European Food Safety Authority

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SCIENTIFIC REPORT OF EFSA

Updated technical specifications for harmonised reporting of food-borne outbreaks through the European Union reporting system in accordance with Directive 2003/99/EC[1]

European Food Safety Authority[2, 3]

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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 specification for harmonised reporting of food-borne outbreaks to the European Union, which allow to better achieve their objectives. The distinction between "verified" and "possible" food-borne outbreaks is abandoned in the reporting. Member States shall report all food-borne outbreaks which meet the definition in the Directive 2003/99/EC. In case of food-borne outbreaks where no particular food vehicle is suspected and for food-borne outbreaks where the evidence implicating a particular food vehicle is weak only a limited dataset is reported. This includes the number of outbreaks per causative agent and the number of human cases, hospitalisations and deaths. A detailed dataset is to be reported for food-borne outbreaks where the evidence implicating a particular food vehicle is strong, based on an assessment of all available evidence. The information to be reported for these outbreaks includes the nature of the evidence to support the link between cases of disease in humans and the food vehicle as well as data on causative agents, food vehicles and the factors in food preparation and handling that contributed to the food-borne outbreaks.

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 produced an update of 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 the first three years of implementing the harmonised reporting specifications.

The update proposes that the distinction between "verified" and "possible" food-borne outbreaks is abandoned in the reporting. Instead Member States should report into the European Union outbreak reporting system all food-borne outbreaks that meet the definition laid down by Directive 2003/99/EC.

In the case of food-borne outbreaks where no particular food vehicle is suspected and for food-borne outbreaks where the evidence implicating a particular food vehicle is weak, only a limited dataset is to be reported. This dataset includes the number of outbreaks, as well as the numbers of human cases, hospitalisations and deaths per causative agent.

A detailed dataset is to be reported for food-borne outbreaks where, based on an assessment of all available evidence, the evidence implicating a particular food vehicle is strong. The information to be reported for these outbreaks includes data on causative agents, food vehicles and the factors in food preparation and handling that contributed to the food-borne outbreaks. Member States shall also report information on the nature of the evidence to support the link between cases of disease in humans and the food vehicle. This evidence can be microbiological or epidemiological in nature.

Strong epidemiological evidence includes statistically significant association in analytical epidemiological study or convincing descriptive evidence. Microbiological evidence covers the detection of the causative agent in 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.

The information to be reported was selected due to its relevance at the European Union level and whether the 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/EC[4] lays down the Community system for monitoring and reporting of information on zoonoses, which places an obligation upon 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 Community 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 that included guidelines to the MSs on the reporting of food-borne outbreaks (EFSA, 2007). These reporting guidelines have been implemented in the reporting of the 2007, 2008 and 2009 food-borne outbreak data. Some difficulties in the reporting and shortcomings in the nature of data reported were encountered during the reporting and also in the analysis of the 2007-2009 food-borne outbreak data, even though generally it was assumed that the quality of the data reported had improved. Therefore, there is a need to review the existing reporting guidelines.

The Task Force on Zoonoses Data Collection and the former working group that prepared the reporting guidelines should be involved in the review.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The Task Force on Zoonoses Data Collection is asked to

- Review the need to amend the existing reporting guidelines for food-borne outbreaks in the Community (as defined in Report on harmonising the reporting of food-borne outbreaks through the Community reporting system in accordance with Directive 2003/99/EC);
- Consider best practices to analyse the food-borne outbreak data reported;
- Produce a report on this need and revise the reporting guidelines, 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 through a web-based reporting application run by EFSA. 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 includes 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 is hereafter 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. From the experience gained during these reporting years, the need to make some adjustments to the reporting system 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. Objectives of collecting information on food-borne outbreaks

The data collected from investigated food-borne outbreaks provide information on a number of interesting factors related to the outbreaks.

Information collected by EU level surveillance should allow the evaluation of trends in food-borne outbreaks, causative agents, food vehicles, and the factors in food preparation and handling that contributed to outbreaks.

In particular the data on food-borne outbreaks is collected at EU level to form an overview of and to assess:

- the importance of different food categories as outbreak vehicles and the agents most frequently associated with these food vehicles;
- factors contributing to the occurrence of food-borne outbreaks;
- trends in the number and size of food-borne outbreaks and the proportion of outbreaks related to different causative agents;
- the severity of disease in the human cases involved as demonstrated by the proportion of cases admitted to hospital and deaths.

The data collection may allow the identification of emerging trends in causative agents and food vehicles in EU. Data on food-borne outbreaks provide information on the number of people affected by such outbreaks each year and thus complements the picture of the burden of food-borne diseases estimated from the total number of cases of infection with gastro-intestinal pathogens in EU. The added value of the food-borne outbreak data is the information on the causative agent/food vehicle -combinations responsible for the food-borne outbreaks. This information is necessary for targeting actions to improve food safety in EU.

In order to obtain more in-depth information on food-borne outbreaks, detailed data may be collected at EU level from food-borne outbreaks that have been investigated in depth. This information can enhance the understanding of the epidemiology of the causative agents and could possibly be used for risk assessments.

3. Definitions

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

Analytical epidemiological evidence: a statistically significant association between consumption of a food vehicle and being a case in an outbreak demonstrated by studies such as a cohort study, a case-control study or similar studies.

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 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.

Food-borne outbreak: '*means 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[5]). This definition includes drinking water and covers single food items as well as composite meals.

Food vehicle: food (or foodstuff) that is contaminated by a causative agent.

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 compatible with / 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 people with recognised 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 alone is not part of the case definition.

[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.

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

Setting: place of exposure to the food vehicle. This is the location 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).

4. Main issues identified in the implementation of the Community Outbreak Reporting System (CORS)

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 text 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 also terms "implicated foodstuff" and "vehicle" are 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 does 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.

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 and microbiological. 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. In the CORS, a food-borne outbreak supported only by descriptive analytical evidence was regarded as a possible food-borne outbreak where only limited data were requested to be sent to EU. Thus in cases, where the descriptive epidemiological evidence was strong in nature, some valuable information may have been lost at EU level.

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).

The strength of the evidence related to an outbreak to be reported to EU level should be based on an assessment of all available categories of evidence. If the evidence is strong in any category, MSs should submit a detailed dataset on the outbreak to EU level analyses.

As a guide:

1. Strong epidemiological evidence is a statistically significant association in a well conducted analytical epidemiological study, or convincing descriptive evidence.

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 compatible clinical symptoms in outbreak cases.

Examples of convincing descriptive epidemiological evidence are provided in the Annex 2.

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 only by prior plausibility should not be collected to EU level. However, prior plausibility may be valuable to inform immediate control measures at local or MS level. To use prior plausibility to inform immediate control is the health protection equivalent of "profiling", to use it for policymaking would be the equivalent of prejudice.

4.3. Legal issues

The Zoonoses Directive does not make provision for distinguishing "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 affect the success 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 reasons.

5. Proposed changes to the Community Outbreak Reporting System (CORS)

Based on the reasons described earlier, a number of changes are proposed to CORS. This new revised reporting system is hereafter referred to as the European Union Food-borne Outbreak Reporting System (EU-FORS)[6].

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 are of little value in informing EU policies on food safety and therefore only limited dataset is requested from such outbreaks (i.e., excluding information on food vehicles). This is because the main interest in formulation of food safety policies is in the causative agent/food vehicle -combinations that are supported by strong evidence.

Thus, in the EU-FORS, information from all food-borne outbreaks is collected, but the detailed data are only requested from outbreaks having strong evidence supporting the link between the food vehicle and the human cases.

It is, furthermore, proposed that the distinction between “verified” and “possible” food-borne outbreaks be abandoned. Instead MSs should report all food-borne outbreaks that meet the definition laid down by the Zoonoses Directive (e.g. outbreaks where the cases are linked, or are probably linked, to the same food source (food vehicle)). These outbreaks are to be reported as follows:

- For food-borne outbreaks where no particular food vehicle is suspected/identified only a limited dataset is required;
- For food-borne outbreaks where the evidence implicating a particular food vehicle is weak only a limited dataset is required; and
- For food-borne outbreaks where the evidence implicating a particular food vehicle is strong a detailed dataset is required.

In the EU-FORS a term “food vehicle” is used throughout since that is the food source most immediate for consumer and therefore of specific interest. Other aspects of 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.

[6] Because of the entry into force of the Lisbon Treaty all references to "Community" is to be replaced by references to "European Union".

In a similar way than the CORS, the 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 on the setting (place of exposure to the food vehicle). Furthermore, the Directive asks for information on the identification of the type of place where the foodstuff incriminated was produced/purchased/acquired/consumed, whereas the specifications of this report provide and use instead a definition for the place of origin of the problem, since this information is relevant to control measures.

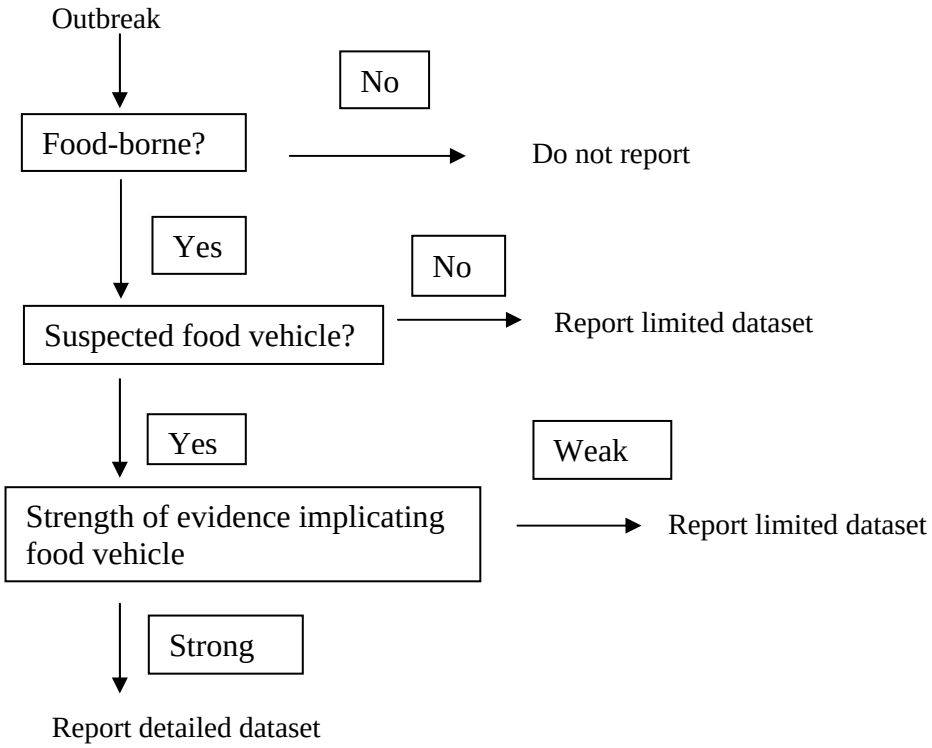
The main differences between reporting of food-borne outbreaks in the CORS and the new EU-FORS are presented in Table 1 and a general scheme for reporting of food-borne outbreaks is given in Figure 1.

Table 1: Main differences between the current and the new 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*	
		weak	**strong**
Analytical epidemiological evidence	DE (verified outbreak)	LI	DE
Descriptive epidemiological evidence	LI (possible outbreak)	LI	DE
Microbiological evidence			
- Detection in food vehicle	DE (verified outbreak)	LI	DE
- Detection in food vehicle's component or in food chain or its environment	LI (possible outbreak)	LI	DE

* Reporting depends on judgement of the overall strength of all available evidence (i.e. strong or weak)
DE = a detailed dataset is reported
LI = a limited dataset is reported

Figure 1. Scheme for reporting of food-borne outbreaks to the European Union Food-borne Outbreak reporting system (EU-FORS)



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

The annual reporting covers the results of the investigations of all food-borne outbreaks, as defined in 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. However, food-borne outbreaks caused by chemical agents are not 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. 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 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 (calculated automatically)
7.3 Limited datasets on food-borne outbreaks (table form)
7.4 Detailed datasets on food-borne outbreaks (table form)

7.5 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[7]. 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 categorised below under section 7.3.

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

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

For food-borne outbreaks where no particular food vehicle is suspected or identified or where the evidence implicating a particular food vehicle is weak, only limited dataset in aggregated format is required to be reported. In case of these outbreaks the following information is provided per causative agent:

[7] 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.

Variable	Field type	Description of the information to be provided
Causative agent	Listed in the table (see below)	
Total number of food-borne outbreaks	Numerical	
Total number of human cases in the outbreaks	Numerical	The number to be reported should include all those meeting the outbreak case definition, including those who were hospitalised or who died as a result of the food-borne outbreak.
Total number of hospitalisations in the outbreaks	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.
Total number of deaths in the outbreaks	Numerical	The known number of outbreak cases who died as a result of the food-borne outbreak(s). Only deaths attributable to the causative agent responsible for the outbreak should be reported.

The outbreaks are categorised according to the causative agents as follows:

- *Salmonella* spp.
  - *S.* Typhimurium
  - *S.* Enteritidis
  - Other serovars
- *Campylobacter* spp.
- *Listeria monocytogenes*
- *Yersinia* spp.
- Verotoxigenic *E. coli* (VTEC)
- *Bacillus*
  - *B. cereus*
  - Other *Bacillus*
- *Staphylococcus* (enterotoxins)
- *Clostridium* spp.
  - *Cl. botulinum*
  - *Cl. perfringens*
  - Other Clostridia
- Other bacterial agents
  - *Brucella*
  - *Shigella*
  - Other
- Parasites
  - *Trichinella*
  - *Giardia*
  - *Cryptosporidium*
  - *Anisakis*
  - Other parasites
- Viruses
  - Norovirus
  - Hepatitis viruses
  - Other viruses
- Other agents
  - Histamine
  - Marine biotoxins
  - Other
- Unknown agent

7.4 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. Detailed data are only reported for food-borne outbreaks where the evidence implicating a particular food vehicle is strong.

The web application is designed for the input of data in individual outbreak format and MSs are strongly encouraged to provide the data on 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 good to notice that this type of reporting will lead to losing some information and it is not recommended.

The following detailed dataset is requested on outbreaks with strong evidence:

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 (annex 1A)	Include, when possible, the speciation, the serotype, and, if available, the phage type. 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)".
Human cases	o 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	o 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	o Numerical	The known number of outbreak cases who died as a result of the food-borne outbreak(s). Only deaths attributable to the causative agent responsible for the outbreak should be reported.

Food vehicle	Pick list (annex 1B)	The foodstuff category (food vehicle) suspected in the food-borne outbreak is reported using the pick list. A "free text field" can be used to define the food vehicle in more detail.
Nature of evidence linking outbreak cases with a food vehicle	Epidemiological - Descriptive - Analytical Microbiological - Detection in food vehicle or its component *or* - Detection in food chain or its environment *And either* - Detection of indistinguishable causative agent in humans *or* - Symptoms and onset of illness pathognomonic to the causative agent found in food vehicle or its component or in food chain or its environment	Specify the level of evidence that the outbreak is food-borne. See definitions. For food-borne outbreaks where more than one type of evidence was observed all relevant evidence types should be reported.
Type of outbreak	o Household o General o Unknown	Specify the type of food-borne outbreak; see definitions of household and general outbreak. If it was not possible to identify the type of outbreak or if the information is not available, please choose the option "Unknown".
Setting	Pick list (annex 1C)	See definitions.
Place of origin of problem	Pick list (annex 1D)	See definitions. 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	o Domestic market o Intra EU trade o Imported from outside EU o Unknown	Information whether the food vehicle originated from domestic market, intra-EU trade or was imported from outside EU.
Contributory factors	Pick list (annex 1E)	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.

Mixed outbreaks (other agent)	Free text	In cases where more than one causative agent was identified in the outbreak, the other agents are reported in free text format.
More information	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[8] or EWRS[9]. This field typically describes the results of the epidemiological investigations, information on the sub-typing of the agents and may include a reference to a publication (e.g. in Eurosurveillance), to international database or to full outbreak report. 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).	

7.5 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 EU-FORS among the MSs' reporters, particularly regarding the strength of evidence. Therefore, in order to ensure harmonised implementation of the new reporting specifications, it is important to provide support to the reporters. Organising training on the new EU-FORS might be needed both at EU and national level. In addition, EFSA's manual on reporting of food-borne outbreaks (EFSA, 2010) 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 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.

[8] Rapid Alert System for Food and Feed.
[9] 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, 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. Also 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 are important to be analysed. 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, by descriptive epidemiological evidence or by microbiological evidence. This analysis 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 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 its impact 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.

In case the number of reported outbreaks with a detailed dataset increases by implementation of the EU-FORS, appropriate analysis should be carried out whether the increase can be attributed to the use of the new reporting specifications or if other factors are responsible. Results from such an analysis should be then clearly communicated in the report.

Since waterborne outbreaks differ in nature from the other food-borne outbreaks it is preferable to analyse and report them separately in the EU Summary Report.

10. References

EFSA (European Food Safety Authority), 2007. Report of the Task Force on Zoonoses Data Collection on harmonising the reporting of food-borne outbreaks through the Community reporting system in accordance with Directive 2003/99/EC. The EFSA Journal (2007) 123, 1-16.

EFSA (European Food Safety Authority), 2010. Manual for Reporting of Food-borne outbreaks in the framework of Directive 2003/99/EC from the reporting year 2009. The EFSA Journal (2010) 8(4), 1578, 1-46.

ANNEX 1

A. Causative agent list

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

B. Food vehicle

Code	Decode
01	Milk
02	Dairy products (other than cheeses)
03	Cheese
04	Eggs and egg products
05	Bovine meat and products thereof
06	Pig meat and products thereof
07	Sheep meat and products thereof
08	Other or mixed red meat and products thereof
09	Broiler meat (*Gallus gallus*) and products thereof
10	Turkey meat and products thereof
11	Other, mixed or unspecified poultry meat and products thereof
12	Fish and fish products
13	Crustaceans, shellfish, molluscs and products thereof
14	Vegetables and juices and other products thereof
15	Canned food products
16	Cereal products including rice and seeds/pulses (nuts, almonds)
17	Fruit, berries and juices and other products thereof
18	Drinks, including bottled water
19	Tap water including well-water
20	Sweets and chocolate
21	Bakery products
22	Herbs and spices
23	Mixed or buffet meals
88	Other foods

C. Setting

Code	Decode
01	Household / domestic kitchen
02	Restaurant/Café/Pub/Bar/Hotel
03	Mobile Retailer / market / street vendor
04	Take-away or fast food outlet
05	Canteen or workplace catering
06	Hospital/medical care facility
07	Residential Institution (nursing home, prison, boarding schools)
08	School, kindergarten
09	Temporary mass catering (fairs, festivals)
10	Camp, picnic
11	Aircraft/ ship/ train
12	Disseminated cases
13	Farm (primary production)

88	Other
99	Unknown

D. Place of origin of problem

Code	Decode
01	Household / domestic kitchen
02	Restaurant/Café/Pub/Bar/Hotel/Catering service
03	Mobile Retailer / market / street vendor
04	Take-away or fast food outlet
05	Canteen or workplace catering
06	Hospital/medical care facility
07	Residential Institution (nursing home, prison, boarding schools)
08	School, kindergarten
09	Temporary mass catering (fairs, festivals)
10	Camp, picnic
11	Aircraft/ ship/ train
12	Slaughterhouse
13	Farm (primary production)
14	Processing plant
15	Retail sale outlet
16	Transport of food
17	Water treatment plant
18	Water distribution system
19	Water source
20	Travel abroad
88	Other
99	Unknown

E. Contributory factor

Code	Decode
01	Unprocessed contaminated ingredient
02	Storage time/temperature abuse
03	Inadequate heat treatment
04	Inadequate chilling
05	Cross-contamination
06	Infected food handler
07	Water treatment failure
88	Other
99	Unknown

ANNEX 2

Examples of convincing descriptive epidemiological evidence to support outbreak 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. In every of the three categories of nature of evidence (microbiological, analytical or descriptive epidemiological), the strength of the evidence decides about the dataset that has to be submitted to EU-FORS. Collecting, collating and analysing these data could provide EFSA with a valuable evidence base.

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. 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.

5. *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. Seventeen cases of illness due to *C. 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 left over foods are available for microbiological testing.