for fine-tuning and clarifying the reporting specifications. In particular, MSs suggested that it would be helpful to provide a more detailed dataset on those food-borne outbreaks supported by weak evidence. Therefore, EFSA reinstated the previous Working Group (WG) which drew the technical specification for EU-FORS in 2011. The outcome of this WG, the revision of reporting specifications for food-borne outbreaks in the EU, was published in March 2014 (EFSA, 2014).

The objective of this manual is to provide MSs with clear guidance on what to report, how to report and why.

## 2. Structure of the food-borne outbreak reporting

Information on food-borne outbreaks can only be submitted electronically through the Data Collection Framework (DCF).

The national food-borne outbreak report is divided into three sections:

- national reporting system description to be reported in the text form data model
- national evaluation of the reported food-borne outbreaks to be reported in the text form data model
- datasets on outbreaks (**the same dataset is used for both strong- and weak-evidence outbreaks**) to be reported in the food-borne outbreak data model

The variables that MSs should report under these headings are described in detail in Section 6, with further guidance in Appendix B.

## 3. Outbreaks to be reported

The reporting system covers all the food-borne outbreaks (as defined in the Zoonoses Directive and in Section 4) occurring in MSs, including those caused by any virus, bacterium, alga, fungus, parasite and their products, such as toxins and biological amines (e.g. histamine), not just zoonotic agents.

Outbreaks caused by ingestion of drinking water are also deemed food-borne since drinking water is defined as a food in Regulation 178/2002/EC.<sup>3</sup>

Food-borne outbreaks caused by chemical agents other than toxins and biological amines produced by microorganisms are not included.

## 4. Definitions

For the purpose of data reporting of food-borne outbreaks, the following definitions apply:

**Analytical epidemiological evidence:** a statistically significant association between consumption of a foodstuff and being a case in an analytical epidemiological study (e.g. cohort or case-control study).

**Causative agent:** the pathogen or its product, such as a toxin or bioactive amine, considered to be the cause of the food-borne outbreak.

**Contributory factor:** fault or circumstance that singly or in combination led to the food-borne outbreak.

**Descriptive environmental evidence:** e.g. evidence from food hygiene inspections.

**Descriptive epidemiological evidence:** suspicion of a food vehicle in an outbreak based on the identification of common food exposures, from the systematic evaluation of cases and their

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<sup>3</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1/2/2002, p. 1–24.

characteristics and food histories over the likely incubation period by standardised means (such as standard questionnaires) from all, or an appropriate subset of, cases.

**Detection in a food vehicle or its component:** identification of the causative agent in a food vehicle or its component taken in the course of the investigation.

**Detection in food chain or its environment:** identification of the causative agent in samples taken from the preparation or processing environment of the suspected food vehicle, or from batches of similar foodstuffs produced under the same conditions or in primary production where the suspected food vehicle originated.

**Detection in human cases:** direct (e.g. culture) or indirect (e.g. serological) identification of the causative agent in clinical samples taken from outbreak cases.

**Epidemiological evidence:** analytical or descriptive epidemiological evidence.

**Extent of outbreak:** outbreaks are either 'General' or 'Household'.

**Food-borne outbreak:** 'an incidence, observed under given circumstances, of two or more human cases of the same disease and/or infection, or a situation in which the observed number of human cases exceeds the expected number and where the cases are linked, or are probably linked, to the same food source' (Directive 2003/99/EC).

**Food (or foodstuff):** any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans (Regulation (EC) No 178/2002). This definition also includes drinking water and covers single food items as well as composite meals.

**Food vehicle:** food (or foodstuff) that is suspected of causing human cases.

**General outbreak:** outbreak involving human cases from more than one household. Outbreaks in residential homes (e.g. nursing homes), schools and other similar institutions are considered to be general outbreaks.

**Household outbreak:** outbreak where all the human cases live in one single household.

**Indistinguishable causative agent:** causative agent that has been characterised to the level (of speciation/sub-typing (e.g. sero-/phage-/ribotyping), or molecular typing) needed to link the human cases to each other and to the food vehicle.

**Microbiological evidence:** detection of a causative agent in a food vehicle or its component or in the food chain or its environment combined with detection in human cases, or clinical symptoms and an onset of illness in outbreak cases strongly indicative/pathognomonic to the causative agent identified in the food vehicle or its component or in the food chain or its environment.

**(Outbreak) case:** Person involved in the outbreak as defined by the investigators. This can include both ill people (whether or not disease is confirmed microbiologically) and people with confirmed asymptomatic infections. Case definitions for human cases for most common zoonotic infections established by ECDC may be used as guidance (available online: [www.ecdc.europa.eu](http://www.ecdc.europa.eu)). Exposure should not be part of a case definition.

**Place of exposure:** this is the location ('setting') where the food was consumed or where the final stages of preparation of the food vehicle took place (e.g. café/restaurant, institution, home, take-away outlet).

**Place of origin of problem:** place where the contributory factors occurred.

**Product-tracing investigation:** investigation to follow the movement of a food product and its constituents through the stages of production, processing and distribution, both backward and forward. Trace-back is the ability to trace a food product from the point of sale back to the source (ultimately the farm). Conversely, trace-forward is the ability to trace a food product from the source (ultimately the farm) forward to the point of sale. Product tracing may encompass trace-back and trace-forward.



## 5. The nature and strength of evidence

The nature of evidence linking the consumption of a particular food to an outbreak case can be epidemiological, microbiological, descriptive environmental or based on product-tracing investigations. The nature of evidence is not necessarily correlated with its strength.

Epidemiological evidence (whether descriptive or analytical) can be strong or weak—although good analytical evidence (e.g. a statistically significant association between exposure and being a case in a well-designed study) is superior to evidence from the systematic evaluation of cases' food histories.

Similarly microbiological evidence can be strong (for example if an indistinguishable causative agent is identified in an outbreak case and from an unopened packet of a foodstuff of a type eaten by a case) or weak (if a causative agent is identified in a case and from an open packet of a foodstuff eaten by a case in their home which could have been contaminated from another source).

Product-tracing investigations may provide strong or weak evidence depending on the nature of the investigation.

Descriptive environmental evidence alone is almost invariably weak evidence.

The strength of the evidence related to an outbreak to be reported at EU level should be based on a carefully considered assessment of all available categories of evidence.

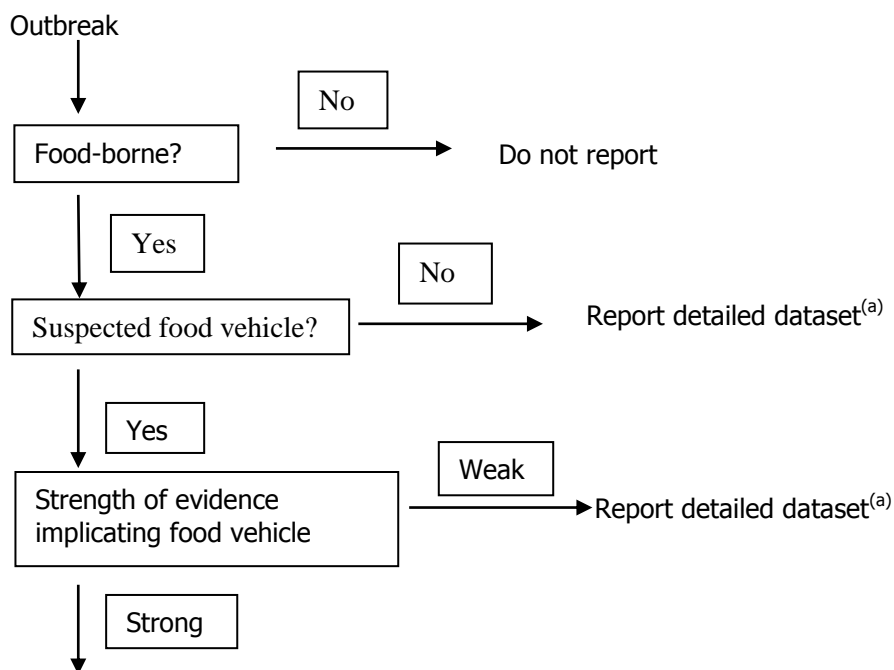
As a guide:

- 1) Strong epidemiological evidence is a statistically significant association in a well-conducted analytical epidemiological study, or convincing descriptive evidence. Examples of convincing descriptive epidemiological evidence are provided in Appendix C.
- 2) Strong microbiological evidence is the identification of an indistinguishable causative agent in a human case and in a food, a food component, or its environment which is unlikely to have been contaminated coincidentally, or after the event, or the identification of a causative agent, such as a toxin or bio-active amine, in the food vehicle, in combination with strongly indicative clinical symptoms and an onset of illness in outbreak cases strongly indicative/pathognomonic to the causative agent.
- 3) Comprehensive product-tracing investigation can provide strong evidence in case a common point along the food-production and distribution chain is identified for all or a large proportion of cases that were exposed and for whom a place of exposure/point of sale could be identified. Examples are given in Appendix C.

Prior plausibility in a food-borne outbreak is the body of evidence pointing to a food vehicle which is available before the investigation of the outbreak under consideration and consists of the evidence from previous outbreaks and studies. Prior plausibility alone does not constitute sufficient evidence to implicate a food vehicle for policy making and therefore data on food-borne outbreaks supported by only prior plausibility should always be deemed 'weak' at EU level. However, this is not to say that it might not be valuable in informing immediate control measures at local or MS level. The use of prior plausibility to inform immediate control is the health protection equivalent of 'profiling'. However, to use prior plausibility for policymaking would be the equivalent of prejudice.

## 6. Data reporting

Figure 1 shows a general scheme for reporting of food-borne outbreaks according with the updated EU-FORS. No information is required for outbreaks which are not deemed to be food-borne. A detailed dataset can be provided for those outbreaks deemed to be food-borne in which no particular food vehicle is suspected, or in which the evidence implicating a food vehicle is weak. For those outbreaks in which the evidence implicating a food vehicle is strong, a detailed dataset should be provided. Thus, in the updated EU-FORS, information from all food-borne outbreaks is collected and the same dataset is used for both strong- and weak-evidence outbreaks.



Report detailed dataset

(a): Within the updated EU-FORS, generic terms (e.g. unknown, none) have been added to overcome problems regarding data availability for food-borne outbreaks where either no particular food vehicle is suspected/identified or where the evidence implicating a particular food vehicle is weak.

**Figure 1:** Scheme for reporting of food-borne outbreaks to the updated European Union Food-borne Outbreak Reporting System (updated EU-FORS)

In the updated EU-FORS, the term ‘food vehicle’ is used throughout since this is the food source most immediate for consumers and, therefore, of specific interest. Other aspects of the food source can be captured by the variables ‘more food vehicle information’, ‘place of origin of the problem’ and ‘origin of food vehicle’, where more detailed information on sources of the food implicated can be reported.

The main differences between reporting of food-borne outbreaks in the previous systems (CORS and the original EU-FORS) and the updated EU-FORS are presented in Table 1.

**Table 1:** Main differences between the old and the updated food-borne outbreak reporting systems with respect to outbreaks for which a limited or a detailed dataset should be reported

Evidence type	CORS	EU-FORS Strength of evidence <sup>(a)</sup>		Updated EU-FORS Strength of evidence <sup>(a)</sup> weak/strong
		weak	strong	
Analytical epidemiological evidence	DE (verified outbreak)	LI	DE	DE <sup>(b)</sup>
Descriptive epidemiological evidence	LI (possible outbreak)	LI	DE	DE <sup>(b)</sup>
Product-tracing investigations	NA		NA	DE <sup>(b)</sup>
Microbiological evidence				DE <sup>(b)</sup>
- Detection in food vehicle	DE (verified outbreak)	LI	DE	DE <sup>(b)</sup>
- Detection in food vehicle’s component or in food chain or its environment	LI (possible outbreak)	LI	DE	DE <sup>(b)</sup>
Descriptive environmental evidence	NA		NA	DE <sup>(b)</sup>

DE: a detailed dataset is reported; LI: a limited dataset is reported; NA: not applicable.

(a): Reporting depends on judgement of the overall strength of all available evidence (i.e. strong or weak).

(b): Within the updated EU-FORS, generic terms (e.g. unknown, none) have been added to overcome problems regarding data availability for food-borne outbreaks where either no particular food vehicle is suspected/identified or where the evidence implicating a particular food vehicle is weak.

In a similar way to the previous reporting specifications, the updated EU-FORS foresees reporting of some additional information compared with the minimum requirements laid down in Annex IV to the Zoonoses Directive. This applies to the number of persons hospitalised and to the place of exposure (to the food vehicle). Furthermore, the Directive asks for information on the identification of the type of place where the implicated foodstuff was produced/purchased/acquired/consumed, whereas the specifications of this report instead provide and use a definition for the place of origin of the problem, since this information is relevant to control measures.

The Zoonoses Directive requires MSs to collect, evaluate and report data on zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks every year. MSs should report outbreaks in which all cases or a significant proportion of cases are believed to have acquired their infection/intoxication from food.

For the annual reporting of the results from food-borne outbreak investigations, two different data models are available, which are described in the following sections:

- 'National reporting system description (text form data model)' (Section 6.1)
- 'National evaluation of the reported food-borne outbreaks (text form data model)' (Section 6.2)
- 'Detailed datasets on food-borne outbreaks (food-borne outbreak data model)' (Section 6.3)

All food-borne outbreaks that have their onset during the reporting year should be reported. Preferably, the onset of the outbreak is defined as the onset of symptoms in the first reported case, but alternative definitions by MSs can be accepted. Some MSs record not the earliest date of onset but the reporting date instead and may use the reporting date to define the onset of the outbreak. Alternative definitions should be specified under the description of the national reporting system.

## **6.1. National reporting system description (to be reported in the text form data model)**

This text form is used to describe the national system in place for identification, epidemiological investigation and reporting of food-borne outbreaks. Consideration of the national context is important for the analysis of the submitted data. The text form is divided into several sections, which are described in detail below.

### **6.1.1. System in place for identification, epidemiological investigation and reporting of food-borne outbreaks**

Under this title the system and procedures in place for identification, epidemiological investigation and reporting of food-borne outbreaks in MSs are described. This should include the authorities and institutions involved in the activities, their roles and the coordination between the authorities, the legal basis for the activities, mandatory and voluntary activities and the frequency of reporting.

All relevant changes in the national reporting system that took place since the last reporting should be indicated. For instance, if new case definitions have been implemented, this should be detailed here.

### **6.1.2. Description of the types of outbreaks covered by the reporting**

Any differences between the national system and the EU system should be outlined here. For example, if a given national reporting system does not record household outbreaks or does not differentiate between general or household outbreaks, this should be mentioned here. In addition, if outbreaks caused by toxins are not reported to the national system, this should be reported here.

## **6.2. National evaluation of the reported food-borne outbreaks (to be reported in the text form data model)**

Inclusion of information on the national evaluation of the reported food-borne outbreaks is envisaged in the Zoonoses Directive. This is required to ensure that the data submitted by MSs are correctly interpreted at the EU level. The areas for which a national evaluation should be provided are explained in detail below.

### 6.2.1. Trends in numbers of outbreaks and numbers of human cases involved

It should be described if the number of food-borne outbreaks and, possibly, also the number of human cases in these outbreaks has increased, decreased or remained stable over the years. Possible reasons for the observed trends should also be given. For example, an increase in the number of food-borne outbreaks over several years might be related to a change in food consumption, trade patterns or other factors.

Example:

'In 2011, the municipal food control authorities notified 58 food poisoning outbreaks, of which 53 were associated with food and five with drinking water.

The number of recorded outbreaks has constantly decreased since 2005. In 2010, the number of outbreaks was 63, almost 60% less than in 2004. In 2009, the number of outbreaks slightly increased for the first time in five years due to changes in the reporting system.'

### 6.2.2. Relevance of the different causative agents, food categories and the agent/food category combinations

The relevance of different agents and the food categories, including possible trends, are described. Epidemiological associations resulting from evaluation of data as regards time, place and/or person can also be reported, if the information is available.

### 6.2.3. Relevance of the different types of places of food production and preparation in outbreaks

The relevance of different types of places of food production and preparation in outbreaks including descriptions of the distribution of the outbreaks according to the location of exposure and the relevance of different locations is reported, including possible trends.

Example:

'More than 60 % of the outbreaks were reported to be linked to mass catering facilities. *Salmonella* outbreaks are detected mainly in private homes and commercial restaurants.'

### 6.2.4. Evaluation of the severity and clinical picture of the human cases

The severity of disease caused by an outbreak can be characterised by reporting the number of deaths and hospitalisations. An evaluation of disease severity could be carried out by presenting the trends developing over a period of several years. In the context of food-borne outbreak reporting, the evaluation of the severity of diseases related to food-borne outbreaks facilitates the evaluation of the public health impact of the outbreaks.

Example:

'On average, an outbreak caused by viruses involved 22 human cases, which was almost three times more than an outbreak caused by *Salmonella* (8 cases) and four times more than *Campylobacter* (4 cases). However, when comparing the proportion of cases admitted to hospital out of the total number of cases, approximately twice as many *Salmonella* cases were admitted to hospital compared to cases infected with *Campylobacter* and almost four times more compared to cases infected with food-borne viruses.'

### 6.2.5. Descriptions of single outbreaks of special interest

Food-borne outbreaks of special interest can be reported providing relevant details.

### 6.2.6. Control measures or other actions taken to improve the situation

Control measures or other actions taken at the national level to control or prevent food-borne outbreaks in a MS during the reporting year should be described. If available, evaluations of the effectiveness of measures should be reported.

Example:

'Since 2005, logistic slaughtering is applied for *Salmonella*-free poultry in order to prevent cross-contamination.'

### 6.2.7. Suggestions to the community for the actions to be taken

Suggestions to the EU risk managers can be provided by MSs regarding proposed actions related to either specific outbreaks or reporting of data.

### 6.2.8. Additional information

Under this title any other information relevant to food-borne outbreaks can be reported.

## 6.3. Detailed dataset on food-borne outbreaks (to be reported in the food-borne outbreaks data model)

Detailed data on food-borne outbreaks should be reported in the food-borne outbreaks data model and the same dataset has to be used for all types of food-borne outbreaks. Considering that problems of data availability can exist for food-borne outbreaks where either no particular food vehicle is suspected/identified or where the evidence implicating a particular food vehicle is weak, generic terms (e.g. unknown, none) have been added to some catalogues.

In the data model MSs are strongly encouraged to provide the data on an individual outbreak basis.

However, in some cases, for weak food-borne outbreaks, data from several similar outbreaks can be reported in aggregate form (e.g. when available data are scarce) and then reported in one row. Data from these outbreaks can be aggregated on the basis of causative agent (where some food-borne outbreaks caused by the same causative agent are reported in one row) and by the food vehicle category. However, it is important to note that this type of reporting will lead to loss of some information and it is not recommended. The detailed dataset shown in Table 2 has to be provided.

**Table 2:** Detailed dataset on food-borne outbreaks

Variable	Field type	Description of the information to be provided
Causative agent	Catalogue (Appendix A)	Include, when possible, the speciation, the serotype and, if available, the phage type and other typing details.  In cases where no agent could be detected, the causative agent should be reported as unknown. In cases where there is more than one causative agent involved (mixed infections) the other agents should be reported under 'Mixed outbreaks (other agent)'.
FBO national code	Free text	This data element is used to include a national code/unique identifier for the food-borne outbreak (national number) for relation to national database, if such a code exists.
Strength of evidence	Strong/weak	Specify if the strength of evidence linking outbreak cases with a food vehicle is considered 'strong' or 'weak' based on an assessment of all available categories of evidence.
Number of outbreaks	Numerical	Use '1' for outbreak-based reporting, but use '2' (or greater) if aggregated data are being reported.
Number of human cases	Numerical	The number to be reported should include all persons meeting the outbreak case definition, including those who were hospitalised or who died as a result of the food-borne outbreak.
Number of hospitalised	Numerical	The known number of outbreak cases in the food-borne outbreak who were hospitalised, defined as an admission to hospital with illness due to the causative agent, including at least one overnight stay.
Number of	Numerical	The known number of outbreak cases who died as a

Variable	Field type	Description of the information to be provided
deaths		result of the food-borne outbreak. Only deaths attributable to the causative agent responsible for the outbreak should be reported.
Food vehicle	Catalogue (Appendix A)	The foodstuff category (food vehicle) suspected in the food-borne outbreak is reported using the specific catalogue. A 'free text data element' can be used to define the food vehicle in more detail.
More food vehicle information	Free text	In cases where more information on the food vehicle is available, report in free text format.
Mixed outbreaks (other agent)	Catalogue (Appendix A)	In cases where more than one causative agent was identified in the outbreak, the other agent(s) should be reported.
Nature of evidence linking outbreak cases with a food vehicle	<ul style="list-style-type: none"> <li>• Epidemiological <ul style="list-style-type: none"> <li>– Descriptive</li> <li>– Analytical</li> </ul> </li> <li>• Product-tracing investigations</li> <li>• Microbiological <ul style="list-style-type: none"> <li>– Detection in food vehicle or its component <i>or</i></li> <li>– Detection in food chain or its environment</li> <li>– <i>And either</i></li> <li>– Detection of indistinguishable causative agent in humans <i>or</i></li> <li>– Symptoms and onset of illness pathognomonic to the causative agent found in food vehicle or its component or in food chain or its environment</li> </ul> </li> <li>• Descriptive environmental evidence</li> <li>• Unknown</li> </ul>	<p>Specify the nature of evidence linking outbreak cases with a foodstuff. See definitions (Section 5).</p> <p>For food-borne outbreaks where more than one type of evidence was observed, all relevant evidence types should be reported.</p>
Extent of outbreak (outbreak type)	<ul style="list-style-type: none"> <li>• Household</li> <li>• General</li> <li>• Unknown</li> </ul>	Specify the extent of the food-borne outbreak; see definitions of household and general outbreak (Section 4). If it was not possible to identify the type of outbreak or if the information is not available, please choose the option 'Unknown'.
Place of exposure (setting)	Catalogue (Appendix A)	See definitions (Section 4).
Place of origin of problem	Catalogue (Appendix A)	See definitions (Section 4). If there is more than one place of origin of the problem, all the relevant ones should be chosen from the catalogue.
Origin of food vehicle	Catalogue	Provide information on the country from which the food vehicle originated
Contributory factors	Catalogue (Appendix A)	Contributory factors are factors that contributed to the occurrence of the food-borne outbreak. These may include deficiencies in food handling or contaminated raw materials. If there is more than one contributory factor involved, all the relevant ones should be chosen from the catalogue.
Additional information - Comment	Free text	A free text data element is provided where additional information can be reported. This data element allows the provision of more information on food-borne outbreaks of special interest, such as those caused by unusual causative agents, vehicles or their combination, or which have been thoroughly investigated and/or

Variable	Field type	Description of the information to be provided
		<p>reported through RASFF<sup>(a)</sup> or EWRS<sup>(b)</sup>.</p> <p>This data element typically describes the results of the epidemiological investigations, information on the sub-typing of the agents and will include references to publications (e.g. in Eurosurveillance), to international databases or to full outbreak reports. In cases where the agent was successfully isolated from the food item and quantified, this data element can be used to report quantitative laboratory results (as CFU/ml or CFU/g or as MPN/ml or MPN/g).</p>

CFU, colony-forming unit; FBO, food-borne outbreak; MPN, most probable number.

(a): Rapid Alert System for Food and Feed.

(b): Early Warning and Response System.

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## Abbreviations

AFLP	amplified fragment-length polymorphism
CFU	colony-forming unit
CI	confidence interval
CORS	Community Outbreak Reporting System
DCF	Data Collection Framework
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EU	European Union
EU-FORS	European Union Food-borne Outbreak Reporting System
EWRS	Early Warning and Response System
MLST	multi-locus sequence typing
MLVA	multiple loci variable-number tandem repeat analysis
MPN	most probable number
MS	Member State
OR	odds ratio
PCR	polymerase chain reaction
PFGE	pulsed-field gel electrophoresis
RR	relative risk
RFLP	restriction fragment length polymorphism
RASFF	Rapid Alert System for Food and Feed
UHT	ultra-high temperature
WG	working group



## Appendix A – Catalogues

**Table 3:** Causative agents-the most commonly reported

Code	Description
RF-00000304-MCG <sup>(a)</sup>	<i>Salmonella</i>
RF-00000042-MCG <sup>(a)</sup>	<i>Campylobacter</i>
RF-00000245-MCG <sup>(a)</sup>	<i>Listeria</i>
RF-00003550-MCG <sup>(a)</sup>	<i>Escherichia coli</i> , pathogenic
RF-00000004-MCG <sup>(a)</sup>	<i>Bacillus</i>
RF-00002485-MCG <sup>(a)</sup>	Staphylococcal enterotoxins
RF-00000080-MCG <sup>(a)</sup>	<i>Clostridium</i>
RF-00002479-MCG	<i>Shigella</i>
RF-00000028-MCG <sup>(a)</sup>	<i>Brucella</i>
RF-00000041-MCG	Calicivirus - norovirus (Norwalk-like virus)
RF-00000229-MCG <sup>(a)</sup>	Hepatitis virus
RF-00003902-MCG	Chemical agents
RF-00000003-BGA	Histamine
RF-00000009-TOX <sup>(a)</sup>	Marine biotoxins
<sup>(b)</sup>	Parasites
RF-XXXX-XXX-X02 <sup>(a)</sup>	Viruses
<sup>(b)</sup>	Other agents
<sup>(b)</sup>	Other bacterial agents
RF-XXXX-XXX-X01	Unknown agent

(a): Please, choose the most detailed levels of specificity for a breakdown to species/serovars/serotypes/phage types/other types level from the catalogue.

(b): Please, choose the relevant term from the catalogue.

The list above provides the most commonly reported agents. The PARAM\_ZOO catalogue allows the addition of other agents and provides more detailed levels of specificity for a breakdown to species/serovars/serotypes/phage types/other types level.

**Table 4:** Food vehicle

Code	Description
B07727B	Milk
B09607B	Dairy products (other than cheeses)
B09627B	Cheese
B09647B	Eggs and egg products
A01QR	Meat and meat products
B09667B	Bovine meat and products thereof
B09687B	Pig meat and products thereof
B09707B	Sheep meat and products thereof
B09727B	Other or mixed red meat and products thereof
B09747B	Broiler meat ( <i>Gallus gallus</i> ) and products thereof
B09767B	Turkey meat and products thereof
B09787B	Other, mixed or unspecified poultry meat and products thereof
B09807B	Fish and fish products
B09827B	Crustaceans, shellfish, molluscs and products thereof
B09847B	Vegetables and juices and other products thereof
B09867B	Canned food products
B09887B	Cereal products, including rice and seeds/pulses (nuts, almonds)
B09907B	Fruit, berries and juices and other products thereof
B09927B	Drinks, including bottled water
B09947B	Tap water, including well-water
B09967B	Sweets and chocolate
B09987B	Bakery products
B10007B	Herbs and spices
B29387B	Mixed food
B29407B	Buffet meals

Code	Description
B10047B	Other foods
B00000B	Unknown

**Table 5:** Place of exposure (settings)

Code	Description
E230A	Household
E910A	Restaurant or Cafe or Pub or Bar or Hotel or Catering service
E920A	Mobile retailer or market or street vendor
E930A	Take-away or fast food outlet
E940A	Canteen or workplace catering
E210A	Hospital or medical care facility
E220A	Residential institution (nursing home or prison or boarding schools)
E240A	School or kindergarten
E950A	Temporary mass catering (fairs, festivals)
E960A	Camp or picnic
E990A	Catering on aircraft or ship or train
E971A	Multiple places of exposure in one country
E972A	Multiple places of exposure in more than one country
E101A	Farm
E099A	Other
E980A	Unknown

**Table 6:** Place of origin of problem

Code	Description
E230A	Household
E910A	Restaurant or Cafe or Pub or Bar or Hotel or Catering
E920A	Mobile retailer or market/street vendor
E930A	Take-away or fast food outlet
E940A	Canteen or workplace catering
E210A	Hospital or medical care facility
E220A	Residential institution (nursing home or prison or boarding schools)
E240A	School or kindergarten
E950A	Temporary mass catering (fairs, festivals)
E960A	Camp or picnic
E990A	Catering on aircraft or ship or train
E311A	Slaughterhouse
E101A	Farm
E301A	Processing plant
E520A	Retail
E800A	Transport
E430A	Water treatment plant
E410A	Water distribution system
E420A	Water source
E850A	Travel abroad
E099A	Other
E980A	Unknown

**Table 7:** Contributory factor

Code	Description
CF08A	Unprocessed contaminated ingredient
CF06A	Storage time/temperature abuse
CF03A	Inadequate heat treatment
CF02A	Inadequate chilling
CF01A	Cross-contamination
CF04A	Infected food handler

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CF10A	Untreated drinking water
CF09A	Drinking water treatment failure
CF05A	Other contributory factor
CF07A	Unknown

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## Appendix B – Further guidance on the variables to be reported

### Causative agent

The agent (bacterium, virus, parasite, toxin) which was detected and/or isolated in the course of the investigation and which is considered to be the cause of the outbreak is reported. A catalogue is provided to facilitate reporting by choosing the particular agent directly from the list, which gives as much detail as needed in terms of serotype, speciation or phagetype. However, it is also possible to report additional information on the subtypes in the comment data element. This might be appropriate if the agent or subtype is not included in the list.

In cases where more than one agent is involved in the outbreak, e.g. in mixed infections, all the relevant agents can be selected from the catalogue.

In cases where no agent could be detected, the causative agent should be reported as unknown.

#### Example:

An outbreak of gastroenteritis occurs among residents of a MS. *Salmonella* Montevideo is isolated from stool samples of the human cases. A case-control study reveals that the illness was linked to consumption of chicken nuggets of brand A. Samples of chicken nuggets of brand A are analysed and *Salmonella* Enteritidis is isolated. None of the samples tested yields any *Salmonella* Montevideo. The negative results of the food samples do not rule out that *S.* Montevideo was present in the food consumed by the human cases. Thus, the causative agent to be reported for this outbreak should be the agent found in the human cases, i.e. *Salmonella* Montevideo. The isolation of *S.* Enteritidis in the incriminated food is considered a secondary finding.

### Food vehicle

The food vehicle in the outbreak is the food considered to have been the vehicle of the causative agent or its toxins. A foodstuff should be considered to have been the vehicle of the causative agent or its toxins when the causative agent or its toxin has been detected either in a foodstuff/its component or food chain/its environment and/or either in humans or when there are strongly indicative/pathognomonic symptoms to the causative agent found in the food vehicle or its component or in the food chain or its environment.

The description of the food vehicle in the outbreak is carried out by using the provided catalogue that gives the main categories of foodstuffs (see Appendix A). Apart from this, the foodstuff in question should be described in more detail in the free text data element. This information may typically include the type of food (e.g. cheese, sausage), the nature of processing of the foodstuff (cooked, raw, made from raw milk). In addition, it is important to report the animal/plant species where the food originates.

However, since the catalogue is not exhaustive and gives only a limited level of detail it is recommended to submit more detailed information, e.g. on the (food animal/plant) species and the treatment of the food in the additional free text data element.

For example, if the food vehicle to be reported was 'roast beef', the category to be selected from the catalogue is 'bovine meat and products thereof'. The additional information on the treatment (e.g. 'roast beef') can be submitted in the free text data element.

If the food vehicle was boiled cauliflower, the category to be selected from the catalogue would be 'vegetables and juices and other products thereof'. Further information like the species or cultivar group ('cauliflower') and the treatment ('boiled') should be submitted in the free text data element.

### Nature of evidence linking outbreak cases with a food vehicle

The nature of evidence linking food in general or a specific food item in particular with outbreak cases can be epidemiological and microbiological. The nature of evidence is not necessarily correlated with its strength.

### *Analytical epidemiological evidence*

This type of evidence applies to outbreaks where a statistically significant association between a foodstuff and the outbreak cases has been demonstrated by either a cohort study or a case-control study.

A cohort study is a study in which individuals with different exposures to a risk factor (e.g. eating the foodstuff implicated) are identified and then observed for the occurrence of certain health effects (e.g. clinical symptoms) over some period. Cohort studies can either be performed prospectively or retrospectively from historical records (e.g. in case of food-borne outbreak investigations).

Retrospective cohort studies are feasible for outbreaks in small, well-defined populations in which all persons exposed (e.g. exposed to one or more foodstuffs) and all non-exposed persons are identifiable. These studies compare the occurrence of disease among those who were exposed to a suspected risk factor (e.g. a particular food) with occurrence among those who were not. For example, all persons attending a reception (the 'cohort') may be interviewed to determine whether they became ill after the reception, and to identify what foods they had consumed. Attack rates for illness are calculated for those who consumed a particular food and for those who did not consume that food. A ratio of the two attack rates, known as the relative risk (RR), can be calculated. The RR is a measure of the strength of association between the particular exposure and the disease. (Food-borne disease outbreaks: guidelines for investigation and control; World Health Organization, 2008.)

A case-control study compares persons with a disease or condition ('human cases') to another group of people from the same population who do not have that disease or condition ('controls'). A case-control study can identify risks (e.g. having eaten the food) and suggest some possible causes for disease, or for particular outcomes (e.g. having eaten the implicated food).

In many circumstances, no clearly defined 'cohort' of all exposed and non-exposed persons can be identified or interviewed. In such situations a case-control study can be carried out. In a case-control study, the distribution of exposures of risk factors (e.g. foodstuffs) among cases and a group of healthy persons ('controls') are compared with each other. In contrast to a cohort study, attack rates (and therefore RR) cannot be calculated since the total number of persons at risk is unknown. Instead, a different measure of association, the odds ratio (OR) is used. For rare conditions (i.e. less than 5 % in the population are affected), the OR is a good estimate of the RR. (Food-borne disease outbreaks: guidelines for investigation and control; World Health Organization, 2008.)

#### Example

An outbreak of *Cryptosporidium* infections occurred among employees at a large private company in week 34, 2005. To investigate the cause of illness a case-control study was initiated. Cases were cryptosporidiosis patients with a positive laboratory result and controls were residents picked from the population register with no history of gastrointestinal illness in the period under study. Results of the case-control study indicated that disease was associated with eating in the company canteen in the first part of week 34. Subsequently, a cohort study was conducted among all employees of the company. An elevated risk of disease was associated with eating in the company canteen on Monday (RR: 4.1, 95 % confidence interval (CI): 2.2–7.6) or Tuesday (RR: 4.4, 95 % CI: 2.2–8.8) in week 34, and eating from the salad bar on those days (RR: 3.1, 95 % CI: 2.0–4.8 and RR: 3.1, 95 % CI: 2.0–4.7, respectively).

### *Descriptive epidemiological evidence*

Descriptive epidemiological evidence refers to generation of hypotheses concerning the food vehicle of an outbreak by systematic collection of information on outbreak cases, description of the outbreak with regard to time, place and person, and examination of the characteristics (e.g. age, sex, race/ethnicity, residence, occupation, recent travel or attendance at events) of those who are ill. It includes the systematic evaluation of cases' food histories, as the identification of common food exposures, by using consistent and standardised means (such as standard trawling questionnaires) to obtain information from all, or an appropriate subset of, outbreak cases about food consumed in the period when infection is likely to have occurred.

### *Detection in food vehicle or its component*

Laboratory detection in implicated food or its component is defined as the detection of the potential causative agent or toxin or bio-active amine in a food sample taken in the course of the investigation. This is the type of evidence to be selected for food-borne outbreaks where the potential causative agent was detected in a sample of the implicated food deriving from the possible food vehicle in common or in a sample of a component used to prepare the possible food vehicle in common.

Detection of the causative agent from the leftovers of the incriminated meal/food item, from samples collected from open packages of the incriminated food and from samples collected from unopened packages from the same batch as the incriminated food is regarded as equivalent to 'laboratory detection in food vehicle or its component'.

### *Detection in food chain or its environment*

Laboratory detection in the food chain or its environment is defined as the detection of the potential causative agents in previous stages along the chain of production of the specific foodstuff. Samples from the preparation or processing environment of the suspected foodstuff, or from batches of other or similar foodstuffs produced under the same conditions, may identify the potential causative agent or toxin or bioactive amine corresponding to the human isolates or clinical symptoms. Furthermore, samples taken in the primary production environment, where the suspected foodstuff originated, are suitable, e.g. dust samples from farms or faecal samples from animals.

### *Detection of indistinguishable causative agent in humans*

Detection of an indistinguishable causative agent in humans is defined as the detection of the potential causative agent or toxin or bio-active amine in clinical samples of the human cases in the outbreak and the further characterisation to the level needed to link the human cases to each other and to the food vehicle.

The choice of laboratory method (e.g. sero-/phage-/ribotyping, pulsed-field gel electrophoresis (PFGE)) depends on national standards and should be included in the report. The link between the human cases and the food source should be verified by microbiological experts taking the epidemiological association into account.

Detection of an indistinguishable causative agent in humans implies automatically that the causative agent is isolated from both the human cases and either the food vehicle/its component or from the food chain/its environment; thus, it is advisable to indicate at least two of the evidence types for the outbreak.

For example, in the course of an outbreak investigation *Salmonella* Typhimurium was isolated from samples from human cases and from a possible common food source. Further laboratory characterisation identified both isolates as *Salmonella* Typhimurium DT 104. In this case, the appropriate type of evidence would be 'Detection in food vehicle or its component' and 'Detection of indistinguishable causative agent in humans'.

For further examples of the level of typing needed see Table 8.

**Table 8:** Level of characterisation recommended to link human cases to a food vehicle or to each other

Causative agent	Level of characterisation recommended to link human cases to a food vehicle or to each other
<i>Brucella</i>	Speciation and where possible biotyping e.g. <i>Brucella melitensis</i> biotype 1
<i>Campylobacter</i>	Speciation and sometimes genotyping (e.g. AFLP, PFGE, MLST)
<i>Cryptosporidium</i>	Speciation, also genotyping (PCR, RFLP) could be used if needed
<i>Enterobacter</i> / <i>Cronobacter</i>	Speciation
Flavivirus	Speciation, sometimes genomic characterisation of strains (e.g. PCR and sequencing of the PCR product) if possible
<i>Giardia</i>	Speciation, also genotyping (PCR, RFLP) may be used
Hepatitis A virus	Speciation, also genomic characterisation of strain (e.g. PCR and sequencing of the PCR product) may be used
<i>Listeria monocytogenes</i>	Speciation, and sometimes serotyping and genotyping (PFGE)
Norovirus	Speciation, also genomic characterisation of strain (e.g. PCR and sequencing of the PCR product) if possible
Pathogenic <i>Escherichia coli</i>	Complete serotyping (O,H), and where possible typing of virulence genes ( <i>vtx</i> and <i>eae</i> ); in addition for frequent serotypes (e.g. O:157) genotyping (PFGE, MLVA) if needed and if possible
Rotavirus	Genomic characterisation of strain (e.g. PCR and sequencing of the PCR product) may be used if needed
<i>Salmonella</i> serovars in general	Serotyping (classification to White–Kaufmann–Le Minor scheme), also antimicrobial resistance patterns and PFGE may be used
<i>Salmonella</i> Typhimurium	Serotyping, and phage typing and antimicrobial resistance if possible; in addition for common phage types (e.g. DT 104) molecular typing, plasmid profiling, PFGE and MLVA may be used
<i>Salmonella</i> Enteritidis	Serotyping, and phage typing and antimicrobial resistance patterns if possible; in addition for common phage types (e.g. PT4) molecular typing, PFGE and MLVA, ribotyping may be used
<i>Shigella</i>	Speciation, and if possible biotyping and serotyping
<i>Trichinella</i>	Only 'laboratory detection' possible as, in humans, only serology is usually carried out, which does not go beyond the genus level
<i>Vibrio</i>	Speciation, and if possible biotyping and serotyping and pathogenic factors
<i>Yersinia</i>	Speciation, biotyping and serotyping if possible e.g. <i>Yersinia enterocolitica</i> biotype 1, serotype O:3

AFLP: amplified fragment-length polymorphism; MLST: multi-locus sequence typing; MLVA: multiple loci variable-number tandem repeat analysis; PCR: polymerase chain reaction; PFGE: pulsed-field gel electrophoresis; RFLP: restriction fragment length polymorphism.

## Extent (type) of outbreaks

The type of outbreak, i.e. household or general outbreak, should be reported if known. A general outbreak is defined as a food-borne outbreak involving human cases from more than one household. Outbreaks in residential homes (e.g. nursing homes), schools and other similar institutions are considered general outbreaks. A household outbreak is defined as a food-borne outbreak involving human cases living in one household. A household, on its part, is defined as one person living alone or a group of persons (who may or may not be related) living at the same address with common housekeeping.

For example:

An outbreak occurs when involving persons from several households, who have all attended a private party in the household of one of the cases and consequently developed a food-borne illness. This outbreak should be reported as a 'general outbreak' with 'household' as the 'place of exposure' (setting) of the outbreak.

In cases where the national reporting system does not collect data on the type of outbreak or if it was not possible to identify the type of outbreak for a particular outbreak, the option 'unknown' should be selected.

*Symptoms and onset of illness pathognomonic to the causative agent found in a food vehicle or its component or in food chain or its environment* is defined as the presence of clinical symptoms and an onset of illness in outbreak cases strongly indicative/pathognomonic to the causative agent identified in the food vehicle or its component or in the food chain or its environment.

## Place of exposure (setting)

The place of exposure typically refers to the location where the food was consumed (e.g. Household, Restaurant or Cafe or Pub or Bar or Hotel or Catering service) or where the final stages of preparation took place (e.g. Canteen or workplace catering, Household).

In cases where the food was prepared in a take-away service and eaten at another place, e.g. a private household, 'take-away' should be reported as the place of exposure.

In the context of this reporting system, a restaurant is considered a take-away service if the food was prepared at the restaurant but taken away by the consumer and consumed somewhere else (e.g. many pizzerias provide take-away service).

## Place of origin of problem

The place of origin of the problem is defined as the place, other than place of exposure, where the contamination or the mishandling of the implicated food occurred. This information is not always available, but in case the problem has been traced in the food chain, it is useful to report.

## Origin of foodstuff

The country of origin of the foodstuff is reported if known,

## Contributory factors

Typical examples for contributory factors include insufficient chilling caused by overstocking of cooling chambers or insufficient hot holding at buffets.

Infected food handlers (e.g. cooks or other kitchen workers) are frequently reported as a contributory factor although they can also be outbreak cases. In practice it is not always possible to make a clear distinction between an infected food handler as a contributory factor or only as one case in the outbreak. It is advisable to choose 'infected food handler' only when it is likely that the infected food handler was the source of infection.



### **Mixed outbreaks (other agents)**

Mixed food-borne outbreaks refer to outbreaks where more than one causative agent is identified. The outbreak is reported under this agent category so that it is possible to add the other causative agents from the catalogue.

## Appendix C – Examples of convincing descriptive epidemiological evidence and evidence from product-tracing investigations

### Background

It is not always possible or appropriate to initiate epidemiological studies as part of the public health response to outbreaks. Factors that should be taken into account when deciding on the epidemiological approach to adopt include:

- availability of a suitable sampling frame from which to select controls;
- the sample size required to test the hypotheses under examination;
- public awareness of the hypotheses under examination.

It is also important to consider whether the time required to conduct an epidemiological study before introducing control measures puts the public at unacceptable risk, or whether conducting a study after control measures have been introduced is valid, and if so justifies the resources required.

Well-presented descriptive epidemiology supported by information from other lines of enquiry can also provide strong evidence which is of sufficient quality to inform both immediate control and policy development.

In addition, a comprehensive product-tracing investigation can provide strong evidence in case a common point along the food-production and distribution chain is identified for all or a large proportion of cases, who were exposed and for whom a place of exposure/point of sale could be identified.

### Examples of outbreaks with strong descriptive evidence

- 1) Outbreak of cholera in London in 1854:
  - a. Well-presented descriptive epidemiology, including:
    - i. mapping of cases
    - ii. exposure histories from patients
      - Evidence that those affected drank water from a specific public water pump (Broad Street), including two cases who lived some distance from the implicated pump.
    - iii. outbreak curve showing that new cases stopped after the implicated vehicle was made inaccessible (removal of the pump handle).
  - b. No supportive microbiology from clinical or water samples.
  - c. No analytical epidemiological study (case-control/cohort).
- 2) Histamine in tuna from a sandwich bar:
  - a. Descriptive epidemiology:
    - i. all identified cases had an onset date within one day of visiting the same sandwich bar with symptoms strongly indicative of histamine poisoning;
    - ii. all identified cases reported eating tuna sandwiches from the implicated outlet;
    - iii. none of the cases had eaten any other likely vehicle from anywhere else during the incubation period;
    - iv. no other concurrent outbreaks of histamine poisoning to indicate that contaminated raw tuna is in circulation.
  - b. Environmental investigation highlights poor temperature control in refrigerated display cabinets.
  - c. No supportive microbiology from food samples.

- d. No analytical epidemiological study (no suitable cohort to follow up, names of customers not known to proprietors).

This evidence would be sufficient to implicate tuna in a histamine outbreak. However, it would be insufficient to implicate egg mayonnaise sandwiches in an outbreak of *Salmonella* Enteritidis. Collecting detailed information on histamine outbreaks in the EU might be of value when considering policy development in relation to the harvesting and processing of tuna and other scombroid fish.

- 1) Cryptosporidiosis linked to municipal water supply:
  - a. Descriptive epidemiology:
    - i. rapid increase in identified cases of cryptosporidiosis;
    - ii. case histories record consumption of unboiled drinking water in cases;
    - iii. mapping of cases demonstrates geographical association with an area consistent with a specific water supply zone.
  - b. Public warnings issued as soon as water supply is suspected. This makes it difficult to conduct a case-control study because the population at risk would be biased.
  - c. Water treatment company records indicate that there were processing problems days before people started to report illness.
  - d. High rainfall recorded at the time that problems were identified in the treatment plant.
  - e. No *Cryptosporidium* spp. oocysts found in water supply chain when sampling was carried out.
- 2) Norovirus outbreak linked to a restaurant:
  - a. Descriptive epidemiology:
    - i. local public health team receive reports of diarrhoeal illness from all 33 individuals belonging to six separate parties who visited a local restaurant over a period of two weeks;
    - ii. dining at the restaurant is the only exposure that is common to all of the parties;
    - iii. all of the cases reported onset of symptoms between 24 and 48 hours after dining at the restaurant;
    - iv. two separate genogroups of norovirus identified in the stool specimens of four of the cases;
    - v. all of the cases reported the consumption of a single set menu.
  - b. Difficult to conduct a case-control study because the restaurant had no records of others who dined at the restaurant over the period in question.
  - c. Investigation of the restaurant:
    - i. no food or environmental specimens showed evidence of norovirus contamination, which included oysters;
    - ii. the dishes served required intensive manual manipulation;
    - iii. staff attendance records showed that nine members of staff reported diarrhoea and vomiting in the week before the first party dined at the restaurant;
    - iv. several members of staff report working while symptomatic;
    - v. one member of staff is confirmed as carrying norovirus but of a different genogroup to the cases.

It is not possible to implicate a single vehicle of infection; however, it can be concluded that the outbreak is food-borne with a number of potential vehicles of infection. It seems likely that the food handlers were infected by preparing or eating previous batches of oysters. A single contaminated oyster can carry a variety of strains of norovirus.

- 3) *Clostridium perfringens* outbreak linked to a care home for the elderly:
- a. Descriptive epidemiology:
    - i. all cases are residents at a care home for the elderly;
    - ii. 17 cases of illness caused by *Clostridium perfringens* reported to local public health team:
      - management records show that all of the residents only eat meals served at the care home;
      - many of the residents are frail and confused and it is not possible to get reliable food histories other than they all ate dinner served last Sunday evening;
      - reheated beef casserole was one of the dishes served on Sunday evening.
    - iii. no leftover foods are available for microbiological testing.

### **Examples of outbreaks with strong evidence from product-tracing investigations**

- 1) STEC O104:H4 outbreak in Germany in 2011:

In the 2011 STEC O104:H4 outbreak, all 41 identified places of exposure could be linked to a single sprout producer by a combination of trace-back and trace-forward investigations (Buchholz et al., 2011).

- 2) Cyclosporiasis outbreak linked to basil:

In a community outbreak of cyclosporiasis, the basil purchased and eaten by 14 patients could be traced back from (different) points of sale to a common distributor in 12 patients. The remaining two cases with basil exposure who were previously unlinked to the distributor were then confirmed through trace-forward from distributor A (Shah et al., 2009).

## Appendix D – Explanation of the catalogues

### **Food vehicle** (please see the terms in Table 4)

Foodstuff, also referred to as 'food', is defined as any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans. Food includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. This definition also includes drinking water and covers single food items as well as composite meals (Regulation (EC) No 178/2002).

The food vehicle in the outbreak is the food considered to have been the vehicle of the causative agent or its toxins. The relevant food category can be chosen from the catalogue shown below and the exact nature of the foodstuff should be described in the free text data element. This description can include the type of the food, the species of origin (food animal/plant) and treatment (e.g. smoked, cooked, frozen).

Please note that all types of canned food are reported as 'canned food products' regardless of the type of product they contain (e.g. fish, meat, vegetables). This is because the canning process is the main factor influencing the safety of the product. Further information on food animal/plant species and treatment prior to canning is given in the free text data element.

In the following paragraphs further guidance is given regarding how to classify different foodstuffs into the catalogue categories.

#### *Milk*

The following products shall be considered as drinking milk:

- raw milk intended for direct human consumption: milk, which has not been heated above 40°C or subjected to treatment having equivalent effect and intended to be consumed raw;
- pasteurised milk: milk heat treated to destroy disease-causing bacteria;
- ultra-high temperature (UHT) milk: milk heated for a short time, around 1–2 seconds, at a temperature exceeding 135°C, which is the temperature required to kill spores in milk.

**Please specify the species of origin of the milk (such as cow, goat, sheep) as well as the treatment of the milk in the free text data element (for example: 'raw goat milk', 'pasteurised cow milk' or 'UHT milk').**

#### *Dairy products (other than cheese)*

Dairy products are defined as processed products resulting from the processing of raw milk or from the further processing of such processed products (Regulation (EC) No 853/2004).

Examples for dairy products are cream, buttermilk, milk powder, butter, yoghurt, ice cream and puddings made from milk.

**Please specify the species, such as cow, goat, sheep, water buffalo, yak or horse, as well as the treatment in the free text data element (for example: 'low-fat yoghurt made of pasteurised cows' milk').**

#### *Cheese*

Cheese is the ripened or unripened soft, semi-soft, hard, or extra-hard product of milk, which may be coated, and in which the whey protein/casein ratio does not exceed that of milk, obtained by coagulating of milk or protein of milk and/or products obtained from milk which give an end product with similar characteristics.

**Please specify the species of origin of the milk (such as cow, goat, sheep) as well as whether the cheese was made from raw, low-heat-treated milk or pasteurised milk. In addition, the main type of cheese (hard, semi-soft or soft) and, if possible, also a detailed type (e.g. Camembert), if possible, in the free text data element. For example: 'soft cheese made from raw goats' milk'.**

#### *Eggs and egg products*

Eggs are defined as eggs in shell that are produced by farmed birds and are fit for direct human consumption or for the preparation of egg products.

Egg products are processed products resulting from the processing of eggs or of various components or mixtures of eggs or from the further processing of such processed products (Regulation (EC) No 853/2004). Examples of egg products include:

- Liquid egg products: the purified whole egg, egg yolk or egg white is pasteurised and chemically preserved (e.g. by addition of salt).
- Frozen egg products: the purified whole egg, egg yolk or egg white is pasteurised and frozen.
- Dried and/or heat-coagulated egg products: sugars are removed from the purified whole egg, egg yolk or egg white, which is then pasteurised and dried.
- Preserved eggs, including alkaline, salted and canned eggs: includes traditional Oriental preserved products, such as salt-cured duck eggs and alkaline treated 'thousand-year-old-eggs'.
- Egg-based desserts: includes ready-to-eat products and products to be prepared from a dry mix. Examples include: flan and egg custard. This also includes custard fillings for fine bakery wares (e.g. pies).

#### *Bovine meat and products thereof*

Bovine meat is defined as edible parts of domestic bovine animals (including *Bubalus* and *Bison* species), including blood (Regulation (EC) No 853/2004).

Please also note the following related definitions in the EU legislation, which can help to specify the foodstuff implicated in the free text data element.

Fresh meat is meat that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped or wrapped in a controlled atmosphere (Regulation (EC) No 853/2004).

Meat preparations are defined as fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat (Regulation (EC) No 853/2004).

Minced meat is boned meat that has been minced into fragments and contains less than 1 % salt (Regulation (EC) No 853/2004), for example steak tartare.

Meat products are defined as processed products resulting from the processing of meat or from further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat (Regulation (EC) No 853/2004).

Examples of bovine meat and products thereof include: beef steak, stewing steak, grilled liver, roast beef, sausages and steak tartare.

**Please specify the treatment (e.g. raw, cooked, grilled) and add the specifications of the product in the free text data element (for example: 'fermented, air-dried cured sausage Italian style'.**

### *Pig meat and products thereof*

Pig meat is defined as edible parts of domestic porcine animals, including blood (Regulation (EC) No 853/2004). For the definition of meat products please see 'Bovine meat and products thereof'.

### *Sheep meat and products thereof*

Sheep meat is defined as edible parts of domestic ovine animals, including blood (Regulation (EC) No 853/2004).

For the definition of meat products please see 'Bovine meat and products thereof'.

### *Other or mixed red meat and products thereof*

Other red meat is meat from species, other than birds, that are not mentioned above, such as wild game and farmed game.

Wild game includes wild ungulates and lagomorphs, as well as other land mammals that are hunted for human consumption.

Meat from wild boars is classified in this category; it would be desirable to indicate in the comment section that the meat pertains to wild boar.

Farmed game includes farmed ratites and farmed land mammals other than those referred to as 'Domestic ungulates' (Regulation (EC) No 853/2004).

Mixed red meat is a mix of red meat from different species, e.g. meatballs consisting of bovine and pig meat.

For the definition of meat products please see 'Bovine meat and products thereof'.

### *Broiler meat (Gallus gallus) and products thereof*

Broiler meat is defined as edible parts of domestic chicken (*Gallus gallus*), including blood.

For the definition of meat products please see 'Bovine meat and products thereof'.

**In this context, meat from hens (e.g. spent hens) is also regarded as broiler meat.**

### *Turkey meat and products thereof*

Turkey meat is defined as edible parts of domestic turkeys, including blood.

For the definition of meat products please see 'Bovine meat and products thereof'.

### *Other or unspecified poultry meat and products thereof*

Other poultry meat is defined as edible parts of 'poultry', including blood. 'Poultry' are farmed birds, including birds that are not considered as domestic but which are farmed as domestic animals, with the exception of ratites, which are considered 'farmed game' (Regulation (EC) No 853/2004). In this case, all poultry EXCEPT *Gallus* and turkey. Examples in this category include duck, goose, pheasant, guinea fowl and ostrich.

For the definition of meat products please see 'Bovine meat and products thereof'.

### *Fish and fish products*

Fish, as a food, describes the edible parts of water-dwelling, cold-blooded vertebrates with gills.

Examples of edible fish include salmon, trout, tuna, eel, silver carp and anchovy.

Examples of fish products include frozen fish fingers, roe and smoked salmon.

**Please specify the fish species (e.g. salmon, herring) as well as the treatment (e.g. smoked, raw, cooked) in the free text data element (for example: 'cold-smoked salmon').**

Shellfish is a broad term for all aquatic animals that have a shell of some kind. Shellfish are separated into two basic categories: crustaceans and molluscs. However, the EU definition of shellfish includes only bivalve and gastropod molluscs (Council Directive 79/923/EEC).

Examples of edible shellfish are sea cucumber and sea urchin.

Crustaceans are one of two main classifications of shellfish (the other being mollusc). Crustaceans have elongated bodies and jointed, soft (crust-like) shells.

Examples of edible crustaceans include shrimp (e.g. Atlantic white shrimp), prawn (e.g. giant river prawn), lobster (e.g. European lobster), crayfish (e.g. European crayfish) and crab (e.g. edible crab).

Molluscs are animals with a soft body, internal or external shell, muscular foot and/or tentacles.<sup>4</sup> Molluscs are divided into three groups: gastropods (also called *univalves*), bivalves (including live bivalve molluscs) and cephalopods.

Examples of edible molluscs include abalone (sea ear), snail (e.g. vineyard snail) and clam.

Examples of edible bivalve molluscs include mussels and oysters.

**Please specify the species as well as the treatment (e.g. live, cooked) in the free text data element (for example: 'deep-fried shrimps').**

#### *Vegetables and juices and other products thereof*

Vegetables are plants or parts of plants cultivated for food. Some foods that are botanically fruits, such as tomatoes and cucumbers, and seeds, such as peas and beans, are included with the vegetables; some plants, such as rhubarb, are classed as fruit, although they are not botanically fruits. The distinction in popular usage depends on whether they are eaten as savoury (vegetables) or sweet (fruit) dishes.

Examples of vegetables include cauliflower, broccoli, pea, cucumber, lentil, avocado and garlic. 'Sea vegetables' like sea lettuce and seaweed are also part of this group.

Vegetable juice is the juice obtained from vegetables and usually made from carrots, beets, pumpkin or tomatoes.

**Please specify the plant species or cultivar group as well as the treatment (e.g. raw, cooked juice) in the free text data element (for example: 'raw iceberg lettuce').**

#### *Canned food products*

Food preserved by canning; the process of preserving food by sterilisation and cooking in a sealed metal can, which destroys bacteria and protects against recontamination.

**Please specify the canned food product (e.g. meat, fish, vegetable) in the free text data element (for example: 'baked beans, canned').**

#### *Cereal products, including rice and seeds/pulses (including nuts, almonds)*

Cereal is grass whose starchy grains are used as food, for example wheat, rice, rye, oats, maize, buckwheat, millet and grain. Foodstuff prepared from the starchy grains of cereal grasses is also referred to as cereal.

<sup>4</sup> Available online: <http://fishspecies.tripod.com/glossary.html>



**Please specify the cereal products (e.g. plant species) and treatment (cut, precut, cooked) in the free text data element.**

*Fruit, berries and juices and other products thereof*

Fruit is defined as all fruit. Tomatoes are not regarded as fruit (Council Directive 2001/112/EC<sup>5</sup>).

Fruit purée is defined as the fermentable but unfermented product obtained by sieving the edible part of whole or peeled fruit without removing the juice (Council Directive 2001/112/EC).

Fruit juice is defined as:

- The fermentable but unfermented product obtained from fruit which is sound and ripe, fresh or preserved by chilling, of one or more kinds mixed together, having the characteristic colour, flavour and taste typical of the juice of the fruit from which it comes. Flavour, pulp and cells from the juice which are separated during processing may be restored to the same juice. In the case of citrus fruits, the fruit juice must come from the endocarp. Lime juice, however, may be obtained from the whole fruit, by suitable production processes whereby the proportion of constituents of the outer part of the fruit is reduced to a minimum.
- The product obtained from concentrated fruit juice by:
  - replacing, in the concentrated fruit juice, water extracted from that juice during concentration, restoring the flavours and, if appropriate, pulp and cells lost from the juice but recovered during the process of producing the fruit juice in question or of fruit juice of the same kind. The water added must display appropriate characteristics, particularly from the chemical, microbiological and organoleptic viewpoints, in such a way as to guarantee the essential qualities of the juice. The product thus obtained must display organoleptic and analytical characteristics at least equivalent to those of an average type of juice obtained from fruits of the same kind within the meaning of (a) (Council Directive 2001/112/EC).

Concentrated fruit juice is the product obtained from fruit juice of one or more kinds by the physical removal of a specific proportion of the water content. Where the product is intended for direct consumption that removal will be of at least 50% (Council Directive 2001/112/EC).

Fruit nectar is the fermentable but unfermented product obtained by adding water and sugars and/or honey to the products to fruit purée or to a mixture of those products, that, moreover, meet the requirements of Annex IV (Council Directive 2001/112/EC).

*Drinks, including bottled water*

Drinks are any liquids suitable for drinking, also called beverages.

Juice drinks are drinks made from fruit juice plus other ingredients, such as water, flavourings, artificial sweeteners, colourings and preservatives. Fruit juice drink can contain as little as 5% juice.

Soft drinks are non-alcoholic, flavoured, carbonated beverages, usually commercially prepared and sold in bottles or cans.

Alcoholic drinks are made by fermenting fruit juices, sugars and fermentable carbohydrates with yeast to form alcohol. These include beer, cider and perry, 4–6% alcohol by volume; wines, 9–13% alcohol; spirits (e.g. brandy, gin, rum, vodka, whisky) made by distilling fermented liquor, 38–45% alcohol; liqueurs made from distilled spirits, sweetened and flavoured, 20–40% alcohol; and fortified wines (aperitif wines, Madeira, port, sherry) made by adding spirit to wine, 18–25% alcohol.

<sup>5</sup> Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption. OJ L 10, 12.01.2002, p. 58–66.

**In the context of the food-borne outbreak system the category 'Drinks, including bottled water' does not include milk, fruit juice, fruit nectar, vegetable juice and tap water, but it includes fruit-flavoured drinks and juice drinks.**

The definition of drinks also includes hot drinks such as coffee and tea.

Bottled water is sold for human consumption. It is sealed in a sanitary container and must meet all regulations for drinking water. Bottled water contains no sweeteners or chemical additives and must be calorie and sugar-free.

'Natural mineral water' means microbiologically wholesome water originating in an underground water table or deposit and emerging from a spring tapped at one or more natural or bore exits. Before water is recognised as a natural mineral water, it has to be demonstrated that it:

- is obtained from an underground source
- has a stable composition
- is protected from all sources of pollution
- meets chemical and microbiological safety standards
- is not subject to treatment which affects its characteristic properties.

Natural mineral water is bottled at source and is sold under one trade description. The name of the source and its place of exploitation are stated on the label together with a statement of the analytical composition (EC Directives 80/777, 96/70 and 80/778).

In contrast, recognition of a spring water underground source is not required. Spring water meets the same chemical and microbiological standards as tap water and, currently, can be subject to treatment. However, like natural mineral water, spring water is bottled at source, sold under one trade description and the name of the source and its place of exploitation are included in labelling (EC Directives 80/777, 96/70 and 80/778).

Bottled drinking water, which is not restricted to a particular type of source, comprises bottled water, other than natural mineral water and spring water, and includes water referred to as 'table water'. Bottled drinking water is required to comply with the same compositional and microbiological standards as tap water (EC Directives 80/777, 96/70 and 80/778).

#### *Tap water, including well-water*

Tap water or ordinary drinking water refers to:

- all water, either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, from a tanker or in bottles or containers (Council Directive 98/83/EC).

**In this context, tap water, including well-water, does not include water in bottles. Water in bottles is included in the item 'Drinks, including bottled water'.**

**Please specify in the free text data element whether the water was treated or untreated.**

#### *Sweets and chocolate*

Sweets are foods, such as candy, milk-free puddings or preserves, which are high in sugar content and milk-free puddings.

Candy, specifically sugar candy, is a confection made from a concentrated solution of sugar in water, to which a variety of flavourings and colorants is added. Some candy, like marshmallows and gummy bears, may contain gelatine.

Preserves refer to fruit, or vegetables, that have been prepared, canned or jarred for long-term storage. Examples for preserves are jam and jelly.

Chocolate is obtained by an adequate manufacturing process from cocoa materials which may be combined with milk products, sugars and/or sweeteners and other additives. Other edible foodstuffs, excluding added flour and starch and animal fats other than milk fat, may be added to form various chocolate products (Directive 2000/36/EC<sup>6</sup>)

### *Bakery products*

Bakery products includes bread and ordinary bakery wares (all types of non-sweet bakery products and bread-derived products) and sweet, salty and savoury fine bakery wares (ready-to-eat products as well as mixes for preparing fine baked goods).<sup>7,8</sup>

Bread and ordinary bakery wares:

- The category bread contains the main sub-categories white bread, brown bread and wholemeal bread.
- Crackers, excluding sweet crackers: the term 'cracker' refers to a thin, crisp wafer, usually of unsweetened dough. Flavoured crackers (e.g. cheese flavoured). Examples include: soda crackers, rye crisps and matzahs.
- Other ordinary bakery products: includes all other ordinary bakery wares, such as bagels, pita, English muffins, cornbread and biscuits. The term 'biscuit' in this category refers to a small cake of shortened bread, leavened with baking powder or baking soda. It does not refer to the British 'biscuit,' which is a 'cookie' or 'sweet cracker' included in the category Cakes, cookies and pies.
- Bread-type products, including bread stuffing and bread crumbs: includes bread-based products, such as croutons, bread stuffing and stuffing mixes and prepared doughs (e.g. for biscuits).

Fine bakery wares (sweet, salty and savoury) and mixes:

- Cakes, cookies and pies (e.g. fruit-filled or custard types): the term 'sweet cracker' or 'sweet biscuit' used in this category refers to a cookie-like product that may be eaten as a dessert. Examples include: butter cake, cheesecake, fruit-filled cereal bars, pound cake, moist cake, western cakes, moon cakes, sponge cake, fruit-filled pies (e.g. apple pie), oatmeal cookies, sugar cookies and British 'biscuits' (cookies or sweet crackers).
- Other fine bakery products: includes products that may be eaten as a dessert or as breakfast. Examples include: doughnuts, sweet rolls, scones, muffins, pancakes, waffles, filled sweet buns, Danish pastries, wafers or cones for ice cream, flour confectionery and trifles. This category also includes tiramisu.

**Please specify the sub-category (e.g. fine bakery wares, pies) and, if available, the filling (e.g. fruit, custard, raw eggs) in the free text data element (for example: 'fine bakery product containing pasteurised dairy products and raw eggs, tiramisu').**

### *Herbs and spices*

Herbs are the aromatic leaves of plants without woody stems that grow in temperate zones. Spices are seasonings obtained from the bark, buds, fruit or flower parts, roots, seeds or stems of various aromatic plants and trees.

Herbs and spices are usually derived from botanical sources, which may be dehydrated and are either ground or whole. Examples of herbs include basil, oregano and thyme. Examples of spices include

<sup>6</sup> Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption. OJ L 197, 03/08/2000, p. 19–25.

<sup>7</sup> Available online: <http://www.codexalimentarius.net>

<sup>8</sup> Available online: <http://www.codexalimentarius.net/gsfonline/foods/details.html?id=113>

cumin and caraway seeds. Spices may also be found as blends in powder or paste form. Examples of spice blends include chilli seasoning, chilli paste, curry paste, curry roux and dry cures or rubs that are applied to external surfaces of meat or fish.<sup>9</sup>

#### *Mixed food*

Mixed meals are meals composed of various foods, for example paella, risotto, curries and nasi goreng. This category also includes miscellaneous foodstuffs served on one plate.

Please also select this category if it was not possible to narrow the suspected food down to an individual food or ingredient during the investigation of the food-borne outbreak.

#### *Buffet meals*

A buffet meal is a meal at which guests serve themselves from various dishes displayed on a large table.

#### *Other foods*

This category should be chosen if the implicated food is none of those mentioned above. In this case, it should be specified in the free text data element.

#### *Unknown*

This category should be chosen if the implicated food is not identified.

### **Place of exposure (settings)** (please see the terms in Table 5)

The place of exposure of the outbreak is the place of exposure to the implicated food. This is the location where the food was consumed or where the final stages of preparation of the suspect food took place, e.g. cafe/restaurant, institution, home.

Please specify the location where the food was consumed, hence the place of exposure.

#### *Household*

If the incriminated food was consumed at home, please choose 'household' as place of exposure.

Household is defined as one person living alone or a group of persons (who may or may not be related) living at the same address with common housekeeping.

**If the incriminated food for a private party was provided by a catering service and eaten at home, please choose 'household' as place of exposure and 'catering service/restaurant' as place of origin of problem, if the contamination or mishandling of the food took place at the catering service.**

**The same rule applies for 'meals on wheels', so please choose 'household' as place of exposure and 'catering service/restaurant' as place of origin of problem.**

*Restaurant or Cafe or Pub or Bar or Hotel or Catering service* If the incriminated food was served and eaten in a restaurant, please choose 'Restaurant or Cafe or Pub or Bar or Hotel or Catering service' as place of exposure.

A restaurant is an establishment where refreshments or meals are served to paying guests.

A café is a small and informal establishment serving various refreshments (as coffee) and usually featuring a limited menu.

Pub (British tavern) consists of a building with a bar and public rooms. It serves alcoholic beverages for consumption on the premises and often provides light meals. Synonyms are: public house, saloon, pothouse, gin mill.

<sup>9</sup> Available online: <http://www.codexalimentarius.net/gsfonline/foods/details.html?id=192>

A bar is a room or establishment where alcoholic drinks and food are served over a counter.

A catering service provides food service at a remote site, for example take-out party service often offered by supermarkets.

#### *Mobile retailer or market/street vendor*

If the incriminated food was served or bought at a mobile food establishment, please choose 'mobile retailer/market/street vendor' as place of exposure.

A mobile retailer is a retail food establishment that is readily movable, a motorised vehicle or a towed wheeled vehicle designed and equipped to serve food. Generally, a mobile food unit does not have a fixed sales location but operates in a variety of locations.

Market refers to the location where goods are traded, sometimes known as a marketplace, or to a street market. A marketplace is a location where goods and services are exchanged. The traditional market square is a city square where traders set up stalls and buyers browse the merchandise. A street market is an outdoor market such as traditionally held in a market square in a market town. Street markets are often held on only particular days of the week. Very similar markets or bazaars can also be found in large enclosed spaces, instead of on a street.

A street vendor is a person, or persons, travelling on public streets, public pavements, public property or private streets, and carrying, conveying or transporting items, such as food, beverages, and offering and exposing the same for sale.

#### **The difference between mobile retailer and catering:**

- **In contrast to the mobile retailer a catering service may prepare the food on site (e.g. home, rented room), i.e. made completely at the event, or the caterer may choose to bring prepared food and put the finishing touches on once it arrives. In addition, an event caterer serves food with waiting staff at dining tables or sets up a self-serve buffet.**

#### *Take-away or fast food outlet*

If the incriminated food was bought or served in a take-away or fast food outlet, please choose 'take-away or fast food outlet' as place of exposure.

Take-away is defined as an outlet where refreshments and meals are sold to customers. The food will be eaten either on the spot or elsewhere. Food that is delivered by a restaurant to a customer in order to be consumed in a place other than the restaurant is also classified as a take-away.

#### *Canteen or workplace catering*

If the incriminated food was served in a canteen, please choose 'canteen or workplace catering' as place of exposure.

A canteen or workplace catering is a private cafe, restaurant or cafeteria at a school, office or military base. It sells food and personal items to personnel at an institution or school. Usually large quantities of food are prepared in advance and only a limited choice of meals is available.

#### *Hospital or medical care facility*

If the incriminated food was served in a hospital or medical care facility, please choose 'hospital/medical care facility' as place of exposure.

A hospital is an institution that provides medical, surgical or psychiatric care and treatment for the sick or the injured.

The definition of medical care facilities includes various institutions, such as day clinics.

### *Residential institution (nursing home or prison or boarding schools)*

If the incriminated food was served in a residential institution, please choose 'residential institution' as place of exposure.

A residential institution is defined as an educational or healthcare facility with integral residential accommodation; this includes nursing homes, prisons and boarding schools.

Nursing homes, also called 'homes for the elderly', are establishments with three or more beds that provide nursing or personal care services to the older population, infirm or chronically ill.

A prison is a correctional institution where persons are accommodated while on trial or for punishment and a boarding school is a private school where students are taught as well as lodged and fed.

### *School or kindergarten*

If the incriminated food was served in an educational establishment, please choose 'school, kindergarten' as place of exposure.

A school is an educational institution where the pupils are educated and fed.

A kindergarten is a school or class intended for young children, usually four to six years of age, as a prominent part of pre-school education. It may refer to nursery school (pre-school) or day care.

### *Temporary mass catering (fairs, festivals)*

Temporary mass catering is the food service provided at large fairs or festivals.

**If the incriminated food served at a festival and the food service was provided by different mobile retailers or street vendors, please chose 'mobile retailer or market/street vendor' as a setting.**

### *Camp or picnic*

If the incriminated food was served at a camp or picnic, please choose 'camp, picnic' as place of exposure.

A camp is a place where tents, huts or other temporary shelters are set up as temporary lodging, for example by scouts or travellers (e.g. summer vacation camp). This category does not include camping.

A picnic is an excursion or outing with food provided by members of the group and eaten in the open.

*Catering on aircraft or ship or train* If the incriminated food was served on aircrafts, ships, trains, buses or coaches, please choose 'aircraft/ship/train' as place of exposure.

### *Multiple places of exposure in one country*

This term should be selected in cases where the incriminated food was served in different places of exposure in one country.

### *Multiple places of exposure in more than one country*

This term should be selected in cases where the incriminated food was served in different places of exposure in more than one country.

### *Farm*

If the incriminated food was served at the level of primary production, please choose 'farm' as place of exposure.

For example, a farm is a place of primary production and the basic unit in agriculture. It is a section of land devoted to the production and management of food, either produce or livestock.

### *Other*

Any other place of exposure that is not listed above.

### *Unknown*

The place of exposure is not identified or ascertained.

## **Place of origin of problem** (please see the terms in Table 6)

Place of origin of problem is the place, other than the place of exposure, where the mishandling of the food took place and/or where contamination occurred.

### *Household*

If the mishandling or contamination of the incriminated food occurred during preparation of food in a private home, please choose 'household/domestic kitchen' as place of origin of problem.

*Restaurant or Cafe or Pub or Bar or Hotel or Catering service* If the mishandling or contamination of the incriminated food occurred in a restaurant/café/pub/bar/hotel or during an event where food was provided by a catering service, please choose 'Restaurant or Cafe or Pub or Bar or Hotel or Catering service' as place of origin of problem.

A restaurant is an establishment where refreshments or meals are served to paying guests.

A café is a small and informal establishment serving various refreshments (as coffee) and usually featuring a limited menu.

Pub (British tavern) consists of a building with a bar and public rooms. It serves alcoholic beverages for consumption on the premises and often provides light meals. Synonyms are: public house, saloon, pothouse, gin mill.

A bar is a room or establishment where alcoholic drinks and food are served over a counter.

A catering service provides food service at a remote site, for example take-out party service often offered by supermarkets.

### *Mobile retailer or market/street vendor*

If the mishandling or contamination of the incriminated food occurred in a mobile food establishment, please choose 'mobile retailer/market/street vendor' as place of origin of problem.

A mobile retailer is a retail food establishment that is readily movable, a motorised vehicle or a towed wheeled vehicle designed and equipped to serve food. Generally, a mobile food unit does not have a fixed sales location but operates in a variety of locations.

Market refers to the location where goods are traded, sometimes known as a marketplace, or to a street market. A marketplace is a location where goods and services are exchanged. The traditional market square is a city square where traders set up stalls and buyers browse the merchandise. A street market is an outdoor market such as traditionally held in a market square in a market town. Street markets are often held on only particular days of the week. Very similar markets or bazaars can also be found in large enclosed spaces, instead of on a street<sup>20</sup>.

A street vendor is a person, or persons, travelling on public streets, public pavements, public property or private streets, and carrying, conveying or transporting items, such as food, beverages, and offering and exposing the same for sale.

### *Take-away or fast food outlet*

If the mishandling or contamination of the incriminated food occurred in a take-away or fast food outlet, please choose 'take-away or fast food outlet' as place of origin of problem.

Take-away is defined as an outlet where refreshments and meals are sold to customers. The food will be eaten either on the spot or elsewhere. Food that is delivered by a restaurant to a customer in order to be consumed in a place other than the restaurant is also classified as a take-away.



### *Canteen or workplace catering*

If the mishandling or contamination of the incriminated food occurred in a canteen, please choose 'canteen or workplace catering' as place of origin of problem.

A canteen or workplace catering is a private cafe, restaurant or cafeteria at a school, office or military base. It sells food and personal items to personnel at an institution or school. Usually large quantities of food are prepared in advance and only a limited choice of meals available.

### *Hospital or medical care facility*

If the incriminated food was served in a hospital or medical care facility, please choose 'hospital/medical care facility' as place of exposure.

A hospital is an institution that provides medical, surgical or psychiatric care and treatment for the sick or the injured.

The definition of medical care facilities includes various institutions, such as day clinics.

### *Residential institution (nursing home or prison or boarding schools)*

If the mishandling or contamination of the incriminated food occurred in a residential institution, please choose 'residential institution' as place of origin of problem.

A residential institution is defined as an educational or healthcare facility with integral residential accommodation, this includes nursing homes, prisons and boarding schools.

Nursing homes, also called 'homes for the elderly', are establishments with three or more beds that provide nursing or personal care services to the older population, infirm or chronically ill.

A prison is a correctional institution where persons are accommodated while on trial or for punishment and a boarding school is a private school where students are taught as well as lodged and fed.

### *School or kindergarten*

If the mishandling or contamination of the incriminated food occurred in an educational establishment, please choose 'school, kindergarten' as place of origin of problem.

A school is an educational institution where the pupils are educated and fed.

A kindergarten is a school or class intended for young children, usually four to six years of age, as a prominent part of pre-school education. It may refer to nursery school (pre-school) or day care.

### *Temporary mass catering (fairs, festivals)*

A temporary mass catering is the food service provided at large fairs or festivals.

### *Camp or picnic*

If the mishandling or contamination of the incriminated food occurred at a camp or picnic, please choose 'camp, picnic' as place of origin of problem.

A camp is a place where tents, huts or other temporary shelters are set up as temporary lodging, for example by scouts or travellers (e.g. summer vacation camp). This category does not include camping.

A picnic is an excursion or outing with food provided by members of the group and eaten in the open.

*Catering on aircraft or ship or train* If the mishandling or contamination of the incriminated food occurred on aircrafts, ships, trains, buses or coaches, please choose 'aircraft/ship/train' as place of origin of problem.

### *Slaughterhouse*

If the contamination was acquired or the mishandling occurred during the slaughtering, chilling or dressing of animals, please choose 'slaughterhouse' as place of origin of problem.



A slaughterhouse is defined as an establishment used for slaughtering and dressing animals, the meat of which is intended for human consumption (Regulation (EC) No 853/2004). Fishing vessels are also part of this category.

#### *Farm*

If the mishandling or contamination of the incriminated food occurred on the level of primary production, please choose 'farm' as place of origin of problem. For example, a farm is a place of primary production and the basic unit in agriculture. It is a section of land devoted to the production and management of food, either produce or livestock.

#### *Processing plant*

If the contamination was acquired in a processing plant, please choose 'processing plant' as place of origin of problem.

Processing is defined as any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes (Regulation (EC) No 852/2004), it also includes packing, labelling and storing.

A processing plant is a commercial plant that manufactures, packages, labels or stores food for human consumption and does not provide food directly to a consumer; quality control and production supervision. A typical example is a dairy processing plant, where milk is converted, for example, into butter, yoghurt or cheese.

#### *Retail*

If the mishandling or contamination of the incriminated food occurred in a retail outlet, please choose this option.

Retail means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes supermarkets, retail sale outlets and shops.

A retail sale outlet is defined as a place of business for retailing goods, e.g. grocer, supermarket, retail store, discounter, department store and shopping centre.

#### *Transport*

If the mishandling or contamination of the incriminated food occurred during the transport of the food, please choose 'transport' as place of origin of problem.

Transport is defined as moving of goods for a commercial purpose.

#### *Water treatment plant*

If the mishandling or contamination of the incriminated food was acquired in a water treatment plant, please choose 'water treatment plant' as place of origin of problem.

A water treatment plant is defined as: (1) plant where, through physical–chemical and biological processes, organic matter, bacteria, viruses and solids are removed from residential, commercial and industrial wastewaters before they are discharged into rivers, lakes and seas; (2) installations to render wastewater, sludge, storm water or cooling water fit to meet applicable environmental standards or other quality norms for recycling or reuse.<sup>10</sup>

#### *Water distribution system*

If the contamination was acquired in the water distribution system, please choose 'water distribution system' as place of origin of problem.

A water distribution system is the system of pipes supplying water to communities and industries.<sup>11</sup>

<sup>10</sup> Available online: [http://glossary.eea.europa.eu/EEAGlossary/W/waste\\_water\\_treatment\\_plant](http://glossary.eea.europa.eu/EEAGlossary/W/waste_water_treatment_plant)

<sup>11</sup> Available online: [http://glossary.eea.europa.eu/EEAGlossary/W/water\\_distribution\\_system](http://glossary.eea.europa.eu/EEAGlossary/W/water_distribution_system)

Domestic distribution system shall mean the pipe work, fittings and appliances which are installed between the taps that are normally used for human consumption and the distribution network, but only if they are not the responsibility of the water supplier, in its capacity as a water supplier, according to the relevant national law (Council Directive 98/83/EC).

#### *Water source*

If the contamination was acquired in a water source, please choose 'water source' as place of origin of problem.

A water source is the basic origin of water, either a surface source (such as a lake, river or reservoir) or a sub-surface source (such as a well) before treatment and pumping.<sup>12</sup>

#### *Travel abroad*

If the infection was acquired on a journey abroad (out of one's own country), please choose 'travel'.

#### *Other*

If the mishandling or contamination of the incriminated food occurred in a place that is not listed above, please choose 'other' as place of origin of problem.

Other is defined as every place of origin of problem that is not listed above.

#### *Unknown*

The place of origin of problem is not identified.

### **Contributory factor** (please see the terms in Table 7)

Contributory factors are factors that contributed to the food-borne outbreak. These may include deficiencies in food handling or contaminated raw materials. If appropriate, more than one factor can be chosen.

#### *Unprocessed contaminated ingredient*

Unprocessed contaminated ingredients are raw ingredients contaminated with the causative agents at the primary production level, during processing or transportation. The contamination occurs before preparation and consumption. Examples are eggs or meats that are contaminated with *Salmonella*. In addition, herbs that may have been contaminated with microbes during irrigation or by wild animals are often used in salads or added to ready-to-eat meals without further heating.

#### *Storage time/temperature abuse*

Please select this category if the time/temperature abuse occurred during the storage of food. This applies to mistakes during hot holding of food or during the cold chain.

If the food is held hot at an improper holding temperature (e.g. < 60°C) for an unsuitable period of time the likelihood of multiplication of microorganisms present on/in the food is high.

The cold chain, on the other hand, is the sequence of temperature-controlled operations after initial harvesting, and including chilled transport, cooling during and after production, chilled storage distribution and retailing, through to domestic storage until preparation for final consumption. If there is, for example, an interruption within the cold chain it can lead to a multiplication of microorganisms present on/in the food. In addition, if food is stored in large containers or stacked too tightly the core of the food may not reach the appropriate cooling temperature.

#### *Inadequate heat treatment*

Please select this category if inadequate heat treatment occurred during the cooking or reheating of the incriminated food. This is the case if food is cooked at an inadequate temperature (for example

<sup>12</sup> Available online: [www.ncruralcenter.org/water2030/glossary.htm](http://www.ncruralcenter.org/water2030/glossary.htm)

< 70°C) and/or for an inadequate period of time or the heat treatment of the core of the food is insufficient to kill the pathogenic microorganisms.

Inadequate heat treatment in terms of cooking can be defined as foods that are cooked at an inappropriate temperature for a suitable period of time or cooked at an appropriate temperature for an unsuitable period of time or cooked at an inappropriate temperature for an unsuitable period of time.

#### *Inadequate chilling*

Chilling is the process of cooling the food. Food is chilled inadequately if the core temperature of the food remains, for example, higher than 2–8°C for too long, which can result in multiplication of microorganisms. Please note that the sufficient chilling temperature is dependent on the type of food. For example, there are slight differences between minced meat and cheese. It is important that the core of the food will reach the appropriate cold temperature as quickly as possible.

#### *Cross-contamination*

Cross-contamination is the contamination occurring during preparation for consumption of a food item by direct or indirect contact with another food item, equipment and work surfaces, including hands.

For example, raw fruits and vegetables can contaminate cooked foods if they are not properly cleaned. In addition, juices from raw meat and poultry which come in contact with ready-to-eat foods can contaminate the cooked foods. Unwashed hands, unclean utensils and food contact surfaces result in a cross-contamination of food if that food is handled on these surfaces, with these utensils or processed by unwashed hands.

#### *Infected food handler*

An infected food handler is defined as cook or kitchen worker with a confirmed infection (regardless of symptomatic or asymptomatic infection) transmitting the causative agent onto food. In practice it is often impossible to differentiate whether the infection of the food handler occurred first and is the source of infection or if the food handler acquired the infection from the food. Please choose this category only if it is likely that the infected food handler is the source of infection.

#### *Untreated drinking water*

Untreated drinking water is defined as non-potable water that has not been subjected to any process designed to remove contaminants or organisms.

#### *Drinking water treatment failure*

A failure in the water treatment system is leading to contamination in the water supply.

Drinking water treatment failures can have their origin in different areas like a failure of water treatment or disinfection, contamination of the water supply; or clusters of illness potentially caused by the former.

#### *Other*

'Other' should be chosen if the contributory factor identified during the outbreak investigation is not listed in the catalogue.

#### *Unknown*

This option should be picked if no contributory factor has been identified during the investigation of the outbreak.