

SCIENTIFIC REPORT OF EFSA

Update of the technical specifications for harmonised reporting of food-borne outbreaks through the European Union reporting system in accordance with Directive 2003/99/EC¹

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ABSTRACT

In the analyses of the reported data on food-borne outbreaks at the European Union level it is important to address the relevance of different food categories as outbreak vehicles and the causative agents most frequently associated with these food vehicles. This report includes an update of the technical specifications for harmonised reporting of food-borne outbreaks to the European Union, to allow for the better achievement of their objectives. Member States shall report all food-borne outbreaks which meet the definition in the Directive 2003/99/EC. A distinction has been made between food-borne outbreaks supported by 'weak' evidence and those supported by 'strong' evidence, based on the strength of evidence implicating a particular food vehicle. The same dataset is used for both weak- and strong-evidence outbreaks. This includes the number of outbreaks per causative agent, and the number of human cases, hospitalisations, and deaths. In addition, other information can be reported by Member States, including the nature of the evidence supporting the suspicion of implicated food vehicles and data on the causative agents, food vehicles, and the factors in food preparation and handling that contributed to the food-borne outbreaks.

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KEY WORDS

food-borne outbreak, reporting system, causative agent, food vehicle, strength of evidence

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SUMMARY

The European Food Safety Authority, together with the European Centre for Disease Prevention and Control, has updated, for a second time, the technical specifications for harmonised reporting of food-borne outbreaks through the European Union reporting system, in accordance with Directive 2003/99/EC. This update takes into account the need for revisions originating from implementing the first updated reporting specifications for 2010, 2011 and 2012 data.

The second update proposes that the distinction between 'strong-' and 'weak-evidence' food-borne outbreaks, based on the evidence implicating a particular food vehicle, is maintained. Member States should report all food-borne outbreaks that meet the definition laid down by Directive 2003/99/EC.

The same dataset is used for food-borne outbreaks where no particular food vehicle is suspected and for food-borne outbreaks where 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 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 always 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.

The information to be reported was selected due to its relevance at the European Union level and whether this information can be analysed at a supra-national level. Specifically, it is important to address the relevance of different food categories as outbreak vehicles and the causative agents most frequently associated with these food vehicles. Waterborne outbreaks should be analysed separately from the other food-borne outbreaks. Also, the analyses of the circumstances that contributed to the occurrence of food-borne outbreaks and the trends in the reported outbreaks over the years are relevant at the European Union level.

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BACKGROUND AS PROVIDED BY EFSA

The Directive 2003/99/EC⁴ lays down the EU system for monitoring and reporting of information on zoonoses which obligates the Member States to collect relevant, and where applicable, comparable data on zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks. The European Food Safety Authority (EFSA) is assigned the tasks of examining the data collected and preparing the EU Summary Report.

In 2007, EFSA issued the report on harmonising the reporting of food-borne outbreaks through the Community reporting system in accordance with Directive 2003/99/EC which included guidelines to the Member States on the reporting of food-borne outbreaks. These reporting guidelines have been implemented in the reporting of the 2007, 2008, and 2009 food-borne outbreak data. A second update of these specifications was made due to some additional requests from the reporting Member States. New reporting specifications were issued in 2011 and were implemented in the reporting of the 2010 and 2011 data. The analysis of the first two years of implementation of these new specifications demonstrated that the quality of the data reported had improved. However, based on the experience gained, Member States requested some fine-tuning and clarification of the reporting specifications. Particularly, the possibility of providing more detailed data on food-borne outbreaks supported by weak evidence. Therefore, there is a need to review the current reporting specifications.

In the review of the reporting specifications, the anticipated collection of molecular typing information from food-borne pathogens at the EU level can be taken into account, as appropriate.

The Task Force on Zoonoses Data Collection has been consulted regarding the review and has supported the suggestion to set up a Working Group to carry out the review and make suggestions to the revised reporting specifications.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The BIOMO Unit was invited to set up an EFSA Working Group comprising external scientific experts representing both the food safety and human health sectors, with the tasks to:

- Review the need to amend the current reporting specifications for food-borne outbreaks in the EU (as defined 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);
- To produce a report on this need and revise the reporting specifications, if needed.

⁴ 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.

TECHNICAL SPECIFICATIONS

1. Introduction

Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents (Zoonoses Directive) covers the epidemiological investigation and reporting of food-borne outbreaks in the Member States (MSs) of the European Union (EU). Thorough investigation of food-borne outbreaks aims to identify the pathogen, the food vehicle involved, and the factors in the food preparation and handling contributing to the outbreak. This information contributes to the prevention of future outbreaks and improvement of food safety. The Zoonoses Directive makes provisions for such investigations and for close co-operation between various authorities.

The competent authority of each MS must provide the Commission with a summary report of the results of the investigation of food-borne outbreaks, which is sent to EFSA. Minimum reporting requirements for the food-borne outbreaks are laid down in Annex IV (E) to the Directive. In practice this information is submitted both through a web-based reporting application run by EFSA, or electronically through the Data Collection Framework (DCF). In addition, in accordance with the procedure referred to in Article 12 of the Zoonoses Directive, detailed rules concerning the assessment of the reports, including the format and the minimum information they must include, may be laid down.

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

- a. Total number of outbreaks over a year;
- b. Number of human deaths and illnesses in these outbreaks;
- c. The causative agents of the outbreaks, including, where possible, serotype or other definitive description of the agents. Where the identification of the agent is not possible, the reason should be stated;
- d. Foodstuffs implicated in the outbreak and other potential vehicles;
- e. Identification of the type of place where the incriminated foodstuff was produced/purchased/acquired/consumed;
- f. Contributory factors, for example, deficiencies in food processing hygiene.

In order to provide harmonised reporting specifications for food-borne outbreaks in EU, EFSA in collaboration with the European Centre for Disease Prevention and Control (ECDC) set up a shared Working Group in 2006 to prepare a proposal for such guidance. The proposed harmonised reporting specifications were adopted on 8 November 2007 by the 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). This reporting scheme was referred to as the Community Outbreak Reporting System (CORS), and it was implemented for the first time in the reporting of data for the year 2007 and, subsequently, for the reporting of 2008 and 2009 data. This reporting system was revised and updated technical specifications for harmonised reporting of food-borne outbreaks through the EU reporting system in accordance with Directive 2003/99/EC were issued on 9 March 2011 (EFSA, 2011). These new reporting guidelines, hereafter referred to as the European Union Food-borne Outbreak Reporting System (EU-FORS), have been implemented in reporting 2010, 2011 and 2012 data. Based on the experience gained, the need to make some adjustments to the updated reporting specifications has been identified.

Many MSs operate human communicable disease surveillance systems in the public health sector which, among others, also cover food-borne diseases, whereas veterinary and food safety authorities

have traditionally concentrated on the managerial aspects of food safety. Therefore, monitoring of food-borne outbreaks is of common interest to food 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 and human health authorities. Food business operators are also interested in these reports to minimise risk of food-borne outbreaks and to produce safe food.

2. Aim and objectives of collecting information on food-borne outbreaks

Aim

To provide information, in routine and ad hoc reports, derived from MSs' investigation of food-borne outbreaks to assist stakeholders – including policymakers, health protection professionals, the food industry (from farm to fork), and the public - in reducing the risk of food-borne outbreaks, in informing risk assessments, and in investigating and controlling food-borne outbreaks when they do occur.

Objectives

1. To collect, collate, and analyse data on MSs' investigation of food-borne outbreaks, and to disseminate information describing the incidence of, and trends in, food-borne outbreaks' characteristics, including their:
 - I. Number and population incidence
 - II. Size
 - III. Severity
 - IV. Suspected food vehicles, suspected food vehicles' categories, and the nature and strength of evidence supporting the suspicion
 - V. Causative agent
 - VI. Place of exposure
 - VII. Contributing factors
2. To bring to the attention of stakeholders investigations of specific food-borne outbreaks which have particular interest, importance, or usefulness.

3. Definitions

For the purpose of this document, the following definitions will apply:

Analytical epidemiological evidence: a statistical 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 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 in 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 178/2002⁵). This definition 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-/ribo-typing), 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 confirmed microbiologically or not) 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 on 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.

⁵ 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.

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.

4. Main issues identified in the implementation of the European Union Food-borne Outbreak Reporting System (EU-FORS)

4.1 Interpretation of the definition for food-borne outbreak

The Zoonoses Directive defines a food-borne outbreak as:

‘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’.

This definition has two components: it defines an outbreak and it then defines what constitutes a food-borne outbreak. It states that, cases must be ‘linked, or ... probably linked, to the same food source’ for an outbreak to be food-borne.

The definition is given in a legal context and, therefore, it is deliberately formulated broadly. For the purpose of more detailed reporting specifications there is a need to further interpret the definition regarding certain aspects. In particular, it needs to be defined what is the strength of the evidence upon which a judgement of ‘human cases ...linked or probably linked to the same food source’ is made. Furthermore, the definition uses the term ‘food source’, while in other parts of the Directive terms ‘implicated foodstuff’ and ‘vehicle’ are also applied.

The CORS, published in 2007 by EFSA, attempted to define the strength of evidence that could link cases to a food vehicle drawing a distinction between ‘verified’ and ‘possible’ food-borne outbreaks.

CORS invited detailed reporting only for ‘verified food-borne outbreaks’, defined as those in which the causative agent had been detected in the implicated food vehicle or the food vehicle had been identified by analytical epidemiology, as only data from such outbreaks were intended to be analysed in detail and used in risk assessments.

This approach of CORS did not acknowledge that:

- an outbreak can be deemed certainly or probably food-borne in the absence of evidence for a particular food vehicle or food source; and
- the nature of evidence is not necessarily correlated with its strength.

In addition, MSs were reluctant to identify a particular food vehicle as ‘verified’ for legal reasons.

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

EU-FORS invited detailed reporting only for strong-evidence food-borne outbreaks, 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, the MSs still saw some need for fine-tuning and clarifying the reporting specifications. In particular, MSs suggested that it would be helpful to provide the more detailed dataset on those food-borne outbreaks supported by weak evidence.

4.2 Nature and strength of evidence

The nature of evidence linking the consumption of a particular food vehicle to being a case in an outbreak 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 descriptive 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 after opening 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 to the EU level should be based on a carefully considered assessment of all available categories of evidence.

As a guide:

1. Strong epidemiological evidence includes a statistical association in a well conducted analytical epidemiological study, or convincing descriptive evidence. Examples of convincing descriptive epidemiological evidence are provided in the Appendix B.
2. Strong microbiological evidence includes 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 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 who were exposed and for whom a place of exposure/ point of sale could be identified. Examples are given in Appendix B.

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, evidence on food-borne outbreaks supported only by prior plausibility alone 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. To use 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.

4.3. Legal issues

The Zoonoses Directive does not make provision for distinguishing between ‘verified’ and ‘possible’ food-borne outbreaks, or ‘verified’ and ‘possible’ food vehicles, but this distinction was introduced in CORS by EFSA. This distinction has legal implications in some MSs. For instance, in the United Kingdom, classification of an outbreak as ‘verified’ or ‘possible’ could prejudice any legal action being taken against a food business operator, or prompt litigation against the authorities. Similar issues surround the categorisation of evidence implicating particular food vehicles. Since it takes time for local enforcement officers to decide whether or not to bring a legal case and, since such cases may take years rather than months to be concluded, such classification of outbreaks cannot be provided in a timely fashion. Moreover, the very existence of a definition of ‘verified’ food-borne outbreaks in EFSA guidance may influence the outcome of a prosecution.

Nevertheless, a classification of the food-borne outbreaks based on the strength of evidence implicating a suspect food-vehicle is vital for health protection within EU. ECDC and EFSA must make it explicit that when a MS reports a suspect food vehicle, and the strength of evidence supporting that suspicion, the attribution does not imply a level of evidence adequate for legal action.

However, the legal implications related to the original distinction between ‘verified’ and ‘possible’ food-borne outbreaks were overcome with the new categorisation proposed by the EU-FORS.

5. Proposed changes to the European Union Food-borne Outbreak Reporting System (EU-FORS)

Based on the reasons described earlier, a number of changes are proposed to EU-FORS. This new revised reporting system is hereafter referred to as the second update to the European Union Food-borne Outbreak Reporting System.

Depending on the size of the outbreak and severity of the disease, the strength of evidence implicating a suspect food vehicle which prompts local or MS or EU level control measures may be less than that required to inform the food safety policies in the MS or in the EU.

Those food-borne outbreaks where either no particular food vehicle is suspected/identified or where the evidence implicating a particular food vehicle is weak could be of little value in informing EU policies on food safety. However, although unlikely to be strong enough to inform policy, weak evidence can be valuable in informing immediate control measures at a local level and would be of interest to other MSs.

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.

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 ‘place of origin of the problem’ and ‘origin of food vehicle’, where more detailed information on sources of the food implicated can be reported.

In a similar way to the previous reporting specifications, the updated EU-FORS foresees reporting of some additional information compared to the minimum requirements laid down in Annex IV to 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 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 and a general scheme for reporting of food-borne outbreaks is given in Figure 1.

Table 1: Main differences between the current 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 ^(a)		Revised EU-FORS Strength of evidence ^(a)	
		weak	strong	weak	strong
Analytical epidemiological evidence	DE (verified outbreak)	LI	DE	DE ^(b)	
Descriptive epidemiological evidence	LI (possible outbreak)	LI	DE	DE ^(b)	
Product-tracing investigations	NA	NA		DE ^(b)	
Microbiological evidence				DE ^(b)	
- Detection in food vehicle	DE (verified outbreak)	LI	DE	DE ^(b)	
- Detection in food vehicle's component or in food chain or its environment	LI (possible outbreak)	LI	DE	DE ^(b)	
Descriptive environmental evidence	NA	NA		DE ^(b)	

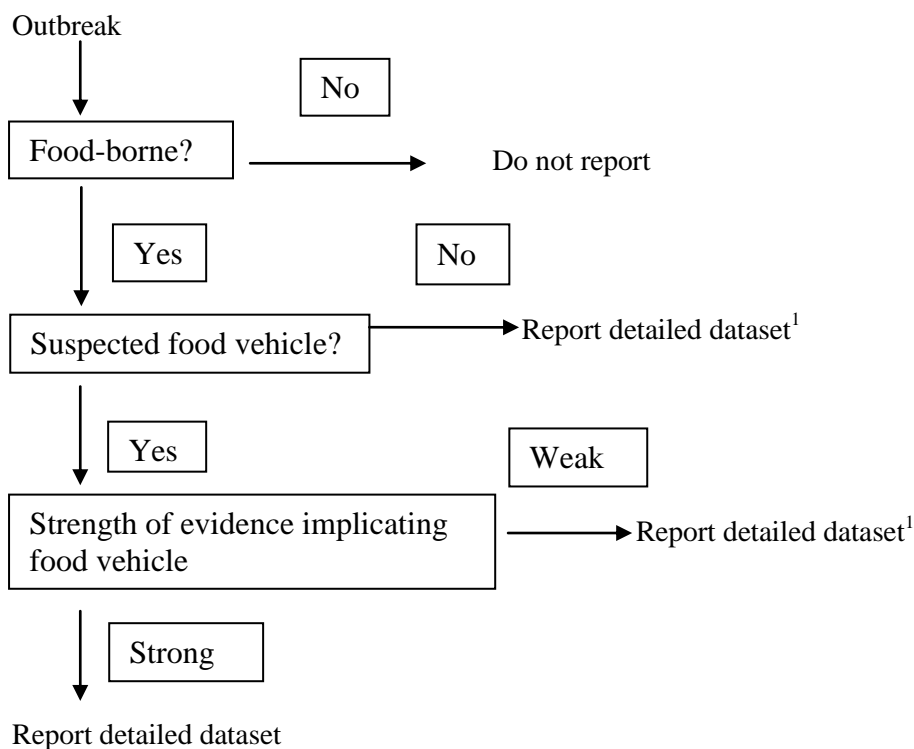
(a) Reporting depends on judgement of the overall strength of all available evidence (i.e. strong or weak).

(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.

DE = a detailed dataset is reported

LI = a limited dataset is reported

NA = Not Applicable



1. 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)

6. Scope of the updated reporting system (updated EU-FORS)

The annual reporting covers the results of the investigations of all food-borne outbreaks, as defined in the Zoonoses Directive, carried out in MSs.

These outbreaks include food-borne outbreaks irrespective of whether the causative agent is known or not. Outbreaks caused by ingestion of drinking water are also considered food-borne, since drinking water is defined as food in Regulation 178/2002/EC. Food-borne outbreaks caused by chemical agents are also covered at this stage by the reporting system.

7. Data reporting

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.

EFSA has established a web-based reporting system to streamline and harmonise this reporting. The information can be entered either manually through the reporting application or uploaded in bulk (i.e. transfer of files) in XML format.

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

- 7.1 National reporting system description (free text form)
- 7.2 Total number of food-borne outbreaks (table form)
- 7.3 Detailed datasets on food-borne outbreaks (table form)
- 7.4 National evaluation of the reported food-borne outbreaks (free text form)

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 do not record 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.

7.1 National reporting system description (free text form)

This free text form in the reporting application is used to describe the national system in place for identification, epidemiological investigation and reporting of food-borne outbreaks.⁶ This is important to understand the tabular data in their context. Typically this text briefly describes:

- Procedures for investigation and reporting (including frequency of reporting) of food-borne outbreaks, and their legal basis;
- Any relevant changes in the reporting system in comparison with previous year(s);
- Differences in the definitions used and in the scope of the system as compared with EU system (e.g. if the national reporting system does not allow a distinction to be made between general and household outbreaks);
- The authorities and institutions involved, their roles and mutual co-ordination.

7.2 Total number of food-borne outbreaks (table form)

The total number of food-borne outbreaks that occurred during the reporting year is automatically calculated in the table provided by the zoonoses web application per each causative agent as well as the breakdown for strong- and weak-evidence outbreaks.

Table 2: Total number of food-borne outbreaks

Variable	Field type	Description of the information to be provided
Total number of food-borne outbreaks	Numerical	This number is calculated automatically from the inputted data on reported outbreaks
Total number of strong-evidence food-borne outbreaks	Numerical	This number is calculated automatically from the inputted data on reported outbreaks
Total number of weak-evidence food-borne outbreaks	Numerical	This number is calculated automatically from the inputted data on reported outbreaks

7.3 Detailed dataset on food-borne outbreaks (table form)

For detailed data on food-borne outbreaks an additional table is available on the zoonoses web application to collect this information. 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 pick lists.

⁶ The text in this form may be automatically copied from the previous year's report in the web application so that the reporting officer only needs to update the free text where appropriate.

The web application and the Data Model are designed for the input of data in individual outbreak format and MSs are strongly encouraged to provide the data on an individual outbreak basis.

However, in some cases data from several similar outbreaks can be reported aggregated (e.g. when the available data are scarce) and then reported in one row. The 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 following detailed dataset has to be provided:

Table 3: Detailed dataset on food-borne outbreaks

Variable	Field type	Description of the information to be provided
Code	Free text	This field 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.
Number of outbreaks	Numerical	1 for outbreak based reporting, 2 or more if aggregated data are being reported.
Causative agent	Pick list (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 are reported under 'Mixed outbreaks (other agent)'.
Mixed outbreaks (other agent)	Free text	In cases where more than one causative agent was identified in the outbreak, the other agent/s are reported in free text format.
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.
Hospitalisations	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 over-night stay.
Deaths	Numerical	The known number of outbreak cases who died as a result of the food-borne outbreak. Only deaths attributable to the causative agent responsible for the outbreak should be reported.
Food vehicle	Pick list (Appendix A)	The foodstuff category (food vehicle) suspected in the food-borne outbreak is reported using the specific pick list. A 'free text field' can be used to define the food vehicle in more detail.

Table 3: Detailed dataset on food-borne outbreaks (continued)

Variable	Field type	Description of the information to be provided
More food vehicle information	Free text	In case more information on the food vehicle is available, reported in free text format.
Nature of evidence linking outbreak cases with a food vehicle	<ul style="list-style-type: none"> ○ Epidemiological <ul style="list-style-type: none"> - Descriptive - Analytical ○ Product-tracing investigations ○ Microbiological <ul style="list-style-type: none"> - Detection in food vehicle or its component <i>or</i> - Detection in food chain or its environment <p style="margin-left: 20px;"><i>And either</i></p> <ul style="list-style-type: none"> - Detection of indistinguishable causative agent in humans <i>or</i> - Symptoms and onset of illness pathognomonic to the causative agent found in food vehicle or its component or in food chain or its environment ○ Descriptive environmental evidence ○ None 	Specify the nature of evidence linking outbreak cases with a foodstuff. See definitions (Section 3). For food-borne outbreaks where more than one type of evidence was observed, all relevant evidence types should be reported.
Strength of evidence linking outbreak cases with a food vehicle	<ul style="list-style-type: none"> ○ Strong ○ Weak ○ Not applicable 	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.
Extent of outbreak	<ul style="list-style-type: none"> ○ Household ○ General ○ Unknown 	Specify the extent of the food-borne outbreak; see definitions of household and general outbreak (Section 3). 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	Pick list (Appendix A)	See definitions (Section 3).
Place of origin of problem	Pick list (Appendix A)	See definitions (Section 3). If there is more than one place of origin of the problem, all the relevant ones are chosen from the picklist.
Origin of food vehicle	<ul style="list-style-type: none"> ○ Domestic market ○ Intra EU trade ○ Imported from outside EU ○ Unknown 	Information whether the food vehicle originated from domestic market, intra-EU trade or was imported from outside EU.

Table 3: Detailed dataset on food-borne outbreaks (continued)

Variable	Field type	Description of the information to be provided
Contributory factors	Pick list (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 are chosen from the picklist.
Additional information	Free text	In the text form a separate free text field is provided where additional information can be reported. This field 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 reported through RASFF ⁷ or EWRS ⁸ . This field 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 has been quantified, this field can be used to report quantitative laboratory results (as cfu/ml or cfu/g or as MPN/ml or MPN/g).

7.4 National evaluation of the reported food-borne outbreaks (free text form)

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 the MSs are correctly interpreted at EU level. Typically this text briefly describes:

- The trend in the number of outbreaks and possible underlying reasons;
- Relevance of the different causative agents, food categories and the agent/food category combinations;
- Relevance of different types of place of food production and preparation in outbreaks;
- Evaluation of the severity of the human cases (e.g. trends in the number of deaths and hospitalisations);
- Measures or other actions taken to control or prevent the outbreaks; and
- Description of single outbreaks of special interest.

8. Support to Member States' reporters

It is possible that there will be differences in the interpretation of how to apply the updated EU-FORS among the MSs' reporters, particularly regarding the strength of evidence. Therefore, in order to ensure harmonised implementation of the updated reporting specifications, it is important to provide support to the reporters. Organising training on the updated EU-FORS might be needed both at EU and national level. In addition, EFSA's manual on reporting of food-borne outbreaks (EFSA, 2013) needs to be revised in light of the new specifications and examples clarifying the interpretation can be provided in the manual. Furthermore, it would be useful to organise annual workshops for the national reporters to facilitate sharing of information on interesting outbreaks and discussions on the interpretation of the updated EU-FORS. This could be supported by establishing an electronic discussion forum for the reporters, where also full outbreak reports could be uploaded for general interest.

⁷ Rapid Alert System for Food and Feed.

⁸ Early Warning and Response System.

9. Analyses of the reported food-borne outbreak data at the European Union level

In the annual EU Summary Reports (EUSRs), food-borne data submitted by MSs are analysed using both descriptive and analytical epidemiological methods. The data analysis shall address, as far as possible, the relevance of different food categories as food vehicles and the causative agents most frequently associated with them. It is also important to analyse the circumstances that, singly or in combination, contributed to the occurrence of food-borne outbreaks, as well as trends in the outbreaks and the outbreak breakdown by causative agent. The outbreaks can be further characterised by analysing the disease severity in humans, as demonstrated by the proportion of hospitalised cases and deaths.

Detailed data are to be regularly analysed from outbreaks where there is strong evidence implicating a particular food vehicle. The analyses could include reporting of the median, or quartiles, if the reported data allow calculation of these statistical parameters.

The reported data will facilitate the separate analysis of information from outbreaks supported by different types of evidence, for example outbreaks supported by analytical epidemiological evidence, descriptive epidemiological evidence, product-tracing investigations, microbiological evidence, or by descriptive environmental evidence. These analyses may reveal if there are systematic differences between these outbreak categories.

The use of trend analyses at EU or individual MS levels can provide information on the impact of control measures taken or on emergence of certain types of outbreaks. In the trend analyses it is essential that data of good quality are available (such as sufficient number of reporting MSs and number of years).

It is important to account for the quality of the data reported and the impact of these data on the analyses in the EU Summary Reports. In most cases, data received in the framework of the annual data collection are not directly comparable between countries due to differences in outbreaks investigation systems, data collection and reporting. Therefore, any direct comparisons between MSs are avoided.

Since outbreaks resulting from the consumption of water, whether treated or untreated, private or public, differ in nature from the other food-borne outbreaks, it is preferable to analyse and report them separately in the EU Summary Report.

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APPENDICES

Appendix A. Pick lists

A. Causative agent

This list, available in the web reporting application and in the DCF Data Model, provides the most commonly reported agents. The reporting system allows addition of other agents and provides deeper levels for a breakdown to species/serovars/serotypes/phage types/other types level.

B. Food vehicle

Code	Decode
B07727B	Milk
B09607B	Dairy products (other than cheeses)
B09627B	Cheese
B09647B	Eggs and egg 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
B10047B	Other foods
B00000B	Unknown

C. Place of exposure

Code	Decode
E230A	Household/domestic kitchen
E911A	Restaurant/Café/Pub/Bar/Hotel/Catering service
E920A	Mobile Retailer/market/street vendor
E930A	Take-away or fast food outlet
E940A	Canteen or workplace catering
E210A	Hospital/medical care facility
E220A	Residential Institution (nursing home, prison, boarding schools)
E240A	School, kindergarten
E950A	Temporary mass catering (fairs, festivals)
E960A	Camp, picnic
E990A	Aircraft/ship/train
E971A	Multiple places of exposure in one country
E972A	Multiple places of exposure in more than one country
E101A	Farm (primary production)
E099A	Other
E980A	Unknown

D. Place of origin of problem

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

E. Contributory factor

Code	Decode
CF08A	Unprocessed contaminated ingredient
CF06A	Storage time/temperature abuse
CF03A	Inadequate heat treatment
CF02A	Inadequate chilling
CF01A	Cross-contamination
CF04A	Infected food handler
CF10A	Untreated drinking water
CF09A	Drinking water treatment failure
CF05A	Other
CF07A	Unknown

Appendix B. Examples of convincing descriptive epidemiological evidence and evidence from product-tracing investigations

Background

It is not always possible or appropriate to mount analytical 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 analytical epidemiological study before introducing control measures puts the public at unacceptable risk, or whether conducting one 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.

Also 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 epidemiological 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 sandwich bar:

- a. Descriptive epidemiology:
 - i. All identified cases had onset date within one day of visiting the same sandwich bar with symptoms compatible with 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* infection. Collecting detailed information on histamine outbreaks in EU might be of value when considering policy development in relation to the harvesting and processing of tuna and other scombroid fish.

3. 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.

4. 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. Norovirus of two separate genogroups 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 has no records of other 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, this includes 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 included in the single set menu. 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.

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 traceback and traceforward 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).

ABBREVIATIONS

CFU	Colony-forming unit
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
EU	European Union
EU-FORS	European Union Food-borne Outbreak Reporting System
EUSR	European Union Summary Report
EWRS	Early Warning and Response System
MPN	Most Probable Number
MS(s)	Member State(s)
RASFF	Rapid Alert System for Food and Feed