TECHNICAL REPORT

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Manual for reporting on zoonoses and zoonotic agents, within the framework of Directive 2003/99/EC, and on some other pathogenic microbiological agents for information deriving from the year 2015

European Food Safety Authority

Abstract

This reporting manual provides guidance for reporting on zoonoses and zoonotic agents in animals, food and feed under the framework of Directive 2003/99/EC and also on the reporting of other pathogenic microbiological agents in food. The objective is to harmonise and streamline reporting by Member States (MSs) to ensure that the data collected are relevant and easy to analyse at the European Union (EU) level. This manual covers all the zoonoses and zoonotic agents included under the current data collection system run by the European Food Safety Authority (EFSA). Detailed instructions are provided on reporting data in both table and text form. This guidance applies to the agents, animal species and food categories to be reported on. The instructions given are related to the description of the sampling and monitoring schemes applied, as well as analysing the results in the national reports. Special reference is made to data elements in which following trends would be desirable. This manual is specifically aimed at guiding the reporting of information deriving from the year 2015.

Key words: animal population, foodstuff, feedingstuffs, zoonotic agent, zoonoses, trend analysis, reporting

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Summary

This reporting manual provides guidance on the reporting of zoonoses and zoonotic agents in animals, food and feed under the framework of the Directive 2003/99/EC. Instructions are also provided on the reporting of other pathogenic microbiological agents in food. The objective is to harmonise and streamline reporting by Member States (MSs) to ensure that the data collected are relevant and easy to analyse at the European Union (EU) level.

These instructions are intended to be applied to reporting through the Data Collection Framework (DCF). The data collection covers the most common reported infections and microbiological contaminants in animal populations including bovine tuberculosis, bovine, ovine and caprine brucellosis, *Salmonella*, *Campylobacter*, *Listeria*, *Yersinia*, verotoxigenic *Escherichia coli*, Q fever, *Trichinella*, *Echinococcus*, *Toxoplasma*, West Nile virus, *Cysticercus*, and rabies in animals, food and feed. Data on some other microbiological contaminants or agents, such as staphylococcal enterotoxins, *Cronobacter* and histamine, are also covered by the manual.

This guidance typically applies to the agents, animal species and food categories to be reported on. Advice is also provided on the agent species, serotypes and serovars to be included in the reporting.

Specific instructions are given to describe the sampling and monitoring schemes, as well as the description of the analysis of the results in the national reports. Special reference is made to data elements in which following trends would be desirable at the EU level and in which MSs are encouraged to provide data on a regular basis.

This manual is specifically aimed at guiding the reporting of the information deriving from the year 2015.

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1. Introduction

1.1. Background and Terms of Reference as provided by EFSA[1]

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

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

EFSA manages a Data Collection Framework (DCF), to which MS have the possibility of submitting data in Extensible Markup Language (XML)/Excel format. New XML reporting schemas are created before the start of the reporting period in April each year, and these are supported by revised guidance documents.

The BIOCONTAM and DATA units are invited to fulfil the following Terms of References (TOR):

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

This technical report specifically addresses the third TOR: revise the manual for reporting on zoonoses, zoonotic agents and antimicrobial resistance each year, and publish it as an EFSA technical report.

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

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

The European Union (EU) system for monitoring and collecting information on zoonoses is established by Directive 2003/99/EC[2] on the monitoring of zoonoses and zoonotic agents. This Directive requires MSs to collect, evaluate and report data, on zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks, to the European Commission (EC) each year. The system is based on current systems in the MSs, and, in a few cases only, data monitoring is harmonised by EC legislation to the extent that the results from the monitoring are comparable between the MSs.

Data collection on human diseases from MSs is conducted in accordance with Decision 1082/2013/EU[3] on serious cross-border threats to health, which in October 2013 replaced Decision 2119/98/EC[4] on setting up a network for the epidemiological surveillance and control of communicable diseases in the EU. The case definitions to be followed when reporting data on infectious diseases to ECDC are described in Decision 2012/506/EU.[5]

MSs are required to send their national report on zoonoses to the EC each year by 31 May. The EC shall submit this information to the EFSA, which shall examine the data and publish the EUSRs from the results. The EUSRs are prepared in collaboration with the ECDC.

For data collection on food-borne outbreaks and antimicrobial resistance there are specific reporting manuals; therefore, food-borne outbreaks and antimicrobial resistance are not covered by this document.

1.2.1. Monitoring of other pathogenic microbiological agents in foodstuffs

At the request of the EC, reporting of some other pathogenic microbiological agents in foodstuffs should take place in combination with the reporting under the Zoonoses Directive 2003/99/EC. This information will be gathered in order to determine if the food safety microbiological criteria laid down for these agents by Commission Regulation (EC) No 2073/2005,[6] Commission Regulation (EC) No 1441/2007,[7] Commission Regulation (EU) No 1086/2011,[8] Commission Regulation (EU) No 209/2013[9] and Commission Regulation (EU) No 217/2014[10] are being met.

1.2.2. Reporting through the Data Collection Framework

Starting with 2015 data reporting data can be submitted only to the Data Collection Framework (DCF) using XML or Excel formats.

[2] 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.

[3] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC. OJ L 293, 5.11.2013, p. 1–15.

[4] Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community. OJ L 268, 3.10.1998, p. 1–7.

[5] Commission Decision 2012/506/EU amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council. OJ L 262, 27.9.2012, p. 1–57.

[6] Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. OJ L 338, 22.12.2005, p. 1–26.

[7] Commission Regulation (EC) No 1441/2007 of 5 December 2007 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. OJ L 322, 7.12.2007, p. 12–29.

[8] Commission Regulation (EU) No 1086/2011 of 27 October 2011 amending Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council and Annex I to Commission Regulation (EC) No 2073/2005 as regards *Salmonella* in fresh poultry meat. OJ L 281, 28/10/2011, p. 7–11.

[9] Commission Regulation (EU) No 209/2013 of 11 March 2013 amending Regulation (EC) No 2073/2005 as regards microbiological criteria for sprouts and the sampling rules for poultry carcases and fresh poultry meat. OJ L 68, 12/03/2013, p. 19–23.

[10] Commission Regulation (EU) No 217/2014 of 7 March 2014 amending Regulation (EC) No 2073/2005 as regards *Salmonella* in pig carcases. OJ L 69, 8.3.2014, p. 93–94.

2. General guidelines for reporting

2.1. Mandatory reporting and reporting based on the epidemiological situation

In accordance with the Zoonoses Directive 2003/99/EC, all MSs have to report on the following zoonoses, zoonotic agents (list A of Annex I of Directive 2003/99/EC) and other subjects:

- brucellosis and agents thereof;
- campylobacteriosis and agents thereof;
- echinococcosis and agents thereof;
- listeriosis and agents thereof;
- salmonellosis and agents thereof;
- trichinellosis and agents thereof;
- tuberculosis due to *Mycobacterium bovis*;
- verotoxigenic *Escherichia coli* (VTEC);
- food-borne outbreaks;
- susceptible animal populations.

Other zoonoses need to be monitored and reported according to the epidemiological situation in each MS. This means that, if a certain zoonosis is of public health importance in a MS, this MS should report on that zoonosis, but the other MSs do not have the same obligation to report on it, if it is of minor importance at the national level.

The zoonoses to be reported based on the epidemiological situation are listed in Annex I of Directive 2003/99/EC (list B) and are described below:

Viral zoonoses

- calicivirus
- hepatitis A virus
- influenza virus
- rabies virus
- viruses transmitted by arthropods

Bacterial zoonoses

- borreliosis and agents thereof
- botulism and agents thereof
- leptospirosis and agents thereof
- psittacosis and agents thereof
- tuberculosis other than tuberculosis due to *Mycobacterium bovis*
- vibriosis and agents thereof
- yersiniosis and agents thereof

Parasitic zoonoses

- anisakiasis and agents thereof
- cryptosporidiosis and agents thereof
- cysticercosis and agents thereof

- toxoplasmosis and agents thereof

Other zoonoses and zoonotic agents

The reporting of other pathogenic microbiological and toxicological agents in foodstuffs includes reporting of *Cronobacter* spp., staphylococcal enterotoxins and histamine. These agents should be reported on a voluntary basis.

Reporting of bovine spongiform encephalopathy (BSE) and other transmissible spongiform encephalopathies (TSEs) and of avian influenza takes place directly to the Commission on the basis of Regulation (EC) No 999/2001[11] and Commission Decisions 2004/111/EC[12] and 2004/615/EC.[13] Based on the mandate received from the European Commission the data collection on bovine spongiform encephalopathy (BSE) and other transmissible spongiform encephalopathies (TSEs) will be transferred to EFSA in 2017. A specific manual with guidelines will be issued for these data reporting.

Information on mandatory zoonoses (list A of Annex I of Directive 2003/99/EC) and the zoonoses to be reported based on the epidemiological situation can be reported in DCF. Text forms can be used for this. The requirements for the content of the annual reports on zoonoses are laid down in Annex IV of Directive 2003/99/EC.

2.2. General guidelines for reporting the prevalence results

2.2.1. General recommendations

The results (data) for prevalence reporting are obtained from different investigations and have to be reported through the DCF. In the following sections and for each zoonoses-/agent- in particular the the animal species/food categories particularly recommended to be reported through the DCF are indicated **by bold text**.

2.2.2. Prevalence for food, animals and feedingstuffs

The prevalence **data model** should be used to report the prevalence of zoonotic agents in food, animals and feedingstuffs.

Information requested to be reported

Data on foodstuffs, animals and feedingstuffs should be categorised using the classification system provided by the catalogues. There will be variability in the degree of detail (level) which can be provided.

For each main category (Food, Animals, Feed) data providers are strongly encouraged to provide as much relevant information and level of detail as possible provided by the **ZOO_CAT_MATRIX catalogue**. The reason is that the information provided by the data catalogues enables relevant epidemiological data analyses**.**

MSs should not **double report** population data for the different category levels provided in the data catalogues: data reported both in the total and in the detailed categories.

For example, if 100 pig herds is the total population to report and these consist of 20 breeding herds, 60 fattening herds and 20 herds for which no information is available, then the different categories breeding, fattening and unspecified should be reported separately as follows: 20 breeding pig herds, 60 fattening pig herds, 20 unspecified pig herds.

- **Matrix: Food and feedingstuff categories—**for the specification of the food and feedingstuffs, a high-level categorisation of foodstuffs or feedingstuffs should first be

[11] Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. OJ L 147, 31.5.2001, p. 1–40.
[12] Commission Decision 2004/111/EC of 29 January 2004 on the implementation of surveys for avian influenza in poultry and wild birds in Member States, to be carried out during 2004. OJ L 32, 5.2.2004, p. 20–21.
[13] Commission Decision 2004/615/EC of 23 July 2004 amending Decision 2004/111/EC on the implementation of surveys for avian influenza in poultry and wild birds in Member States, to be carried out during 2004. OJ L 278, 27.8.2004, p. 59 63.

provided; thereafter, the reporting of more detailed information is allowed. For example: Meat from bovine animal/meat preparation/raw but intended to be eaten cooked'.

Definitions for food are presented in Appendix E and definitions for feedingstuffs in Appendix G.

- Where specific information is unavailable, one may use the unspecified option, e.g. 'Meat from poultry, unspecified' or 'Milk from other animal species or unspecified'. **The 'Unspecified' option should only be used when there is no information available.**
- **Matrix: Animal species—**for the specification of the animal species, the name of the animal species is first provided. Subsequently, more detailed information can be provided such as the type of animals (wild, farmed, pet), the animal production category (e.g. breeding animals, fattening animals), the animal production period (e.g. rearing, laying, adult) or the animal production system and/or housing conditions (e.g. not raised under controlled housing conditions, raised under controlled housing conditions) and the age category (e.g. day old chicken, piglets, gilts, sows).

An example for Matrix-Animal Species: '*Gallus gallus* (fowl)/laying hens/day-old chicks'. It is recommended for all animal species to provide the information with relation to the type (wild, farmed, pet). Definitions of animal species are presented in Appendix F.

- **Sampling stage—**to allow for comparability, data with relation to the 'place' or the 'stage' at which sampling took place a classification system provided in the catalogue. The catalogue ZOO_CAT_SMPNT provides the main 'Places' or 'Stages' where samples may be taken, e.g. farm, slaughterhouse, retail.
- **Sample origin—**is used to indicate the country of origin of the animal, food or feed sampled; this information allows for further characterisation of the sample's origin. Reporting 'Sample origin' might be of importance for the reporting of some positive cases of certain zoonoses such as West Nile Virus (WNV, e.g. imported horses) and *Salmonella* in feed (e.g. imported from third countries).
- **Sample type—**the sample type is used to characterise the sample that is used for the reporting. The characterisation of the sample is done by reporting the category using relevant terms from the ZOO_CAT_SMPTYP catalogue (i.e. 'animal sample', 'food sample', 'feed sample' or 'environmental sample') and the sample type (e.g. 'faeces', 'lymph nodes').
- **Sampling context—**the sampling context is used to describe the context or the reason for which samples at national level are collected.

The sampling context must be reported using terms from the ZOO_CAT_SRCTYP catalogue (i.e. 'survey' (national, EU baseline), 'monitoring' (passive, active), 'surveillance', 'clinical investigations', 'control and eradications' programmes). The term 'unspecified' can only be used if the no information about the sampling context is available. Definitions regarding sampling context are presented in Appendix D.

- **Sampler—**the sampler is used to characterise the person or 'responsible' for the final sample taken. To identify the sampler, relevant terms from the ZOO_CAT_SMPLR catalogue must be reported (e.g. competent authority ('official sampling') or industry ('HACCP (Hazard Analysis and Critical Control Point_ and own checks').
- **Sampling strategy—**the sampling strategy is describing the methodology (='the sampling method') how the samples are obtained within a certain context.

The sampling strategy must be reported using terms from the ZOO_CAT_SAMPSTR catalogue (i.e. 'census', 'convenience sampling', 'objective sampling', 'selective sampling', 'suspect sampling'). The term 'unspecified' can only be used if no information about the sampling strategy is available. Definitions regarding sampling context are presented in Appendix D.

- **Sampling details—**if necessary, free text fields can be used to give further information on the sampling stage or context or other further information in brief that is not covered by the data model.

MSs are invited to report all relevant information on the type of animals or food sampled including the sampling stage and the sampling context, when appropriate. This information may include:

- the type of animal population sampled, e.g. wild/farmed/zoo animals/pet animals for those populations that could fall under more than one typology, e.g. wild boar;
- the stage along the food chain at which samples have been collected.

- **Area of sampling—**this data element is recommended to be used when regional reporting is of epidemiological relevance and for zoonoses for which no harmonised monitoring schemes across EU are in place.

For diseases such as rabies, *Echinococcus multilocularis* and West Nile virus it is recommended to give further information with relation to the area, region or province of the sampling in which the animal/food/feed sample has been collected according to the NUTS coding system.

- **Sampling unit—**for foodstuffs and feedingstuffs the terms 'single' and 'batch' are used. For animals, the sampling unit may be 'animal', 'flock', 'holding', 'herd' 'herd/flock' or 'slaughter batch'.

The sampling unit often corresponds with the **epidemiological unit** for reporting purposes. In case prevalence at batch level is reported it should be made clear how sampling of a batch is performed (= 'x' number of single samples). This accounts also for prevalence at flock, holding or herd level. If the reported epidemiological unit is herd/flock or holding it should be made clear how a herd/flock/holding sampling is performed (='x' number of animals per flock/herd/holding.

- **Sample weight—**the weight or volume of the sample/specimen used in the laboratory for the analysis of the sample can be specified: e.g. 10, etc.; for carcase swabs the area sampled could be reported (e.g. 100).
- **Sample weight unit—**described the unit to be used for the sample weight e.g. gram, millilitre, squared centimetre.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comments section.
- **Analytical methods—**the diagnostic or analytical methods used in testing of the sample; this information is requested for data on Listeria, VTEC, *Toxoplasma*, Q fever, West Nile virus and tuberculosis in the other animals (e.g. International Organization for Standardization (ISO) 16654:2001 or ISO/PRF TS 13136 for VTEC; modified agglutination test (MAT), latex agglutination test (LAT) or enzyme-linked immunosorbent assay (ELISA) for *Toxoplasma*; fluorescence *in situ* hybridisation (FISH) or polymerase chain reaction (PCR) for Q fever; reverse-transcription PCR (RT-PCR), immunoglobulin G (IgG) ELISA, IgM-capture ELISA (MAC-ELISA), indirect haemagglutination test (IHA), sero-neutralisation test for West Nile virus, and PCR for tuberculosis in the other animals). It is highly recommended for all the reported zoonoses to provide the information about the analytical method used.
- **Total units tested—**the total number of sampling units that are analysed in laboratories, slaughterhouses and institutes or tested in another way and for which results are available. A sampling unit (e.g. flock) should not be counted twice even if it has been checked more than once for a specific zoonotic agent. Take into consideration 'the epidemiological sampling unit' to report the total units tested.
- **Total units positive—**the total number of sampling units considered infected (contaminated) based on the testing results should be reported. In case that no positive units were detected, a '0' (zero) should be reported. Take into consideration 'the epidemiological sampling unit' and how this unit is/was defined as 'positive (infected, contaminated)' in the reporting.
- **Number of units tested—**the number of units that are analysed in the laboratories, slaughterhouse and institutes, or tested in another way, in total, and for which results are available. This data element is mandatory when reporting data on *Listeria* in food and should be left empty in all other cases.

- **Number of units positive—**the total number of units considered infected (contaminated) based on the testing results. This data element is mandatory when reporting positive results and for all results referring to *Listeria* or histamine. It indicates the number of units tested positive for the agent species, serovar (e.g. *Salmonella* Typhimurium, *Salmonella* Infantis, *Campylobacter jejuni*) or phagetype (e.g. *Salmonella* Enteritidis-PT 1) reported in the data element zoonosis. Sampling definitions are presented in Appendix C.

The total number of samples positive for a zoonotic agent reported in the in the data element 'Total units positive' (e.g. *Salmonella* spp., *Brucella* spp.) must equal the sum of the 'Number of units positive' reported for species/serotypes/serovar in their specific rows including the unspecified category row. An exception is the case where more than one species/serotype/serovar is isolated from the same sample. In this case, that fact should be stated in the comment adjacent to the reporting row for that specific species/serotype/serovar.

Information that could be reported in the data elements (such as agent species or information on the sampling stage and context) should not be reported in the 'comment' data element, as this would make the data extraction difficult.

2.3. General guidelines on reporting the narrative part in the text forms data model

The narrative part should include a short description of the monitoring and/or control system from which the data are derived. This information facilitates the interpretation of the results in the correct framework. The description should be detailed enough to give an accurate picture of the monitoring and control activities in place and facilitate, where possible, the comparison of the results between reporting years.

In addition, an analysis of the results should be provided in the narrative part. This analysis may cover comparison of current results with those from previous years, in order to identify any trend. The sources of zoonotic agents should be evaluated, particularly in relation to the relevance of the findings of zoonotic agents in foodstuffs, animals and feedingstuffs to human zoonoses cases.

For reporting the narrative part of the report, the text forms data model should be used. The information is entered in the text data elements bearing the titles listed below.

It is recommended that the information below is given under each title.

2.3.1. Monitoring system

Sampling strategy—this part describes, in general, the sampling strategy chosen and the purpose of the sampling:

The sampling strategy must be reported using terms from the ZOO_CAT_SAMPSTR catalogue (i.e. 'census', 'convenience' sampling, 'objective' sampling', 'selective' sampling, 'suspect' sampling). The term 'unspecified sampling' can only be used if there is no information about the sampling method available. Definitions regarding sampling context are presented in Appendix D.

- It is useful to state whether or not the sampling covered the whole MS or only parts of it.
- The target population should be identified. It should be explained, for example, whether the entire animal population was covered or only a subset of it and the reasons for choosing this subset for sampling. Similarly, the categories of foodstuffs and feedingstuffs sampled were identified.
- If the sampling was stratified, for example, by geographical regions, by risk factor (risk based monitoring and surveillance) or other criteria (herd size, age of the animals, etc.), this should be described.
- It is important to explain how the sampling units were selected, regardless of whether 'objective', 'selective', 'suspected', 'convenience' or 'census' sampling was applied or if several sampling methods are applied.

- It should be specified who was performing the sampling, e.g. samples taken by the competent authority as part of an 'official sampling', samples taken by the farmers, veterinary practitioner, food or feed business operators, or by other representatives of private enterprises, in the context of 'HACCP and own checks'.
- It is also essential to explain where the samples were taken, e.g. 'farm', 'slaughterhouse', 'hatchery', 'processing plant' or 'retail'. Equally important is the stage of sampling, which can be any step in the animal-rearing process or the food chain. For example, the sample may be taken during the animal-rearing period, during production period (laying, fattening) before or after chilling of the carcase in the slaughterhouse, or before or after the expiration of the shelf-life of foodstuffs.
- The framework of the sampling is an important part of the strategy; to this end, it should be stated whether or not the sampling was part of a permanent or temporary 'monitoring' programme, linked to 'surveillance', 'control or eradication programmes' or if it was the result of a single 'survey'.

The sampling context must be reported using terms from the ZOO_CAT_SRCTYP catalogue (i.e. 'survey' (national, EU baseline), 'monitoring' (passive, active), 'surveillance', 'clinical investigations', 'control and eradications' programmes). The term 'unspecified' can only be used if the sampling method is no information about the sampling method is available. Definitions regarding sampling context are presented in Appendix D.

Frequency of the sampling—this part is intended to explain how frequent the samples are taken within a certain sampling context. The standard terms (e.g. every week, once a month, *x* times a year) provided in the catalogue in the text forms should be used where possible. A more general statement can also be used, such as 'Detection of annual prevalence of *xx* with *yy*% confidence level and at *zz*% accuracy'.

Type of specimen taken—under this title, the specimen taken from the units sampled is described. For example, in the case of animals, the specimen tested could be faeces, blood, organs or milk.

Methods of sampling (description of sampling techniques)—the sampling techniques, meaning the procedures on how the sample was technically taken, are described. This should include information on the site of sampling (e.g. part of a carcase, part of the facilities for an environmental sample), size of sample taken (e.g. in g, cm^2, ml), use of swabs or other instruments in the sampling, where relevant, the number of (sub)samples/sample units taken, pooling of samples where conducted (refers to the number of samples combined by pooling, if available), the possible storage of samples and the length of storage, where relevant.

Case definition/definition of a positive finding—this covers the description of when the sample is considered to be positive for the zoonotic agent or when the animal, herd or flock is considered to be infected with the zoonotic agent. Regarding food and feed, it should describe when the foodstuff, feedingstuff or the batch sampled is considered to be positive or contaminated with the zoonotic agent.

For reporting of cases and positive findings 'the epidemiological sampling unit' should be taking into account and how this unit was defined as 'positive (infected, contaminated)' in the reporting. For food and feed the differences and definitions with relation to single samples and batches should be clear. For reporting of positive findings in animals or herds/flock it must be clear how a flock was defined positive.

Example: five samples/animals were taken per batch/herd/flock and the batch/herd/flock was considered positive if at least 1 sample/animal was tested positive with that specific analytical method.

Diagnostic/analytical methods used—under this title, the diagnostic or analytical methods used in the laboratory to test the specimens are described. Whenever possible, a reference to standard methods used is made (such as national, ISO or European Norm (EN) standard methods), or to the methods prescribed by the legislation. The year of reference of the method should be included. If these methods have been modified, the modifications made should be indicated to enable the comparison of the methods. It is also important to describe the quality assurance procedures in place

in the laboratories. In addition, the procedure to prepare the sample in the laboratory should be described if it is relevant for the results. **Appendix A provides more detailed information on how to describe an analytical method.**

Vaccination policy—this policy can cover different kinds of situations: vaccination of animal populations against the zoonotic agent may be prohibited or it may be mandatory or voluntary. There can be recommendations in place to vaccinate certain animal populations or to use a certain type of vaccination scheme. There could be no official policy regarding vaccination. If a vaccination policy exists, it should be described; if no policy exists, the established way of using the vaccines in the MS can be explained. The description should include, at least, a description of the vaccine, characteristics of the animals to be vaccinated (age, sex), area where vaccination is to be implemented, special measures for marking the vaccinated animals, etc.

For certain zoonoses and for some species it is recommended to provide the vaccination status of the animals/flocks/herds (e.g. WNV in horses, *Toxoplasma* in small ruminants and Q-fever in ruminants).

Preventative measures other than vaccination in place—other preventative measures may include actions taken at different levels of the food chain. Regarding animals, it may cover, for example, bio-security measures at the farms or recommendations concerning petting zoos. For foodstuffs, it may include, for example, prohibition on marketing of unpasteurised milk and recommendations on food consumption for susceptible consumer groups.

2.3.2. Control programmes/mechanisms

The control programmes/strategies in place—under this title, the control programmes in place in the MS are described. The control programmes may be national or regional, and they may be approved nationally or by the Commission and co-financed by the EU, based on Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014[14] on expenditure in the veterinary field. Control programmes run by the industry/food business operators are also included. The nature of the control programmes should be described including whether the programme is, for example, voluntary or mandatory, national or regional, approved by the EU or at national level or co-financed. The main features of the programme are given. It is advisable to report separately the information derived from official programmes and from programmes run by the industry.

Other control mechanisms may include control measures prescribed in the EU or national legislation, such as rejection of contaminated carcases during meat inspection. The relevant legislation should be mentioned.

Measures in the event of positive findings or single cases—actions required by the legislation or control programmes as a consequence of positive findings in animals, foodstuffs or feedingstuffs should be explained. These measures may cover withdrawal of the products from the market, destruction of animals and others.

Notification system in place—the notification system is described, including its legal basis and since when the disease or infection has been notified.

Recent actions taken to control the zoonoses—specific measures undertaken during recent years to contain zoonoses are described. In the case of measures initiated in previous years, the initial implementation year should be indicated. These actions could include new legislation, recommendations issued, new control programmes, etc.

Suggestions to the EU for the actions to be taken—this item provides an opportunity to propose measures to be taken by **risk managers** at the EU level. Typically, this could involve suggestions for new EU legislation.

[14] Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC. OJ L 189, 27.6.2014, p. 1–32.

2.3.3. Results of the investigation

The results reported and presented in the reporting tables should be summarised. The important findings and the relevant conclusions based on the results should be presented.

National evaluation of the recent situation, the trends and sources of infection—under this title, the results are interpreted in relation to their importance to public health in the MS. It is essential to evaluate the trend when compared with the previous year, when there is a decreasing or increasing trend or if the situation is stabilised. The important sources of infections should also be discussed.

Relevance of the findings in feedingstuffs/animals/foodstuffs and to human cases (as a source of infection)—in light of the results reported, the importance of feedingstuffs/animals/foodstuffs as sources of human infections should be evaluated. The role of feedingstuffs as a source of infection for animals, and similarly the role of animals as a source of contamination for foodstuffs, should also be considered.

History of the disease and/or infection in the country—the history of the zoonoses cases in humans and animals in the past is reflected under this title. For example, the number of cases in the past and the impact of control and eradication programmes can be addressed.

Additional information—under this title, any other information relevant to the monitoring of the zoonoses in question can be given.

3. Reporting on susceptible animal populations

Reporting data on susceptible animal populations should be done in **the animal population data model**.

Susceptible animal population data model: the investigated animal populations should be delineated as accurately as possible, at the level of the animal species and of the animal species subcategory. To this end, the animal population profile of the reporting year needs to be documented as follows:

Information requested to be reported

- **The unit** of measurement for the selected matrix which should be chosen from the ZOO_CAT_UNIT catalogue:

  herds/flocks—the number of existing herds or flocks of animals;

  holdings—the number of existing holdings rearing farmed animals;

  animals—the number of live animals (livestock data at animal level);

  slaughter animal (heads)—the number of slaughtered animals.
- **Population—**the number of population for the selected matrix expressed in the unit.
- **Matrix—**the animal species reported on. Detailed breakdown information can be included, such as the type of animals (e.g. wild, farmed, pet) or the production category (e.g. breeding, fattening animals).
- **Source year—**the relevant year should be indicated in case that the information derives from previous years, in the specific data element

The nature of the data should be indicated, whether the figure relates to the average number of animals during the year, the number of animals for the year, a specific time point during the year or whether it is an accumulated sum for the year. This can be done either in comment field or in the text form.

The **text form for susceptible animal populations should be reported in the text form data model** and MSs/reporting countries should specify:

- **Sources of information—**in this field, the origin of the reported numbers and figures are described e.g. national identification and registration database, official statistics, institutions involved, etc.

- **Dates of the numbers/figures relate to and the content of the figures—**in this data element the date from which the information is derived or the period for which the data are reported: e.g. the number of animals reported are obtained from a census counting at the end of the year XXXX, the number of animals is an average taken at a certain time point of the year or over a period of the year, the yearly slaughtered animals per year, etc.
- **Definitions used for different types of animals, herds, flocks and holdings as well as the types covered by the information—**the definitions used in the national statistics for the relevant animal population are described in case that these differ from those given in Appendix F of this manual or in the web reporting application.
- **National evaluation of the numbers on susceptible populations and trends in these figures—**under this title, the size of animal populations and the trends in these are reflected.
- **Geographical distribution and size distribution of the herds, flocks and holdings—**the general picture of the (farm) animal population in the country is described, e.g. the typical size distribution of holdings and possible concentration of animal production in certain regions. A reference or links towards national maps describing the density at animal and flock/herd level for each (livestock) species can be described or provided.
- **Additional information—**under this title, any other information relevant to the monitoring of the zoonoses in question can be given.

4. Reporting on tuberculosis and brucellosis in animals

For the purpose of following trends the information to be reported each year is:

—number of infected/positive herds for bovine tuberculosis;

—number of infected/positive herds for bovine brucellosis;

—number of infected/positive herds for ovine/caprine brucellosis.

The mandatory annual reporting for bovine tuberculosis and for brucellosis is described in Directive 2003/99 that makes in Recital 7 a link to Directive 64/432. On the basis of Article 8 of Directive 64/432/EEC, Commission Decision 2003/886/EC laid down the format on which this information must be based.

For **the disease status reporting for** tuberculosis (*Mycobacterium bovis* in cattle) and brucellosis (cattle, sheep and goat), MSs receiving EU co-financing for their eradication programme report the number of positive herds, whereas MS not receiving EU co-financing report the number of infected herds. It is recommended to describe how 'positive' and 'infected' herds are defined.

Case definitions and definition of positive samples should be reported according the current legislations (Decision 2014/288/EC and Directive 64/432/EEC).

Example: Also the confirmation of *Mycobacterium bovis* can be done using a specific PCR or isolation methods. This confirmation is often required in herds/flocks where one or some animals reacted positive with a screening test (e.g. singular or comparative intradermal skin test). In case there is no confirmation of *M. bovis* the level of 'positivity' remains at the *Mycobacterium tuberculosis* complex level. The latter is important for prevalence or incidence and the reporting of *Mycobacterium tuberculosis* complex spp. cases.

4.1. Bovine tuberculosis and tuberculosis in farmed deer

Bovine tuberculosis due to *M. bovis* in cattle and tuberculosis data in farmed deer should be reported in the disease status data model. For complementary reporting on *M. bovis* in cattle or farmed deer or in other animal species and on *Mycobacteria* other than *M. bovis* in animals the prevalence data model ought to be used (see further 4.2).

Relevant animal species to be reported

Bovine animals (cattle), including the species *Bison bison* and *Bubalus bubalus*, and farmed deer.

Relevant agent species to be reported

The information provided should on *Mycobacterium bovis* (*M. bovis*).

According to the epidemiological situation, other species that belong to the *Mycobacterium tuberculosis* complex such as *Mycobacterium tuberculosis* (*M. tuberculosis senso stricto*), *Mycobacterium caprae* (*M. caprae*), *Mycobacterium africanum* (*M. africanum*), *Mycobacterium microti (M. microti)*, *Mycobacterium canetti (M. canetti)*, *Mycobacterium pinnipedii (M. pinnipedii)*, *Mycobacterium mungi* and *Mycobacterium orygis* may also be reported, but thereto the **prevalence data model** ought to be used (see further 4.2.).

Information to be reported in in the text form:

Description of the monitoring and control system

It is desirable to provide a description of the eradication or surveillance system:

- for the non-Officially bovine Tuberculosis Free (non-OTF) MSs, the eradication, control and surveillance programmes in place to combat the disease;
- for OTF regions or MSs, the procedures laying down the methods of surveillance for maintaining the OTF status of bovine herds;
- the approved EU co-financed eradication programmes, including the adopted measures;
- in non-OTF MSs, this information should be provided preferably at the regional level, if appropriate.

Reporting on the status as officially free

According to Council Directive 64/432/EEC,[15] regions or MSs can be OTF and therefore MSs and regions can be classified in three categories for reporting purposes:

- OTF MSs or region, meaning a MS or part of a MS that has been found to fulfil the conditions laid down in Annex AI of the amended Council Directive 64/432/EEC and has been declared OTF accordingly;
- non-OTF MSs with eradication programmes receiving EU co-financing;
- non-OTF MSs with eradication programmes that do not receive EU co-financing.

The MSs fall into three categories as well:

- MSs where the whole country is OTF;
- MSs where some regions are OTF and some non-OTF;
- MSs where the whole country is non-OTF.

[15] Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine. OJ L 121, 29.7.1964, p. 1977–2012.

Type of specimen taken/methods of sampling

Abnormal lymph nodes and parenchymatous organs (e.g. lungs, liver and spleen) are typically sampled in the event that pathological lesions exist. If no lesions exist, liver and the following lymph nodes are usually collected: retropharyngeal, bronchial, mediastinal, supramammary, mandibular and some mesenteric. In the case of the gamma-interferon test, blood samples are collected.

Case definition/definition of a positive sample

- **Positive herd (prevalence)—**herd with at least one positive animal during the reporting year, independently of the number of times the herd has been checked, as defined in Annex III of Decision 2014/288/EC[16]
- **Positive animal—**animal with positive reaction using an official diagnostic method specified in Annex B of Council Directive 64/432/EEC. In MSs with approved programmes, the definition of the programme should be used.
- **New positive herd (incidence)—**herd whose status in the previous period was unknown, non-free negative, officially free or suspended and has at least one positive animal newly detected in this period, as defined in Annex III of Decision 2014/288/EC.

Diagnostic/analytical methods used

- The methods to be used are laid down in Annex B of Council Directive 64/432/EEC: the gamma-interferon assay (as referred to in the World Organisation for Animal Health (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals) and the tuberculin skin test (single or comparative). A reference to the legislation is recommended in case that these methods have been used.
- If other methods have been used, these diagnostic tests should be described, including the interpretation of the results applied, e.g. stained smears or immunoperoxidase techniques followed by cultivation of the organism on a primary isolation medium, determination of cultural and biochemical properties, PCR and genetic fingerprinting (Directive 64/432/EEC).

Analyses of the results

- The analyses should preferably be made at both regional and national level, when appropriate. Long-term trends are recommended (for the last five years), and reflection on the sources of infection is of special interest.
- For reporting of data on farmed deer, the same definitions and instructions used for bovine tuberculosis apply; the relevant data should be reported in the table 'Tuberculosis in farmed deer', which is similar to the table used for non-OTF MSs with eradication programmes that do not receive EU co-financing.
- For reporting of data on other animal species, the table named 'Tuberculosis in other animals' should be used.

4.2. Mycobacteria in animal species other than bovine animals and farmed deer

Complementary reporting on *M. bovis* in cattle or farmed deer or in other animal species and reporting on Mycobacteria other than *M. bovis* in animals should be done using the **prevalence data model**.

Relevant animal and agent species to be monitored and reported on

It is recommended to report at *Mycobacterium tuberculosis* complex level even if *M. bovis* was excluded. According to the epidemiological situation, other species that belong to the *Mycobacterium tuberculosis* complex such as *Mycobacterium tuberculosis* (*M. tuberculosis* senso stricto),

[16] Commission Implementing Decision 2014/228/EC of 12 May 2014 as regards the standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Union and repealing Decision 2008/940/EC. OJ L 147, 17.5.2014, p. 88–113.

Mycobacterium caprae (*M. caprae*), *Mycobacterium africanum* (*M. africanum*), *Mycobacterium microti (M. microti)*, *Mycobacterium canetti (M. canetti)*, *Mycobacterium pinnipedii (M. pinnipedii)*, *Mycobacterium mungi* and *Mycobacterium orygis* may reported in animals such as sheep, goats, pigs and wild deer, zoo animals, pet animals and wildlife (wild ruminants, badgers, wild boar and wild birds).

Typical interesting information to be reported

- Results of routine post-mortem examination at slaughterhouse (visual meat inspection).
- Results of bacteriological examination of the animal species (confirmation assays).
- Results of serological tests or other tests (skin test, interferon-gamma); describe the test used and other relevant information.

Reporting the results in the prevalence data model

- **Matrix—**the relevant animal species and category (e.g. bovine, sheep, goats, pigs and wild deer).
- **Sampling stage—**where the samples have been collected (e.g. 'farm', 'slaughterhouse') should be reported.
- **Sample origin—**this allows for further characterisation of the country of origin.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'animal sample—blood').
- **Sampling context—**information on the context of the sampling (e.g. 'surveillance') should be reported.
- **Sampler—**who performed the sampling should be reported here (e.g. 'official sampling' or 'industry sampling').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling', 'census', 'suspect sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Area of sampling—**data element that should be used to give further information on the area, region or province of the sampling in which the animal/food/feed sample has been collected according to the NUTS coding system.
- **Sampling unit—**the sampling unit is typically 'animal', 'herd' or 'holding' or 'slaughter batch'.
- **Source of information** the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Analytical methods—**the diagnostic or analytical method used in testing of the sample should be reported here (e.g. PCR).
- **Total units tested—**the number of sampling units that are analysed in the laboratory, or tested in another way, in total, and for which results are available. A sampling unit (e.g. flock) should not be counted twice even if it has been checked more than once for a specific zoonotic agent.
- **Total units positive—**the total number of sampling units considered infected (contaminated) based on the testing results for *Mycobacterium*. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of units considered infected based on the testing results for the specific *Mycobacterium tuberculosis* complex species (e.g. *M. bovis, M. caprae*).

Please ensure that the number of units sampled is correctly reported, for example representing the number of animals inspected in the slaughterhouse. In the case of reporting testing animals having suspected lesions, please report the correct sampling strategy 'suspect sampling'.

4.3. Bovine brucellosis

Bovine brucellosis data to be reported in **the disease status data model.**

Relevant animal species to be reported

Bovine animals, including the species *Bison bison* and *Bubalus bubalus*.

Relevant agent species to be reported

Brucella abortus (*B. abortus*), *Brucella melitensis* (*B. melitensis*), *Brucella suis* (*B. suis*), *Brucella canis* (*B. canis*).

Information to be reported in the text form:

Description of the monitoring and control system

It is recommended that a brief description of the eradication or surveillance system is provided:

- for the non-Officially bovine Brucellosis Free (non-OBF) MSs, the eradication, control and surveillance programmes in place to combat the disease;
- in the case of OBF regions or MSs, the procedures laying down the methods of surveillance for maintaining the OBF status of bovine herds;
- figures on existing herds and their status at the end of the period;
- preventative and control measures in place;
- results of surveillance and investigations of suspected cases;
- approved EU co-financed eradication programmes, including specific measures;
- in non-OBF MSs, this should be provided preferably at the regional level, if appropriate.

Reporting on the status as officially free

According to Council Directive 64/432/EEC, regions or MSs can be OBF and therefore MSs could be classified in the following three categories for reporting purposes:

- OBF MS or region, meaning a MS or a part of a MS which has been found to fulfil the conditions lay down in Annex AII of Council Directive 64/432/EEC and has been declared OBF accordingly;
- non-OBF MS with eradication programmes that have received EU co-financing;
- non-OBF MS with eradication programmes that do not receive EU co-financing.

The MSs fall into three categories as well:

- MSs where the whole country is OBF;
- MSs where some regions are OBF and some non-OBF;
- MSs where the whole country is non-OBF.

Type of specimen taken/methods of sampling

A description of the material sampled and the correspondent method, such as:

- serum for serological blood test (e.g. Slow Agglutination test (SAT), Rose Bengal test (RBT), ELISA, Complement Fixation Test (CFT));
- milk for pooled milk samples (e.g. ELISA, milk ring test (MRT));
- abortion material, vaginal discharges, milk, lymph nodes or other tissues—for diagnostic identification of the agent.

Case definition/definition of a positive sample

- **Positive herd (prevalence)—**herd with at least one positive animal during the period, independently of the number of times the herd has been checked as specified in Annex III of Decision 2014/288/EC.
- **Positive animal—**animal with positive reaction using an official diagnostic method specified in Annex C of Council Directive 64/432/EEC, as defined in the approved programme of a MS.
- **New positive herd (incidence)—**herd whose status in the previous period was unknown, non-free negative, officially free or suspended, and has at least one positive animal newly detected within the tested period.

Diagnostic/analytical methods used

- The methods to be used are laid down in Annex C of Council Directive 64/432/EEC: ELISA (in serum or milk), Rose Bengal test (RBT), slow agglutination test (SAT), complement fixation test (CFT), MRT. If other complementary tests are used, such as the brucellosis skin test (BST), cytochrome ELISA (c-ELISA) and isolation/identification or PCR, they should be described, including interpretation of results applied, e.g. tests used for diagnostic and confirmation purposes.
- A reference to the legislation is recommended in case those methods from Directive 64/432/EEC have been used.

Analyses of the results

Both national and regional analyses should be reported, if appropriate. Long-term trends, reflecting the last five years, and information on sources of infection, are of special interest.

4.4. Ovine and caprine brucellosis

Ovine and caprine brucellosis data to be reported in **the disease status data model.**

Relevant animal species to be reported on

Sheep and goats.

Relevant agent species to be reported

B. melitensis, *B. abortus*, *B. suis* and *B. canis*.

Information to be reported in in the text form:

Description of the monitoring and control system

It is recommended that a description of eradication or surveillance systems is provided, including:

- for the non-Officially *B. melitensis* Free (non-ObmF) MSs, the eradication, control and surveillance programmes in place to combat the disease;
- in the case of ObmF regions or MSs, the procedures laying down the methods of surveillance for maintaining the ObmF status of bovine herds;
- figures on existing herds and their status at the end of the period;
- preventative and control measures in place;
- results of surveillance and investigations of suspected cases;
- approved EU co-financed eradication programmes, including specific measures;
- in non-ObmF MSs, this should be provided preferably on a regional level, if appropriate.

Reporting on the status as officially free

Following the legal basis, regions/MSs can be qualified, for reporting effects, in three categories:

- ObmF MS or region—any MS or region within the meaning of Article 2(10) to the amended Council Directive 91/68/EEC[17] may be recognised as being officially free under the procedure laid down in Article 15;
- non-ObmF MS, with control and eradication programmes that receive EU co-financing;
- non-ObmF MS with control and eradication programmes that do not receive EU co-financing.

The MSs fall into three categories as well:

- MSs where the whole country is ObmF;
- MSs where some regions are ObmF and some non-ObmF;
- MSs where the whole country is non-ObmF.

Type of specimen taken/methods of sampling

- Serum for serological test (RBT, CFT).
- Abortion material, vaginal discharges, milk, lymph nodes or other tissue for the identification of the agent.

Case definition/definition of a positive sample

- **Positive herd (prevalence)—**herd with at least one positive animal during the period, independently of the number of times the herd has been checked as specified in Annex III of Decision 2014/288/EC.
- **Positive animal—**animal with positive reaction using an official diagnostic method specified in Annex C of Council Directive 91/68/EEC. In MSs with approved programmes, 'Positive animal' is as defined in the programme.
- **New positive herd (incidence)—**herd whose status in the previous period was unknown, non-free negative, officially free or provisionally suspended and has at least, newly detected one positive animal in this period.

Diagnostic/analytical methods used

- The methods to be used, RBT/CFT, are laid down in Annex C of Council Directive 91/68/EEC. A reference to the legislation is recommended in case that these methods have been used.
- If other methods have been used, such as BST, ELISA, isolation/identification or PCR, these tests or methods should be described, including the interpretation of results applied, e.g. tests used for confirmation purposes.

Analyses of the results

Both national and regional analyses should be reported, if appropriate. Long-term trends, reflecting evolution over the last five years, and information on sources of infection are of special interest

4.5. Brucellosis in other animal species

Brucellosis in other animal species should be reported in **the prevalence data model**.

Relevant animal and agent species to be reported on

It is recommended, depending on the epidemiological situation, that information is reported on *Brucella* isolations (*B. abortus*, *B. melitensis*, *B. suis*, *B. canis*) in wildlife (mainly ruminants, wild boar

[17] Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals. OJ L 46, 19.2.1991, p. 19–36.

and hares), zoo animals, marine mammals, pet animals (mainly dogs used in herd/holding management) and other farm animals (pigs).

Additional interesting information to be reported

Results of serological tests and bacteriological examinations in all animals (specify units tested by serological methods and units tested by bacteriological examinations).

Definitions

Definitions should be used, as far as possible, in accordance with those given for bovine brucellosis and for ovine/caprine brucellosis.

Reporting the results in the prevalence data model

Specific guidelines for data reporting data

- **Matrix—**the relevant animal species and category (e.g. wild boar, dogs).
- **Sampling stage—**where the samples have been collected (e.g. 'farm', 'slaughterhouse') should be reported.
- **Sample origin—**this allows for further characterisation of the country of origin.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'animal sample—blood').
- **Sampling context—**information on the context of the sampling (e.g. 'surveillance') should be reported.
- **Sampler—**who performed the sampling should be reported here (e.g. 'official sampling' or 'industry sampling').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling', 'census', 'suspect sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Area of sampling—**data element that should be used to give further information on the area, region or province of the sampling in which the animal/food/feed sample has been collected according to the NUTS coding system.
- **Sampling unit—**the sampling unit is typically 'animal', 'herd' or 'holding' or 'slaughter batch'.
- **Source of information** the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Analytical methods—**the diagnostic or analytical method used in testing of the sample should be reported here (e.g. PCR).
- **Total units tested—**the number of sampling units that are analysed in the laboratory, or tested in another way, in total, and for which results are available. A sampling unit (e.g. flock) should not be counted twice even if it has been checked more than once for a specific zoonotic agent.
- **Total units positive—**the total number of sampling units considered infected (contaminated) based on the testing results for *Brucella*. In case that no positive units were detected, a '0' (zero) should be reported.

Number of units positive—the number of units considered infected based on the testing results for the *Brucella* species (e.g. *B. abortus, B. melitensis, B. suis, B. canis*). A herd/flock can be reported as seropositive for *Brucella* using serological screening methods but not be confirmed by confirmation methods (isolation).

4.6. Guidelines for reporting tuberculosis and brucellosis results in the disease status data model

Disease status data model should be used for reporting on tuberculosis in bovine animals and brucellosis in bovine animals, as well as in sheep and goats. Four types of tables' titles exist:

- tables for data on herds with EU co-financed programmes;
- tables for data on animals with EU co-financed programmes;
- tables for data on the status of herds with EU co-financed programmes at the end of the reporting period;
- tables for countries or regions that do not receive EU co-financing for their monitoring or eradication programmes.

MSs or regions with approved co-financed programmes should report the data in the disease status tables provided for EU co-financed eradication programmes. According to the 'Outcome of evaluation procedure of eradication, control and surveillance programmes submitted by Member States for 2015 Union financial contribution' (http://ec.europa.eu/dgs/health_food-safety/funding/cff/animal_health/vet_progs_en.htm), the following MS were co-financed during 2015;

- as regards bovine tuberculosis: Austria, Croatia, Ireland, Italy, Portugal, Spain and United Kingdom
- as regards bovine brucellosis: Croatia, Italy, Portugal, Spain and United Kingdom
- as regards small ruminant brucellosis: Croatia, Greece, Italy, Portugal and Spain

The other MSs use the tables 'Countries and regions that do not receive EU co-financing for eradication programmes'. The mentioned co-financed MSs may use these tables to report data originating from their OF regions and this regional reporting should best be aligned to the (annexes to) Decision 2003/467/EC and respectively Decision 93/52/EEC as regards which regions are OF.

Note that the control of these tuberculosis and brucellosis is harmonised in EU legislation. If definitions and concepts other than those given in that legislation are used, they should be explained in the comments/footnotes or in the text forms.

4.6.1. Information requested to be reported for data on herds with EU co-financed eradication programmes

- **Table name—**the official EU reporting tables to which the data refer. For example: 'Bovine tuberculosis - data on herds - Community co-financed eradication programmes' (code ZT10A).
- **Regions—**the regions of the MS for which data is reported should be indicated. If no regional information exists, the results from the entire MS should be reported by using the whole country code. Reporting the total for the whole country is mandatory. To report the total for the country, the ZOO_CAT_NUTS code corresponding to the whole country should be reported in this data element. In a MS that has an approved eradication programme, the term 'Region' should be understood and aligned as defined in the programme.
- **Disease status unit—**the data elements of the official EU reporting tables whose numeric value (e.g. population) is reported in the data element Number of units. From ZOO_CAT_UNITDS catalogue the following terms can be chosen:

  Total number of herds—the total number of existing herds in the region, including both herds eligible and non-eligible for the programme. Eligible herds are those for which it is compulsory to apply the programme. Non-eligible herds are those that can be excluded from the application of the programme.

  Number of herds under the program—herds under official control (by region in non-officially free MSs) should be reported.

In **officially free MSs or regions**, usually all herds are under clinical supervision of a veterinarian and all suspicious cases have to be reported. Therefore, this figure is usually the total number of bovine herds.

In non-officially free MSs or regions, the number of herds that are included in the control programmes should be reported here. If all the herds in these non-officially free MSs or regions are routinely tested, this number will be the total number of herds. In any other case, the number of herds under the programme should be clearly mentioned and can be equal to the number of herds tested under surveillance.

Number of herds under the program tested/checked—herds on which tests have been performed. Herds should not be counted twice even if they have been checked more than once. The number of herds tested under surveillance can be the same for as the number of herds under the programme.

Number of positive herds—herds with at least one positive animal during the period, independently of the number of times the herd has been checked.

Number of new positive herds—herds whose status in the previous period was unknown, non-free negative, free, officially free or suspended and have at least newly detected one positive animal in this period.

Number of depopulated herds—positive herds for which a stamping-out policy has been applied. This stamping out can be partial or complete stamping-out policy.

- **Number of units—**the value (e.g. population) of the unit reported in the data element Disease status unit.

4.6.2. Information requested to be reported for data on animals with EU co-financed eradication programmes

- **Table name—**the official EU reporting tables to which the data refer. For example: 'Ovine or caprine brucellosis - data on animals - Community co-financed eradication programmes' (code ZT05A)
- **Regions—**the regions of the MS for which data is reported should be indicated. If no regional information exists, the results from the entire MS should be reported by using the whole country code. Reporting the total for the country is mandatory. To report the total for the country, the ZOO_CAT_NUTS code corresponding to the whole country should be reported in this data element. In a MS that has an approved eradication programme, the term 'Region' should be understood as defined in the programme.
- **Disease status unit—**the data elements of the official EU reporting tables whose numeric value (e.g. population) is reported in the data element Number of units. From ZOO_CAT_UNITDS catalogue the following terms can be chosen:

  Total number of animals—number of animals existing in the region, including those from herds both eligible and non-eligible for the programme.

  Number of animals tested under the programme—total number of animals under official control, including animals tested individually or under a bulk scheme level.

In **officially free MSs or regions**, usually all animals are under the clinical supervision of a veterinarian and all suspicious cases have to be reported. Furthermore, upon slaughter, all animals have to be individually inspected ante mortem and post mortem. Therefore, this figure is usually the total number of animals. In **non-officially free MSs or regions**, the number of animals that are included in the control programmes should be reported here. If all animals are routinely tested, this figure will be the total number of animals. Otherwise, the number of animals tested should be clearly stated.

Number of animals tested—number of animals tested, including animals to be tested individually or under a bulk scheme level.

Number of animals tested individually—number of animals individually tested, excluding animals tested under a bulk scheme level (e.g. tests on a bulk milk tank).

Number of positive animals—total number of animals tested with a positive result.

Number of positive animals slaughtered—total number of animals with a positive result, slaughtered, dead or killed (culled).

Total number of animals slaughtered—total number of animals that were slaughtered, including all positive, suspected and inconclusive and also the negative animals slaughtered under the programme.

4.6.3. Information requested to be reported for data on status of herds with EU co-financed eradication programmes at the end of the period

- **Table name—**the official EU reporting tables to which the data refer. For example: Bovine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes (code ZT03A)
- **Regions—**the regions of the MS for which data is reported should be indicated. If no regional information exists, the results from the entire MS should be reported by using the whole country code. Reporting the total for the country is mandatory. To report the total for the country, the ZOO_CAT_NUTS code corresponding to the whole country should be reported in this data element. In a MS that has an approved eradication programme, the term 'Region' should be understood as defined in the programme.
- **Disease status unit—**the data elements of the official EU reporting tables whose numeric value (e.g. population) is reported in the data element Number of units. From ZOO_CAT_UNITDS catalogue the following terms can be chosen:

  Total number of herds/animals under the programme—total number of herds/animals covered by the EU co-financed programme. When reporting the totals for animals, all animals under the programme from herds with the referred status should be included.

  Number of herds/animals with unknown status, at the end of the period—total number of herds/animals covered by the programme for which no previous information on status and/or testing results was available. When reporting the totals for animals, all animals under the programme from herds with the referred status should be included.

4.6.4. Specific guidelines for bovine tuberculosis

The following definitions are to be used when reporting in the table named '**Bovine tuberculosis—data on status of herds at the end of the period—Community co-financed eradication programmes**' (code ZT11A):

- **Number of herds with status officially free, at the end of the period** (code DU24A)**—**bovine herds that satisfy the conditions laid down in paragraphs I.1 and I.2 of Annex A of Council Directive 64/432/EEC and that have been declared as such by the competent authority.
- **Number of herds with status free or officially free suspended, at the end of the period** (code DU20A)**—**bovine herds that fall under the conditions laid down in paragraph I.3.A of Annex A of Council Directive 64/432/EEC and that have been declared as such by the competent authority. These herds do not fulfil the conditions to retain OTF status (paragraph I.2, Annex A of Council Directive 64/432/EEC), or one or more animals are deemed to have given a positive reaction to a tuberculin test, or a case of tuberculosis is suspected at post-mortem examination.
- **Number of herds with status not free or not officially free and last check negative, at the end of the period** (code DU18A)**—**herds checked with negative results in latest check, but not being OTF.

- **Number of herds with status not free or not officially free and last check positive, at the end of the period** (code DU16A)—herds checked with at least one positive result in the latest check.

The following definitions are to be used when reporting in the table named '**Bovine tuberculosis in countries and regions that do not receive Community co-financing for eradication programme**' (code ZT12A):

- **Number of infected herds** (code DU56A)—all herds under control which are non-OTF during the reporting period/year. This figure summarises the results of different activities (tuberculin testing, meat inspection, follow-up investigations, tracing).
- **Interval between routine tuberculin tests** (code DU26A)—when reporting in this data element, the number of **months between routine tuberculin tests should be reported**, while any additional information concerning the interval should be reported in the Comment data element (resComm DST.10).
- **Number of animals tested with tuberculin routine testing** (code DU27A)—total number of animals tested by official tuberculin testing (Annex B of Council Directive 64/432/EEC) during the reporting year, within the investigation schedule. In case that tuberculin testing is not performed yearly, only those animals tested during the reporting period should be recorded.
- **Number of tuberculin tests carried out before introduction into the herds** (code DU28A)—detailed regional information is required, unless the official status has been granted to the whole territory of the MS.
- **Number of animals with suspicious lesions of tuberculosis examined and submitted to histopathological and bacteriological examinations** (code DU29A)—the number of bovine animals slaughtered showing suspicious lesions of tuberculosis at the post-mortem examination are reported, together with the number of samples in which the presence of *M. bovis* in clinical and post-mortem specimens has been demonstrated by any of the techniques specified in Annex B, paragraph 1, of Council Directive 64/432/EEC.
- **Number of animals detected positive in bacteriological examination** (code DU30A)—number of bovine animals in which *M. bovis* has been confirmed by a bacteriological examination specified in Annex B, paragraph 1, of Council Directive 64/432/EEC.

4.6.5. Specific guidelines for bovine brucellosis

The following definitions are to be used when reporting in the table named '**Bovine brucellosis—data on status of herds at the end of the period—Community co-financed eradication programmes**' (code ZT03A):

- **Number of herds with status officially free, at the end of the period** (code DU24A)—bovine herds that satisfy the conditions laid down in Annex AII, paragraphs 1 and 2, of Council Directive 64/432/EEC and that have been declared as such by the competent authority.
- **Number of herds with status free, at the end of the period** (code DU22A)—bovine herds that satisfy the conditions laid down in Annex AII, paragraphs 4 and 5, of Council Directive 64/432/EEC and that have been declared as such by the competent authority;
- **Number of herds with status free or officially free suspended, at the end of the period** (code DU20A)—bovine herds that fall under the conditions lay down in Annex AII, paragraphs 3A (Officially free) and 6A (Free), of Council Directive 64/432/EEC and that have been declared as such by the competent authority.
- **Number of herds with status not free or not officially free and last check negative, at the end of the period** (code DU18A)—herds checked with negative results in latest check but not free or OBF.

- **Number of herds with status not free or not officially free and last check positive, at the end of the period** (code DU16A)—herds checked with at least one positive result in the last check.

The following definitions are used when reporting in the table named '**Bovine brucellosis data from countries and regions that do not receive Community co-financing**' (code ZT04A):

- **Number of infected herds** (code DU56A)—the total number of bovine herds under control which are non-free or non-OBF during the reporting period/year. This figure summarises the results of different activities (notification of clinical cases, including abortions, routine testing, follow up investigations and tracing).
- **Number of herds tested under surveillance** (code DU31A)—total number of herds with animals tested individually with serological tests performed, as mentioned in Annex C of Council Directive 64/432/EEC.
- **Number of herds tested under surveillance by bulk milk** (code DU34A)—total number of herds in which routine tests have been performed by examination of bulk milk samples, according to Annex C of Council Directive 64/432/EEC.
- **Number of notified abortions whatever the cause** (code DU37A)—abortions notified on a mandatory basis to retain the status of OBF by a region or MS (those suspected of being due to brucellosis and investigated by the competent authority).
- **Number of isolations of *Brucella* infection** (code DU38A)—total number of animals with isolations, species and serotypes of *Brucella* spp. resulting from abortions, in accordance with the proper identification methods, as documented in Annex C of Council Directive 64/432/EEC.
- **Number of abortions due to *Brucella abortus*** (code DU39A)—total number of animals with an abortion from which *B. abortus* has been isolated.
- **Number of animals serologically tested under investigations of suspect case** (code DU40A)—total number of animals tested with the serological test mentioned in Section II, paragraph 10, of Annex A of Council Directive 64/432/EEC.
- **Number of suspended herds under investigations of suspect cases** (code DU41A)—total number of OBF herds of origin or of transit of a suspected bovine animal and herds linked epidemiologically to it.
- **Number of animals positive to BST under investigations of suspect cases** (code DU43A)—total number of animals with positive results on the BST, as specified in paragraph 3 of Annex C of Council Directive 64/432/EEC.
- **Number of seropositive animals under investigations of suspect cases** (code DU42A)—total number of animals with a positive result on the serological test mentioned in Section II, paragraph 10, of Annex A of Council Directive 64/432/EEC.
- **Number of animals tested by microbiology under investigations of suspect cases** (code DU44A)—total number of animals examined for identification of the agent.
- **Number of animals positive in microbiological testing under investigations of suspect cases** (code DU45A)—total number of animals with a positive result on the test described in paragraph 1 of Annex C of Council Directive 64/432/EEC for identification of the agent.

A description of the diagnostic scheme/decision tree used for bovine brucellosis is recommended including the serological assays/tests used for screening purposes as well as the confirmatory assays used after a positive serological screening test.

4.6.6. Specific guidelines for ovine and caprine brucellosis

The following definitions are to be used when reporting in the table named '**Ovine or caprine brucellosis—data on status of herds at the end of the period—Community co-financed eradication programmes**' (code ZT07A):

- **Number of herds with status officially free, at the end of the period** (code DU24A)—ovine or caprine herds that satisfy the conditions laid down in Section I of Chapter I of Annex A of Council Directive 91/68/EEC.
- **Number of herds with status free, at the end of the period** (code DU22A)—ovine or caprine herds that satisfy the conditions laid down in Chapter 2 of Annex A of Council Directive 91/68/EEC.
- **Number of herds with status free or officially free suspended, at the end of the period** (code DU20A)—ovine or caprine herds that satisfy the conditions laid down in Section I of Chapter I (officially free) or Chapter 2 (free) of Annex A of Council Directive 91/68/EEC.
- **Number of herds with status not free or not officially free and last check negative, at the end of the period** (code DU18A)—herds checked with negative results in latest check but not free or OBF.
- **Number of herds with status not free or not officially free and last check positive, at the end of the period** (code DU16A)—herds checked with at least one positive result in the last check.

The following definitions are used when reporting in the table named '**Ovine or Caprine brucellosis in countries and regions that do not receive Community co-financing for eradication programme** (code ZT08A):

- **Number of infected herds** (code DU56A)—the total number of ovine or caprine herds under control which are non-free or non-ObmF during the reporting period/year. This figure summarises the results of different activities (notification of clinical cases, including abortions, routine testing, follow-up investigations, tracing).
- **Number of herds tested under surveillance** (code DU31A)—total number of herds on which animals over six months were tested in accordance with paragraph II2 of Annex A of Council Directive 91/68/EEC.
- **Number of infected herds tested under surveillance** (code DU33A)—total number of herds tested with at least one animal with a positive result.
- **Number of seropositive animals under investigations of suspect cases** (code DU42A)—total number of investigated animals positive to a serological test.
- **Number of animals positive in microbiological testing under investigations of suspect cases** (code DU45A)—total number of animals in which the presence of *Brucella* has been confirmed following microbiological examination.
- **Number of suspended herds under investigations of suspect cases** (code DU41A)—total number of herds for which an epidemiological investigation is being carried out.

A description of the diagnostic scheme/decision tree used for ovine and caprine brucellosis is recommended including the serological assays/tests used for screening purposes as well as the confirmatory assays used after a positive serological screening test.

5. Reporting on other zoonoses in animals

5.1. *Salmonella* spp. in animals

For the purpose of following trends the information to be reported each year or at regular intervals (e.g. every two or three years) is:

—*Salmonella* spp. and *Salmonella enterica* subsp. *enterica* serovar Enteritidis (*S.* Enteritidis), *Salmonella* Typhimurium (*S.* Typhimurium), *Salmonella* Hadar (*S.* Hadar), *Salmonella* Infantis (*S.* Infantis), and *Salmonella* Virchow (*S.* Virchow) in parent breeding flocks of *Gallus gallus* (broiler production line/egg production line);

—*Salmonella* spp. and *S.* Enteritidis and *S.* Typhimurium in flocks of laying hens (*Gallus gallus)*;

—*Salmonella* spp. and *S.* Enteritidis and *S.* Typhimurium in flocks of broilers (*Gallus gallus)*;

—*Salmonella* spp. and *S.* Enteritidis and *S.* Typhimurium in flocks of breeding turkeys;

—*Salmonella* spp. and *S.* Enteritidis and *S.* Typhimurium in flocks of fattening turkeys;

—*Salmonella* spp. in fattening pigs.

Please note that the monophasic *S.* Typhimurium strains should also be reported for trend-following purposes.

5.1.1. *Salmonella* spp. in animal populations with control programmes set by EU legislation—*Gallus gallus* (fowl) and turkeys

Relevant animal categories to be reported on

For breeding flocks of *Gallus gallus* and turkeys: elite breeding flocks, grandparent breeding flocks, parent breeding flocks. When possible, the stage of sampling (age groups: day-old chicks, rearing flocks, adult) may be indicated and, in the case of *Gallus gallus*, the production line (egg and meat).

Laying hen flocks of *Gallus gallus*, broiler flocks of *Gallus gallus*, fattening turkey flocks.

Please note that for the purpose of verifying whether or not the EU *Salmonella* reduction target set by Commission Regulation (EU) No 200/2010[18] for breeding flocks of *Gallus gallus* is met, MSs shall report the results separately at least for adult flocks, because the target is set for adult breeding flocks.

Please note that for the purpose of verifying whether or not the EU *Salmonella* reduction target set by Commission Regulation (EU) No 517/2011[19] for laying hen flocks of *Gallus gallus* is met, MSs shall report the results separately at least for adult flocks, because the target is set for adult laying hen flocks. Furthermore, if results from flocks other than those under the *Salmonella* control programme are reported, these flocks should be reported separately, in order to facilitate the verification of the target.

Please note that for the purpose of verifying whether or not the EU *Salmonella* reduction target set by Commission Regulation (EC) No 200/2012[20] for broiler flocks of *Gallus gallus* is met, MSs shall report separately the results from sampling within the three weeks before the birds are moved to the slaughterhouse (= before slaughter), because the target is set for this period.

[18] Commission Regulation (EU) No 200/2010 of 10 March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of *Salmonella* serotypes in adult breeding flocks of *Gallus gallus.* OJ L 61, 11.3.2010, p. 1–9.

[19] Commission Regulation (EU) No 517/2011 of 25 May 2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of certain *Salmonella* serotypes in laying hens of *Gallus gallus* and amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) No 200/2010. OJ L 138, 26.5.2011, p. 45–51.

[20] Commission Regulation (EU) No 200/2012 of 8 March 2012 concerning a Union target for the reduction of *Salmonella* Enteritidis and *Salmonella* Typhimurium in flocks of broilers, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council Text and repealing Regulation (EC) No 646/2007/OJ L 71, 9.3.2012, p. 31–36.

Please note that for the purpose of verifying whether or not the EU *Salmonella* reduction target set by Commission Regulation (EC) No 1190/2012[21] for turkey flocks is met, MSs shall report separately the results from breeding turkey flocks during production (adult flocks) and, in the case of fattening turkey flocks, the results from sampling within the three weeks before the birds are moved to the slaughterhouse (= before slaughter), because two different targets are set for turkeys.

Relevant agent species/serovars/phagetypes to be reported

Salmonella serovars and phagetypes should be reported, where available.

As regards breeding flocks of *Gallus gallus*, the serovars *S.* Enteritidis, *S.* Typhimurium, *S.* Hadar, *S.* Infantis and *S.* Virchow should all be reported separately, as these are the serovars covered by the target. Monophasic *S.* Typhimurium strains with the antigenic formula 1,4,[5],12:i:-[22] should also be included.

For flocks of laying hens of *Gallus gallus*, *S.* Enteritidis and *S.* Typhimurium should be reported separately on account of the target set for these serovars. In addition, it is recommended that the five most frequent serovars be reported, and also always *S.* Infantis, *S.* Hadar and *S.* Virchow, even though these serovars may not be included in the top five serovars. Monophasic *S.* Typhimurium strains with the antigenic formula 1,4,[5],12:i:-[22] should also be included.

In the case of broiler flocks, *S.* Enteritidis and *S.* Typhimurium should be reported separately on account of the target set for these serovars. In addition, it is recommended that the five most frequent serovars and also *S.* Infantis, *S.* Hadar and *S.* Virchow be reported, even though these serovars may not be included in the top five serovars. Monophasic *S.* Typhimurium strains with the antigenic formula 1,4,[5],12:i:- [22] should also be included.

In the case of turkey breeding flocks and turkey fattening flocks, *S.* Enteritidis and *S.* Typhimurium should be reported separately on account of the target set for these serovars. Monophasic *S.* Typhimurium strains with the antigenic formula 1,4,[5],12:i:- [22] should also be included.

Data on monophasic *S.* Typhimurium should be reported as follows: this group comprises *S.* Typhimurium strains lacking the second phase H antigen (1,4,[5],12:i:-[22]). Whenever feasible, as much detail as possible of the antigenic formula as determined by testing should be reported (e.g. 1,4,[5],12:i:- or 1,4,12:i:-). If the full antigenic formula is not available but a phagetype that is consistent with *S.* Typhimurium lacking phase 2 flagellar antigen has been confirmed, and the lack of the second flagellar antigen has been verified by PCR, then it is recommended that the term 'monophasic *S.* Typhimurium' be used.

Information on the serovars covered by the EU reduction target for the specific animal populations should be always reported in the related prevalence tables for the purpose of verifying the achievement of the reduction target.

Type of specimen taken

For breeding flocks: faeces, boot/sock swabs, internal linings of delivery boxes, dead chicks, eggshells, fabric swabs. Other samples could include blood, dust, environmental samples, fluff, hatched eggs, hatching eggs, meconium and organs. Blood or eggs are collected in the case of serological examinations.

For laying hens: dust, faeces, boot/sock swabs. Other samples could include environmental samples, blood, etc.

For broilers: boot/sock swabs, hand drag swabs. Other samples could include environmental samples, dust samples, litter samples, blood, etc.

For breeding turkeys: faeces, boot/sock swabs, internal linings of delivery boxes, dead chicks, eggshells, fabric swabs. Other samples could include blood, dust, environmental samples, fluff,

[21] Commission Regulation (EU) No 1190/2012 of 12 December 2012 concerning a Union target for the reduction of *Salmonella* Enteritidis and *Salmonella* Typhimurium in flocks of turkeys, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council. OJ L 340, 13.12.2012, p. 29–34.

[22] The following antigenic formula can also be used for reporting monophasic *S.* Typhimurium 1,4,12:i:- or 4,[5],12:i:-.

hatched eggs, hatching eggs, meconium and organs. Blood or eggs are collected in the case of serological examinations.

For fattening turkeys: boot/sock swabs, hand drag swabs. Other samples could include environmental samples, dust samples, litter samples, blood, etc.

Methods of sampling

For breeding flocks: it should be described whether the sampling was in accordance with the Annex of Commission Regulation (EU) No 200/2010.

For laying hens: it should be described whether the sampling was in accordance with the Annex of Commission Regulation (EU) No 517/2011.

For broilers: it should be indicated if the sampling was in accordance with the Annex of Commission Regulation (EU) No 200/2012.

For turkeys: it should be indicated if the sampling was in accordance with the Annex of Commission Regulation (EU) No 1190/2012.

Case definition/definition of a positive sample

- **Positive flock/unit—**each flock should be reported positive only once, irrespective how many positive samples were received.
    - **A breeding flock (EU No 200/2010)** shall be considered positive when the presence of the relevant *Salmonella* serotypes (other than vaccine strains) has been detected in one or more samples taken in the flock, even if the relevant *Salmonella* serotypes is only detected in the dust sample, or — when the confirmatory sampling as part of official controls in accordance with point 2.2.2.2(b) does not confirm the detection of relevant *Salmonella* serotypes but antimicrobials or bacterial growth inhibitors have been detected in the flock. This rule shall not apply in exceptional cases described in point 2.2.2.2(c) where the initial *Salmonella* positive result from sampling at the initiative of the food business operator has not been confirmed by the sampling as part of official controls.
    - **A laying flock (EU No 517/2011)** shall be considered positive where: (a) the presence of the relevant *Salmonella* serotypes (other than vaccine strains) has been detected in one or more samples taken in the flock, even if the relevant *Salmonella* serotype is only detected in the dust sample or dust swab; or (b) antimicrobials or bacterial growth inhibitors have been detected in the flock. This rule shall not apply in exceptional cases described in Annex II D point 4 of Regulation (EC) No 2160/2003, where the initial *Salmonella* positive result has not been confirmed by that respective sampling protocol.
    - **A flock of broilers (EU No 200/2012)** shall be considered positive where the presence of *Salmonella* Enteritidis and/or *Salmonella* Typhimurium (other than vaccine strains) was detected in the flock. Positive flocks of broilers shall be counted only once per round, irrespective of the number of sampling and testing operations and only be reported in the year of the first positive sampling
    - **A flock of turkeys (1190/2012)** shall be considered positive where the presence of *Salmonella* Enteritidis and/or *Salmonella* Typhimurium (other than vaccine strains, but including monophasic strains with the antigenic formula 1,4,[5],12:i:-) was detected in the flock. The prevalence shall be calculated separately for flocks of fattening turkeys and flocks of adult breeding turkeys.

Diagnostic/analytical methods typically used

Method recommended by EU Reference Laboratory for *Salmonella* in Bilthoven, the Netherlands: a modification of ISO 6579:2002, in which a semi-solid medium, Rappaport–Vassiliadis medium semi-solid modified (MSRV), is used as the single selective enrichment medium. This method is described in Annex D of ISO 6579:2002 (ISO, 2007).

Analyses of the results

Analyses of results from flocks at different production levels, as well as corresponding serovar distributions, is important. The impact of the control programmes in place on the prevalence and number of human cases is also very relevant.

Reporting the results in the prevalence data model

Specific guidelines for reporting data on samples collected in breeding flocks of *Gallus gallus* according to Commission Regulation (EU) No 200/2010 (target regulation)

Information requested to be reported:

- **Matrix—**for level 1 use '*Gallus gallus* (fowl)'; for level 2 use 'parent breeding flocks', 'grandparent breeding flocks' or 'elite breeding flocks'; for level 3 use 'adult'; in addition, the results from sampling carried out on 'day-old chicks' and 'during rearing period' could be reported.
- **Sampling stage—**use 'farm' or 'hatchery'.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**use the sample category ('animal sample' or 'environmental samples') and sample type ('faeces' or 'boot swabs') based on the sampling carried out. If several types of samples were taken, use separate rows to report the data.
- **Sampling context—**use 'control or eradication programme' for all data.
- **Sampler—**use 'official and industry sampling'. In addition, the results from sampling carried out by competent authorities ('official sampling') and from sampling by food business operators ('industrial sampling') could be reported separately.
- **Sampling strategy—**use 'census'.
- **Sampling unit—**use 'flock'.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Target verification—**use 'yes' for the value to be used for the target verification.
- **No of flocks under control programme—**the number of all breeding flocks in the country under the programme during the year.
- **Total units tested—**the number of flocks in the specified production type, production level and age group under investigation. Each flock should be counted only once, irrespective of the number of times it is tested.
- **Total units positive—**the total number of flocks considered positive for *Salmonella* based on the results of the analyses. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of flocks considered positive based on the testing results for a specific *Salmonella* serovar (e.g. *Salmonella* Typhimurium, *Salmonella* Infantis) or phagetype (e.g. *Salmonella* Enteritidis-PT 1).

  For matrix, when possible, report the information allocated to different production lines (egg and meat), as well as the level of the production pyramid (elite, grandparent and parent flocks) and separated by age groups (day-old chicks, rearing flocks, adult, unspecified). If results for the different types of breeding flocks are not available, use the 'Breeding flock' line.
- Use 'Unspecified' only when it is not known whether the results are derived from testing on day-old chicks, young birds in the rearing period or adults.

  The number of flocks where *Salmonella* vaccine strains were detected may be reported in the comment data element regarding the specific animal population. However, these flocks are not counted as *Salmonella* positivesPT 1

Specific guidelines for entering data on samples collected in laying hens according to Commission Regulation (EU) No 517/2011 (target regulation)

Information requested to be reported:

- **Matrix—**for level 1, use '*Gallus gallus* (fowl)'; for level 2 use 'laying hens'; for level 3 use 'adult'; and if needed add 'flocks under control programme'.
- **Sampling stage—**use 'farm'.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**use the sample category ('animal sample' or 'environmental sample') and the relative sample type ('faeces' or 'boot swabs' or 'dust') to report results from sampling under the programme. If several types of samples were taken, use separate rows to report the data.
- **Sampling context—**use 'control or eradication programme' for all data.
- **Sampler—**use 'official and industry sampling'. In addition, the results from sampling carried out by competent authorities ('official sampling') and from sampling by food business operators ('industrial sampling') could be reported separately.
- **Sampling strategy—**use 'census'.
- **Sampling unit—**use 'flock'.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Target verification—**use 'yes' for the value to be used for the target verification.
- **No of flocks under control programme—**the number of all laying hen flocks in the country under the programme that were in production (laying) during the year.
- **Total units tested—**the number of flocks under investigation. Each flock should be counted only once, irrespective of the number of times it is tested.
- **Total units positive—**the total number of flocks considered positives for *Salmonella* spp. based on the results of the analyses. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of flocks considered positive based on the testing results for a specific *Salmonella* serovar (e.g. *Salmonella* Typhimurium, *Salmonella* Infantis) or phagetype (e.g. *Salmonella* Enteritidis-PT 1).

Specific guidelines for entering data on samples collected in broiler flocks according to Commission Regulation (EU) No 200/2012 (target regulation)

Information requested to be reported:

- **Matrix—**for level 1 use '*Gallus gallus* (fowl)'; for level 2 use 'broilers'; for level 3 use 'before slaughter'.
- **Sampling stage—**use 'farm'.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**use the sample category ('environmental sample') and the relative sample type ('boot swabs' or 'dust') to report results from the sampling under the programme. If several types of samples were taken, use separate rows to report the data.
- **Sampling context—**use 'control or eradication programme' for all data.
- **Sampler—**use 'official and industry sampling'. In addition, the information shall be provided separately for the sampling carried out by the food business operators, according to point 2.1.(a) of the regulation (using 'census' in combination with 'industry sampling'), and for the sampling performed by the competent authority, according to point 2.1.(b) of the regulation (using 'official sampling' in combination with the applied sampling strategy).

- **Sampling strategy—**use 'census'.
- **Sampling unit—**use 'flock'.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Target verification—**use 'yes' for the value to be used for the target verification.
- **No of flocks under control programme—**the number of all broiler flocks in the country under the programme during the year.
- **Total units tested—**the number of flocks under investigation. Each flock should be counted only once, irrespective of the number of times it is tested.
- **Total units positive—**the total number of flocks considered infected for *Salmonella* based on the results of the analyses. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of flocks considered positive based on the testing results for a specific *Salmonella* serovar (e.g. *Salmonella* Typhimurium, *Salmonella* Infantis) or phagetype (e.g. *Salmonella* Enteritidis-PT 1).

Specific guidelines for entering data on samples collected in turkeys according to Commission Regulation (EU) No 1190/2012 (target regulation)—for breeding flocks of turkeys

Information requested to be reported:

- **Matrix—**for level 1 use 'turkeys'; for level 2 use 'breeding flocks, unspecified'; for level 3 use 'adult'; in addition, the results from sampling carried out on 'day-old chicks' and 'during rearing period' could be reported.
- **Sampling stage—**use 'farm' or 'hatchery'.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**use the sample category ('animal sample' or 'environmental samples') and sample type ('faeces' or 'boot swabs') based on the sampling carried out. If several types of samples were taken, use separate rows to report the data.
- **Sampling context—**use 'control or eradication programme' for all data.
- **Sampler—**use 'official and industry sampling'. In addition, the information shall be provided separately for the sampling carried out by the food business operators, according to point 2.1.(a) of the regulation (using 'census' in combination with 'industry sampling'), and for the sampling performed by the competent authority, according to point 2.1.(b) of the regulation (using 'official sampling' in combination with the applied sampling strategy).
- **Sampling strategy—**use 'census'.
- **Sampling unit—**use 'flock'.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Target verification—**use 'yes' for the value to be used for the target verification.
- **No of flocks under control programme—**the number of all turkey breeding flocks in the country under the programme during the year.
- **Total units tested—**the number of breeding flocks under investigation. Each flock should be counted only once, irrespective of the number of times it is tested.
- **Total units positive—**the total number of flocks considered positive for *Salmonella* based on the results of the analyses. In case that no positive units were detected, a '0' (zero) should be reported.

- **Number of units positive—**the number of flocks considered positive based on the testing results for a specific *Salmonella* serovar (e.g. *Salmonella* Typhimurium, *Salmonella* Infantis) or phagetype (e.g. *Salmonella* Enteritidis-PT 1).

Specific guidelines for entering data on samples collected in turkeys according to Commission Regulation (EU) No 1190/2012 (target regulation)—for fattening flocks of turkeys

Information requested to be reported:

- **Matrix—**for level 1 use 'turkeys'; for level 2 use 'fattening flocks, unspecified'; for level 3 use 'before slaughter'.
- **Sampling stage—**use 'farm'.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**use the sample category ('environmental sample') and the relative sample type ('boot swabs' or 'dust') to report results from the sampling under the programme. If several types of samples were taken, use separate rows to report the data.
- **Sampling context—**use 'control or eradication programme' for all data.
- **Sampler—**use 'official and industry sampling'. In addition, the information shall be provided separately for the sampling carried out by the food business operators, according to point 2.1.(a) of the regulation (using 'census' in combination with 'industry sampling'), and for the sampling performed by the competent authority, according to point 2.1.(b) of the regulation (using 'official sampling' in combination with the applied sampling strategy).
- **Sampling strategy—**use 'census'.
- **Sampling unit—**use 'flock'.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Target verification—**use 'yes' for the value to be used for the target verification.
- **No of flocks under control programme—**the number of all fattening flocks in the country under the programme during the year.
- **Total units tested—**the number of fattening flocks under investigation. Each flock should be counted only once irrespectively of the number of times it is tested.
- **Total units positive—**the total number of flocks considered positive for *Salmonella* based on the results of the analyses. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of flocks considered positive based on the testing results for a specific *Salmonella* serovar (e.g. *Salmonella* Typhimurium, *Salmonella* Infantis) or phagetype (e.g. *Salmonella* Enteritidis-PT 1).

5.1.2. *Salmonella* spp. in animal populations without EU control programmes

Relevant animal species to be reported on

Ducks and geese: whenever possible, differentiate the types of flocks (e.g. breeding, broiler production and egg production) and the age (e.g. day-old chicks, adult).

Pigeons, guinea fowl, pheasants, partridges and ostriches: indicate, when possible, the type of birds (e.g. farmed, wild, pets) and, in the case of wild birds, the animal species.

Pigs (both fattening and breeding pigs), cattle, sheep, goats, domestic solipeds.

Pet animals (dogs, cats).

Wildlife species, such as hedgehogs, are also interesting.

Relevant agent species/serotypes/phagetypes to be reported

It is recommended that *Salmonella* serovars and phagetypes are reported, where available.

As regards pigs, the serovars *S.* Enteritidis, *S.* Typhimurium and *S.* Infantis should be reported separately. Monophasic *S.* Typhimurium strains should also be included.

Data on monophasic *S.* Typhimurium should be reported as follows: this group comprises *S.* Typhimurium strains lacking the second phase H antigen (1,4,[5],12:i:-[22]). Whenever feasible, as much detail as possible of the antigenic formula as determined by testing should be reported (e.g. 1,4,[5],12:i:- or 1,4,12:i:-). If the full antigenic formula is not available but a phagetype that is consistent with *S.* Typhimurium lacking phase 2 flagellar antigen has been confirmed, and the lack of the second flagellar antigen has been verified by PCR, then it is recommended that the term 'monophasic *S.* Typhimurium' be used.

Type of specimen taken

In the case of poultry, typical specimens collected are blood, dead chicks, dust, environmental samples, faeces, fluff, hatched eggs, hatching eggs, internal linings of delivery boxes, eggshells, meconium, organs and sock/boot swabs.

In the case of pigs and cattle, typical specimens are blood, dust, faeces, meat juice, milk and organs (ileocaecal lymph nodes).

Diagnostic/analytical methods typically used

Method recommended by EU Reference Laboratory for *Salmonella* in Bilthoven, the Netherlands: a modification of ISO 6579:2002 in which a semi-solid medium (MSRV) is used as the single selective enrichment medium. This method is described in Annex D of ISO 6579:2002 (ISO, 2007).

For blood and meat juice: ELISA and serological methods are used.

Analyses of the results

The analyses of results from different animal species, as well as the corresponding serovar distributions, are important, especially concerning their contributions to human salmonellosis cases. The impact of the control programmes in place on the prevalence and number of human cases is also very relevant.

Reporting the results in the prevalence data model

- **Matrix—**the relevant animal species and category.
- **Sampling stage—**where the samples have been collected (e.g. 'farm', 'slaughterhouse') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'animal sample-faeces' or 'environmental sample-boot swabs').
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring') should be reported.
- **Sampler—**in this data element who performed the sampling should be reported (e.g. 'official sampling' or 'industry sampling').
- **Sampling strategy—**the type of sampling should be reported in this column (e.g. 'objective sampling', 'census', 'suspect sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**use 'Flock', 'herd', 'holding', 'slaughter batch' or 'animal'.

- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Total units tested—**the number of sampling units in the specified production type, production level and age group under investigation. Each flock should be counted only once, irrespective of the number of times it is tested.
- **Total units positive—**the total number of sampling units considered positive for *Salmonella* based on the results of the analyses reported. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of units tested positive for a specific *Salmonella* serovar (e.g. *Salmonella* Typhimurium, *Salmonella* Infantis) or phagetype (e.g. *Salmonella* Enteritidis-PT 1).

Information regarding matrix to be reported:

- As regards domestic poultry, when possible, report the information allocated to the level of the production pyramid (breeding flocks and meat production flocks, or even more specifically) as well as separated by age groups (day-old chicks, young birds during the rearing period, adult, unspecified).
- In addition, where possible, give the breakdown of the results by different types of cattle (e.g. calves, adults, etc.) and pigs (breeding and fattening pigs).
- Use 'Unspecified' only when it is not known whether the results are derived from testing day-old chicks, young birds during the rearing period or adults.

5.2. *Campylobacter* spp. in animals

For the purpose of following trends, the information to be reported each year or at regular intervals (e.g. every two or three years) is:

—*Campylobacter* in flocks of broilers (*Gallus gallus*).

Relevant animal species to be reported on

Broilers of *Gallus gallus*, turkeys, pigs, bovine animals, sheep, birds, dogs, cats and wildlife (e.g. wild birds).

Relevant agent species to be reported

Thermotolerant *Campylobacter* spp. differentiation at species level should be provided, where available. The main species of interest are *Campylobacter jejuni* (*C. jejuni)* and *Campylobacter coli* (*C. coli*); however, *Campylobacter lari* (*C. lari*), *Campylobacter upsaliensis* (*C. upsaliensis*) and *Campylobacter helveticus* (*C. helveticus*), which are known to cause human infections, may also be reported. *Campylobacter fetus* (*C. fetus*) may also be reported.

Type of specimen taken

Typically, the following types of specimen are taken:

- broiler flocks: intact caecae taken at time of evisceration (caecal content), cloacal swabs;
- turkeys: cloacal swabs, intact caecae;
- cattle and pigs: faecal material, rectal swabs;
- environmental samples (rearing house, environment), e.g. before arrival of the animals, overshoes/sock/boot samples;
- feed.

Case definition/definition of a positive sample

- **Positive holding/herd/flock/batch/animal—**a holding, herd, flock, batch, animal in which thermotolerant *Campylobacter* spp. have been detected.
- **Positive slaughter batch—**a batch in which thermotolerant *Campylobacter* spp. have been detected in at least one of the samples in the batch or if the agent is confirmed in the pooled sample from this batch.

Diagnostic/analytical methods typically used

For detection of *Campylobacter*, the method used is ISO 10272-1:2006 (ISO, 2006a).

Speciation of *Campylobacter* by the use of recognised DNA-based methods, i.e. validated and published PCR methods, is recommended. The method used shall be indicated. PCR is the preferred method for *Campylobacter* speciation, as phenotypical methods (e.g. detection of hippurate hydrolysis) have a certain risk of giving intermediate or incorrect test results.

Reporting the results in the prevalence data model

Specific guidelines for reporting data

- **Matrix—**the relevant animal species and category.
- **Sampling stage—**where the samples have been collected (e.g. 'farm', 'slaughterhouse') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'animal sample-faeces' or 'environmental sample-boot swabs').
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring') should be reported.
- **Sampler—**in this data element who performed the sampling should be reported (e.g. 'official sampling' or 'industry sampling').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling', 'census', 'suspect sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'flock', 'herd', ' herd/flock', 'holding', 'slaughter batch' or 'animal' should be used as the terms to be reported.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Total units tested—**the number of sampling units that are analysed in total, and for which results are available.
- **Total units positive—**the total number of sampling units considered positive for *Campylobacter* based on the analytical results reported. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the total number of units tested positive for the *Campylobacter* species (e.g. *Campylobacter jejuni, Campylobacter coli*).

5.3. *Listeria* spp. in animals

Relevant animal species to be reported

A wide variety of animal species can be infected with *Listeria monocytogenes* (*L. monocytogenes)*, but clinical listeriosis is mainly a ruminant disease, affecting sheep, goats and cattle.

Relevant agent species to be reported

The information provided should concentrate on *L. monocytogenes*.

Type of specimen taken

Typically, the type of specimens taken are faeces, abortion material, uterus excretions and other clinical specimens, e.g. lesions from liver, spleen or kidneys.

Case definition/definition of a positive sample

- **Positive sample—**an animal, a herd or a slaughter batch in which *L. monocytogenes* has been detected.

Diagnostic/analytical methods typically used

Standard bacteriological methods are used for detecting *L. monocytogenes*, such as ISO 11290-1:1996 (ISO, 1996).

Preventative and control measures in place

The measures in place targeting the prevention and control of *Listeria* spread should be described, e.g. disposal of potentially infective materials such as aborted animal foetuses, birth excretions and the bodies of dead animals.

Reporting the results in the prevalence data model

Specific guidelines for reporting data

- **Matrix—**the relevant animal species and category.
- **Sampling stage—**where the samples have been collected (e.g. 'farm', 'slaughterhouse') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'animal sample-faeces' or 'environmental sample-boot swabs').
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring') should be reported.
- **Sampler—**who performed the sampling (e.g. 'official sampling' or 'industry sampling').
- **Sampling strategy—**the type of sampling should be reported in this column (e.g. 'objective sampling', 'census', 'suspect sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'flock', 'herd', 'herd/flock', 'holding', 'slaughter batch' or 'animal' should be used as the terms to be reported.
- **Source of information—**the Institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- 'domestic').
- **Units tested—**the number of sampling units that are analysed in total, and for which results are reported.
- **Total units positive for *Listeria*—**in this column, the total number of sampling units with a positive result for *Listeria*, based on the analytical results, should be inserted. This total should be distributed according to the columns below:
- **Number of units positive—**the total number of units tested positive for the *Listeria* species (e.g. *L. monocytogenes*) or serotypes. This data element is mandatory when reporting all

results referring to *Listeria*, meaning that also the negative results '0' should be reported in this case.

The prevalence can also be reported for different animal species and subcategories of these species, for different types of sampling stages/locations, for different types of sampling units and for different types of agent species.

Clinical listeriosis cases in individual animals should be clearly distinguished from those resulting from survey, control or monitoring schemes by indicating that the information is coming from 'clinical investigations'.

5.4. *Yersinia* spp. in animals

Relevant animal species to be reported on

- **Pigs**, **bovine animals**, **sheep**, **goats**, (dogs and cats, wildlife animal species).

Relevant agent species/serotypes/biotypes to be reported

Yersinia spp. differentiation at species level should be provided, whenever possible (e.g. *Yersinia enterocolitica* (*Y. enterocolitica*), *Yersinia pseudotuberculosis* (*Y. pseudotuberculosis*)). The main pathogenic *Y. enterocolitica* serotypes (O:3, O:5,27 and O:9) and/or biotypes (1B, 2, 3, 4, 5) should be reported, where available. If information on both serotype and biotype is available, the results should be reported as the biotype/serotype combinations, as recommended in the report 'Technical specifications for harmonised national surveys of *Y. enterocolitica* in slaughter pigs' (EFSA, 2009b), for example biotype 4/O:3.

Type of specimen taken

A description of the specimen taken, e.g. tonsils, faeces, caecal content, mesenteric lymph nodes, or blood.

Case definition/definition of a positive sample

- ***Yersinia*-positive unit—**an animal, a herd or a slaughter batch in which *Yersinia* spp. have been isolated.

Diagnostic/analytical methods typically used

Information on the analytical and diagnostic methods used could be provided. Isolation is usually made by culture methods, e.g. cold enrichment, selective enrichment, direct plating or other. Serological identification may be used for the main pathogenic serotypes. The reference method for the detection of *Y. enterocolitica* in food (ISO 10273:2003 (ISO, 2003)) is also applicable for examination of the tonsils and lymph nodes.

Reporting the results in the prevalence data model

Specific guidelines for reporting data

- **Matrix—**the relevant animal species and category.
- **Sampling stage—**where the samples have been collected (e.g. 'farm', 'slaughterhouse') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'animal sample-faeces' or 'environmental sample-boot swabs').
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring') should be reported;
- **Sampler—**who performed the sampling should be reported here (e.g. 'official sampling' or 'industry sampling').

- **Sampling strategy—**the type of sampling should be reported in this column (e.g. 'objective sampling', 'census', 'suspect sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'flock', 'herd', 'herd/flock', 'holding', 'slaughter batch' or 'animal' should be used as the terms to be reported.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Total units tested—**the number of sampling units that are analysed in total, and for which results are available.
- **Total units positive—**the total number of sampling units positive for *Yersinia* based on the analytical results reported. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of units tested positive for the *Yersinia* species (e.g. *Yersinia enterocolitica, Yersinia pseudotuberculosis*), serotypes (e.g. O:3, O:5,27 and O:9) and/or biotypes (e.g. 1B, 2, 3, 4, 5).

5.5. Verotoxigenic *Escherichia coli* in animals

Relevant animal species to be reported on

- **Cattle, sheep, goats, wild game** (ruminants), which are recognised as the principal animal reservoirs.

Relevant agent species/serotypes to be reported

Strains of *Escherichia coli* (*E. coli*) which are capable of producing verocytotoxin (VT)/Shiga toxin (Stx) (VTEC or Shiga toxin-producing *E. coli* (STEC)). Information on the serogroup (O antigen) should be reported. Serogroups of particular interest are: O157, O111, O103, O26 and O145.

MSs are strongly invited to report information on the STEC/VTEC serogroup, when available.

Information on genes encoding verocytotoxin 1 (*vtx1*), verocytotoxin 2 (*vtx2*) or the respective cytotoxins (VT1, VT2) is essential to be reported or intimin (*eae*), where available, as stated in the report 'Technical specifications for the monitoring and reporting of verotoxigenic *Escherichia coli* (VTEC) on animals and food' (EFSA, 2009a), for example VTEC O157 *eae* positive *vtx1* positive vtx2 negative.

For the serogroup O104, it is recommended that the virulence characters are reported, including the presence of verocytotoxin VT2 positive (*vtx2 positive*+) and enteroaggregative virulence plasmid (*EAgg*+).

The serogroups non-O157 should be differentiated based on the presence/absence of the gene for intimin (*eae*), which is considered to be a marker of potential high virulence.

Type of specimen taken

Rectal faeces samples, hide and fleece swabs (brisket or ears).

Case definition/definition of a positive sample

- **VTEC-positive animal/sample/herd/flock/batch—**an animal/sample/herd/flock from which VTEC has been isolated.

MSs are strongly encouraged to only report data on STEC/VTEC as indicated in the Directive 2003/99/EC.

It is important to note that the positive result to be reported, according to the EFSA Data dictionaries' guideline, is an E. coli isolate producing VT or possessing the vtx genes. The correct reporting of the positive results is strongly recommended.

To make the data reporting easier and harmonized across the MSs, the following proposal for data reporting at the Zoonosis L3 level is made. Values for Zoonosis L3 reporting should include the following:

- *VTEC, serogroup identified*: to be used when a strain carrying the *vtx* genes or producing VT has been isolated, and information on the STEC serogroup is available. The VTEC serogroup identified to be selected from the whole list of VTEC serogroups (From O1 to O…).
- *VTEC non-O157*: to be used only when a strain carrying the *vtx* genes has been isolated but its serogroup does not belong to O157 or to any of the other serogroups the laboratory is able to detect.
- *VTEC non* O157, O26, O111, O103, O145: to be used only when a strain carrying the *vtx* genes has been isolated but its serogroup does not belong to O157, O26, O111, O103, O145 (the serogroups identified by the ISO/TS13136:2012) or to any of the other serogroups the laboratory is able to detect.
- *VTEC unspecified*: to be used only when a strain carrying the *vtx* genes or producing VT is isolated, but no information on the STEC serogroup is available.

Algorithm for reporting VTEC serogroup detection at the Zoonosis L3 level

1. Isolation of an *E. coli* strain producing VT or carrying the *vtx1* or *vtx2* or both genes.
2. Was an attempt to identify the serogroup of the VTEC strain performed?
   - Yes → go to point 3
   - No→ report as **VTEC, unspecified**.
3. Did the isolated VTEC strain belong to O157?
   - Yes → to be reported as **VTEC, O157**
   - No → go to point 4
4. Was the identification of the VTEC serogroup obtained?
   - Yes → to be reported as **VTEC, serogroup identified** (detailing the information on the specific serogroup)
   - No → to be reported as:
     - **VTEC, non-O157** or
     - **VTEC non O157, O26, O111, O103, O145** if the typing attempt included not only O157 but also the serogroups O26, O111, O103, O145

Please consider the following **REMARKS**

- Double reporting is no longer required/allowed for VTEC. Please note that the results should be reported only once.
- Since the list of values for Zoonosis L3 would now be exhaustive, missing values should not be reported for records with 'Total Units Positive' > 0.
- The *VTEC, NT (Non Typeable*) value should not be accepted. This information strongly depends on the panel of serotyping reagents available in the laboratories. As a result, the information provided by the MSs with this value is not homogeneous and cannot be analysed, because its merging would be meaningless.

Reporting countries are strongly encouraged to submit information on the presence of virulence genes in the VTEC strains using the Zoonosis level 4 term.

Diagnostic/analytical methods typically used

The standard methods ISO/TS 13136:2012 (ISO, 2012), ISO 16654:2001 (ISO, 2001) and NMKL 164:2005 (NMKL, 2005) are intended for testing food and feed, but have been adapted to test animal samples by many reporting countries. In addition, The OIE Manual for Diagnostic Tests and Vaccines for Terrestrial Animals (OIE, 2009a), Chapter 2.9.11, describes a screening method for VTEC O157 in animal faeces.

Two main categories of analytical methods are typically used:

a) Methods aiming at detecting any VTEC, regardless of the serotype. These methods are usually based on PCR screening of sample enrichment cultures and isolated colonies for the presence of *vtx* genes, followed by the characterisation of the isolated VTEC strains. This category includes the adaptation of the method ISO/TS 13136:2012 (ISO, 2012), other PCR-based methods, and also methods based on the detection of verocytotoxin production by immunoassays.

b) Methods designed to detect only VTEC O157, such as the adaptation of method ISO 16654:2001 (ISO, 2001) and the equivalent NMKL 164:2005 (NMKL, 2005). VTEC O157 is the serotype most commonly reported in the EU as a cause of both outbreaks and sporadic cases in humans and has also been identified as the major cause of HUS in children. The focus has therefore traditionally been on this serotype in many of the MS surveillance programmes.

Details should be provided on the diagnostic method used, including how verification of VTEC is carried out and the serotypes for which screening is carried out.

Specific guidelines for reporting data

- **Matrix—**the relevant animal species and category.
- **Sampling stage—**where the samples have been collected (e.g. 'farm', 'slaughterhouse') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'animal sample-faeces' or 'environmental sample-boot swabs');
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring') should be reported.
- **Sampler—**who performed the sampling should be reported here (e.g. 'official sampling' or 'industry sampling').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling', 'census', 'suspect sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'herd', 'holding', 'slaughter batch' or 'animal' should be used as the terms to be reported.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Total units tested—**the number of sampling units that are analysed in total, and for which results are available.
- **Total units positive—**the total number of sampling units positive for VTEC. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the total number of units tested positive for the VTEC serogroups (e.g. O157, O111, O26).
- **Analytical methods—**the diagnostic or analytical method used in testing of the sample should be reported here (e.g. ISO 16654:2001 or ISO/PRF TS 13136);

Please use the following available analytical methods to report on VTEC:

ISO 16654:2001 or NMKL 164:2005 or DIN 10167 or any alternative method validated against these methods, according to the ISO 16140[23]

- ISO/TS 13136:2012 (including the EU-RL adaptation for O104:H4) or any alternative method validated against this method, according to the ISO 16140[24]

[23] These methods are specific for VTEC O157.
[24] Real time PCR-based methods able to detect any VTEC by detection of *vtx* genes.

- In house real time PCR methods based on ISO/TS 13136:2012[24]
- Other methods based on PCR detection of *vtx* genes[24]
- DIN 10118:2004 or any alternative method validated against this method, according to the ISO 16140[25]
- Other methods based on the immunochemical detection of VT[25]
- Other methods. In this case, basic details on the method should be specified in the 'Comment' data element.

Please report the type of diagnostic method used in the analytical method data element, in order to facilitate the correct interpretation of the reported results.

5.6. *Coxiella burnetii* (Q fever) in animals

Relevant animal species to be reported on

- **Cattle**, **sheep** and **goats**, other mammals, birds, wildlife and arthropods. Reporting of information on animal production type (e.g. dairy cows, milk goats/sheep, meat production animals, calves) is recommended, if available.

Relevant agent species to be reported

C. burnetii.

Type of specimen taken

Coagulated blood, serum for serological method.

Aborted placenta, abortion materials, vaginal swabs, faeces, milk, when analysed by PCR.

Case definition/definition of a positive sample

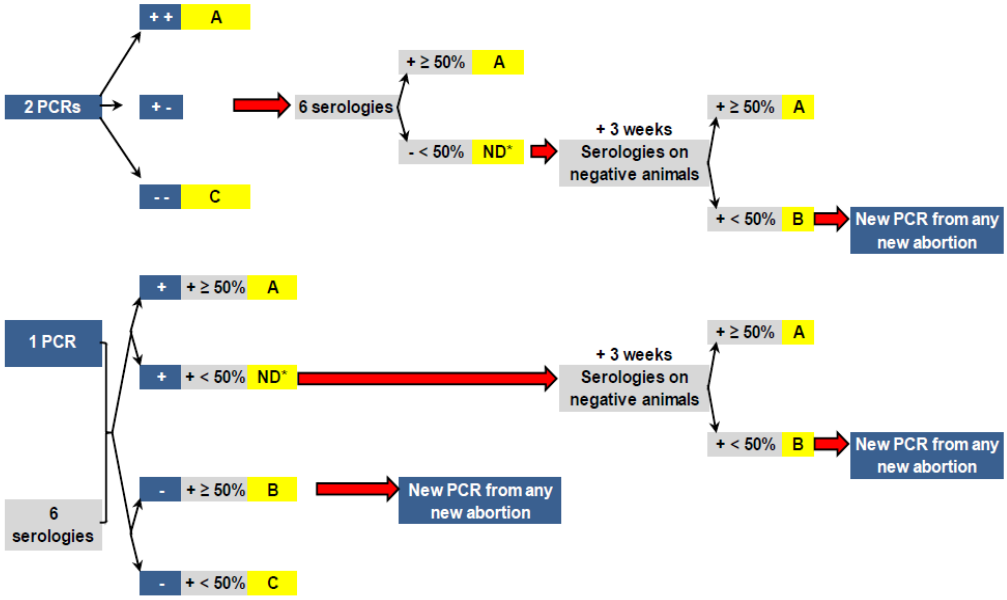
A positive case is an **animal**/**herd** that tested positive for *C. burnetii* on the test carried out by a serological test or PCR, in accordance with the OIE Manual of Diagnostic Test and Vaccines for Terrestrial Animals (OIE, 2009b) or by isolation of the agent, staining, or immunofluorescence assay test (IFA).

It is recommended to describe how a positive herd/flock is defined (e.g. at least one animal seropositive or at least one animal that tested positive in PCR or seropositive bulk milk sample or PCR positive milk sample, etc.).

A herd or flock should be considered to be **clinically affected**, based on the results of diagnostic tests, as reported below.[26]

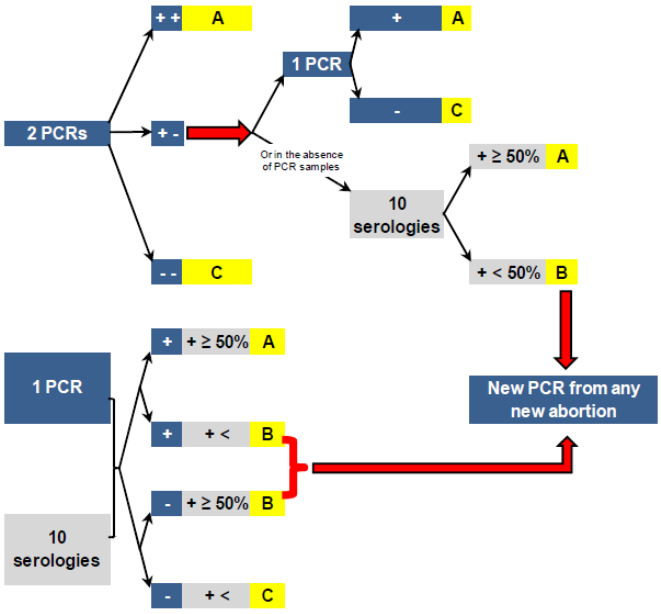
[25] ELISA-based methods able to detect any VTEC by detection of VT toxin.

[26] Scientific report submitted to EFSA. Development of harmonised schemes for the monitoring and reporting of Q fever in animals in the European Union. Available online: http://www.efsa.europa.eu/en/supporting/pub/48e.htm



ND: not determined.

Figure 1: Flow chart for laboratory diagnosis of Q fever in cattle herds. A: Situation A, the herd/flock is considered to be clinically affected. B: Situation B, Q fever cannot be excluded at the herd/flock level. C: Situation C, abortion is not related to *C. burnetii* at the herd/flock level



ND: not determined.

Figure 2: Flow chart for laboratory diagnosis of Q fever in small ruminant herds. A: Situation A, the herd/flock is considered to be clinically affected. B: Situation B, Q fever cannot be excluded at the herd/flock level. C: Situation C, abortion is not related to *C. burnetii* at the herd/flock level

Diagnostic/analytical methods typically used

Serological testing: ELISA or CFT in animals.

Isolation of the agent by cell culture or identification by PCR (conventional or real-time PCR), IFA, FISH or immunohistochemistry (ICH).

It is recommended that the type of test (serological or PCR) is always reported in order to ease the interpretation of the results.

Preventative measures in place

These measures can cover, for example, specific measures when introducing a new animal into a Q fever-free area, such as investigation of the flocks of origin, as well as births taking place in specific locations in infected flocks, disinfection of utensils used for delivery, and placentas and foetuses picked up and destroyed as soon as possible in order to prevent their ingestion by domestic or wild carnivores.

Reporting the results in the prevalence data model

Specific guidelines for reporting data

- **Matrix—**the relevant animal species and category.
- **Sampling stage—**where the samples have been collected (e.g. 'farm', 'slaughterhouse') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'animal sample-blood' or 'animal sample-mucosal swab-placental swab').
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring') should be reported.
- **Sampler—**who performed the sampling (e.g. 'official sampling' or 'industry sampling').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling', 'census', 'suspect sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'herd', 'holdings', or 'slaughter batch' or 'animal' should be used as the terms to be reported.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Number of clinically affected herds—**the number of herds clinically affected based on the case definition should be reported.
- **Total units tested—**the number of sampling units that are analysed in total, and for which results are available.
- **Total units positive—**the total number of sampling units considered positives for *Coxiella* based on the analytical results is reported. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of units tested positive for *C. burnetii*.
- **Analytical methods—**the diagnostic or analytical method used in testing of the sample must be reported here (e.g. PCR or IFA or FISH).

In order to facilitate the correct interpretation of the results reported it is mandatory to report the type of diagnostic method used (e.g. serology, PCR, direct isolation) in the analytical method data element.

5.7. *Trichinella* spp. in animals

Relevant animal species to be reported on

- **Breeding sows**, **boars** and **fattening pigs, horses**, carnivorous game animals, e.g. **farmed and wild boar**, **bears**, **foxes**, **raccoon dogs**, lynxes, rats, badgers, wolves and stone martens.

Relevant agent species to be reported

Trichinella spiralis (*T. spiralis*) and other zoonotic species, such as *Trichinella britovi* (*T. britovi*), *Trichinella nativa* (*T. nativa*) and *Trichinella pseudospiralis* (*T. pseudospiralis*). *T. nativa* is a cold-resistant species and circulates only among carnivores living in cold regions (in Arctic and sub-Arctic regions of some northern European countries). All the other *Trichinella* species detected in animals or meat derived products imported from outside the European countries.

Description of the monitoring and control system

The following information would be useful:

- information on the use of *Trichinella* testing relating to meat inspection, specifically whether or not all slaughtered pigs and horses are investigated;
- monitoring and surveillance schemes or programmes in farmed and wild boar, horses, breeding pigs (sows and boars) and fattening pigs and other indicator animals, especially in wildlife, e.g. foxes, raccoon dogs;
- **information on whether pigs (breeding (sows, boars) and fattening) are raised under controlled housing conditions or have outdoor access or are raised organically.**

In the text forms, the information on monitoring and control systems in place is asked for the following different categories:

- general;
- *Trichinella*-free holdings;
- officially recognised holdings/compartment applying controlled housing conditions;

In case that the categories 'free holdings' and/or 'officially recognised holdings/compartment applying controlled housing conditions' are not available or do not apply for the MS the category 'general' should be used.

Reporting on the status as officially free

According to Commission Regulation 215/1375[27]and Commission Regulation (EC) No 218/2014[28], there are currently provisions for approval of holdings officially recognised free. Information on this status is useful.

Type of specimen taken

Diaphragm muscles or tongue are typically taken during meat inspection.

Methods of sampling/frequency of sampling/location of sampling

Detailed sampling methods and procedures used during meat inspection at slaughterhouse level are laid down in Commission Regulation (EC) 2015/1375 with the amendments.

[27] Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for *Trichinella* in meat OJ L 212, 11.8.2015, p. 7–34.

[28] Commission Regulation (EU) No 218/2014 of 7 March 2014 amending Annexes to Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council and Commission Regulation (EC) No 2074/2005. OJ L 69, 8.3.2014, p. 95–98.

Case definition/definition of a positive sample (animal)

- **Positive animal—**animal in which *Trichinella* sp. larvae have been detected.

Diagnostic/analytical methods typically used

Methods for detection of *Trichinella* in fresh meat are specified in Commission Regulation (EC) 2015/1375:

- magnetic stirrer method for pooled sample digestion;
- equivalent methods to pooled sample digestion methods:
  - mechanically assisted pooled sample digestion method/sedimentation technique;
  - mechanically assisted pooled sample digestion method/on filter isolation technique;
  - automatic digestion method for pooled samples of up to 35 g.
  - Magnetic stirrer method for pooled sample digestion/on filter isolation and larva detection by a latex agglutination test (only equivalent for testing meat of domestic swine).
  - Artificial digestion test for *in vivo* detection of T*richinella* spp. larvae in meat samples, PrioCheck *Trichinella* AAD Kit (only equivalent for testing meat of domestic swine).
- trichinoscopic examination: this method is considered not suitable anymore according Regulation 2015/1375.

For horses and animal species other than pigs the prescribed method is the digestive method (as it is described in the Annex III of Commission Regulation (EC) 2015/1375). The method used should be described in detail (e.g. sample size and type of sample used).

Preventative measures in place

Typical preventative measures include controlled housing conditions in pig farms, effective waste and garbage management, pest control and education and training for farmers and the public.

Analyses of the results

In the analyses of results, it is preferable to address:

- the results of meat inspection for *Trichinella* spp.;
- the results of other monitoring and control programmes, especially in indicator animals and wild animals.

Regarding the positive cases in slaughtered animals, the following information is requested:

- a description of positive cases and of the *Trichinella* species identified, as well as the age of the affected animals;
- the type of management system they originated from;
- the diagnostic method used;
- the degree of infestation with the name of the tested muscle;
- outdoor access during the animals' lifetime;
- feeding practices;
- any other relevant information.

If possible, the results should be reported under the following categories:

- fattening pigs raised under recognised controlled housing conditions;
- fattening pigs not raised under recognised controlled housing conditions;
- fattening pigs raised under organic farming conditions;

- backyard and free-range pigs;
- wildlife (farmed and wild)—generally, it is recommended that information about the farmed or wild status of animal species be reported in the case of animal species that can have either status;
- breeding sows and boars raised under recognised controlled housing conditions;
- breeding sows and boars not raised under recognised controlled housing conditions;

Reporting the results in the prevalence data model

In accordance with the reporting requirements in Regulation (EU) No 216/2014, the following information has to be reported:

- The number of tests and the results of testing for *Trichinella* in domestic swine, wild boar, horses, game and any other susceptible animals shall be submitted in accordance with Annex IV of Directive 2003/99/EC. Data on domestic swine shall, at least, provide specific information related to:
  - tests on animals raised under controlled housing conditions;
  - tests on breeding sows, boars and fattening pigs.

The information whether or not the pigs tested were raised under officially approved controlled housing conditions shall be reported. Furthermore, information on fattening or breeding sows and boars shall be reported. These options are available in the animal species catalogue ZOO_CAT_MATRIX.

Specific guidelines for reporting data

- **Matrix—**the relevant animal species and category.
- **Sampling stage—**where the samples have been collected (e.g. 'slaughterhouse') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**use 'animal samples—organ/tissue'.
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring') should be reported.
- **Sampler—**use 'official sampling'.
- **Sampling strategy—**use 'census'.
- **Sampling details—**free text to be used for further information on samples.
- **Area of sampling—**information on the region from which the data originate is **strongly recommended** to be reported; the NUTS standards are made available in the specific catalogue.

  NUTS is a geographical nomenclature subdividing the territory of the EU into regions at three different levels (NUTS 1, 2 and 3, respectively, moving from larger to smaller territorial units).MSs are asked to report data at the lowest level of granularity available, following the rule that the **total units tested**, **total units positive** and **units positive** for the selected NUTS level should be reported. Examples of regional reporting can be found in Appendix H.

  Depending on the available data the following scenarios of reporting are possible:

  - If only country-level data are available, select the NUTS level corresponding to the whole country and report the total at national level.
  - If data are available at both country level and from all regions, select the NUTS level corresponding to the whole country and report the total at national level, and then report the data for each region.

– If data are available at country level and **only partially** at regional level, select the NUTS level corresponding to the whole country and report the total at national level, and then report data for which you have data.

In case that MSs have data at a finer level of detail (province/city level), report also the data available at the requested NUTS level.

Please refer to Appendix H for practical examples on regional reporting.

- **Sampling unit—**the sampling unit is typically 'Animal'.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Total units tested—**the number of sampling units that are analysed in total, and for which results are available.
- **Total units positive—**the total number of sampling units considered positives *Trichinella* based on the analyses results. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of units tested positive for the *Trichinella* species (e.g. *Trichinella spiralis, Trichinella britovi*).

In the case of positive *Trichinella* findings in pigs (breeding, fattening), please indicate whether or not the pig originated from a holding (farm) having approved controlled housing conditions.

5.8. *Echinococcus* spp. in animals

For the purpose of following trends the information to be reported each year or at regular intervals (e.g. every two or three years) is:

—*Echinococcus multilocularis* (*E. multilocularis*) in red foxes.

Other relevant animal species to be reported on

For ***Echinococcus granulosus*** **(*E. granulosus*)—sheep**, **goats**, **cattle**, **pigs** and horses, and other animal species, such as camels, reindeer, deer, moose and wild boar.

For ***E. multilocularis*****—definitive hosts**: **foxes**, dogs, cats and other wild animal species, such as **raccoon dogs**; **intermediate hosts**: voles, musk rats and other rodents.

The distribution of *Echinococcus* in animal species varies between European countries.

Relevant agent species to be reported

E. granulosus and ***E. multilocularis***. The relevant *Echinococcus* species should be reported, whenever possible, in order to facilitate analyses of the data. Reporting of the zoonotic strains/(sub)species most prevalent in Europe (G1, G3, G5) is also encouraged.

Description of the monitoring and control system

- Monitoring schemes/surveillance strategies separately in domestic and stray dogs and food-producing animals for *E. granulosus*.
- Monitoring schemes/surveillance strategies in wildlife, especially in foxes and raccoon dogs for *E. multilocularis*.
- Monitoring policy at slaughterhouse level for *E. granulosus* (meat inspection based on national and EU legal requirements) for intermediate hosts. It is extremely important to group the investigated animals per species and age category (e.g. <1 year; >1 year)
- Differentiation of the regions according to the status (endemic, emerging, free) for both *E. granulosus* and *E. multilocularis*, if available.

Type of specimen taken

For *E. granulosus*: typically the hydatid cysts from viscera of intermediate hosts.

For *E. multilocularis*: faeces or intestine from definitive hosts.

Case definition/definition of a positive sample

- ***E. multilocularis positive animal*—**animal with a positive test result for eggs in feces or adult worms in the gut
- ***E. granulosus positive animal*—**animal in which *E. granulosus* cysts have been detected. Important additional information is the cyst fertility.

Diagnostic/analytical methods typically used

For *E. granulosus*: post-mortem visual examination of intermediate hosts, in the context of meat inspection procedures established in Regulations (EC) No 854/2004[29] (including the last amendments laid down in Regulation (EU) No 218/2014), No 2074/2005[30] and No 2076/2005[31] and the diagnostic method for the identification of the species/subspecies.

For *E. multilocularis*: faecal examination and post-mortem intestine analysis for definitive hosts and the diagnostic method for the identification of the species/subspecies.

Preventative measures in place

These measures may include anti-parasitic treatments in pets (dogs) and wildlife, meat inspection procedures at slaughterhouses, good management practices when handling intestines and organs of infected animals (in order to avoid consumption by dogs or cats), recommendations to consumers and food handlers (especially for berries and mushrooms) and effective management of stray dogs.

Analyses of the results

Information to be reported should include, if available, the analyses of results from meat inspection, dogs and wildlife for *E. granulosus* and *E. multilocularis* separately.

Reporting the results in the prevalence data model

Specific guidelines for reporting data

- **Matrix—**the relevant animal species and category.
- **Sampling stage—**where the samples have been collected (e.g. 'slaughterhouse') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**use 'animal samples-faeces' or 'animal samples-organ/tissue'.
- **Sampling context—**information on the context of the sampling (e.g. 'surveillance') should be reported.
- **Sampler—**use 'official sampling'.
- **Sampling strategy—**use: 'suspect sampling', 'objective sampling' or 'census sampling'.

[29] Commission Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. OJ L 139, 30.4.2004, p. 206–320.

[30] Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004. OJ L 338, 22/12/2005, p. 27–59.

[31] Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004. OJ L 338, 22/12/2005, p. 83–88.

- **Sampling details—**free text to be used for further information on samples.
- **Area of sampling—**information on the region from which the data originate strongly recommended to be reported; the NUTS standards are made available in the specific catalogue.

  NUTS is a geographical nomenclature subdividing the territory of the EU into regions at three different levels (NUTS 1, 2 and 3, respectively, moving from larger to smaller territorial units).MSs are asked to report data at the lowest level of granularity available, following the rule that the **total units tested**, **total units positive** and **units positive** for the selected NUTS level (where animal was raised) should be reported. Examples of regional reporting can be found in Appendix H.

  Depending on the available data the following scenarios of reporting are possible:

  – If only country-level data are available, select the NUTS level corresponding to the whole country and report the total at national level.

  – If data are available at both country level and from all regions, select the NUTS level corresponding to the whole country and report the total at national level, and then report the data for each region.

  – If data are available at country level and **only partially** at regional level, select the NUTS level corresponding to the whole country and report the total at national level, and then report data for which you have data.

  In case that MSs have data at a finer level of detail (province/city level), report also the data available at the requested NUTS level.

  Please refer to Appendix H for practical examples on regional reporting.
- **Sampling unit—**use 'animal'.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Total units tested—**the number of sampling units that are analysed in total and for which results are available**.**
- **Total units positive—**the total number of sampling units considered positive for *Echinococcus*, based on the results reported. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the total number of units tested positive for the *Echinococcus* species (e.g. *Echinococcus multilocularis* and *Echinococcus granulosus*).

5.9. *Toxoplasma* spp. in animals

Relevant animal species to be reported on

- **Sheep**, **goats**, **pigs** (pigs from organic and free-range farms) and **cats**.

Relevant agent species to be reported

Toxoplasma gondii (*T. gondii*).

Description of the monitoring and control system

It is relevant for domestic cats, sheep, goats and pigs.

Type of specimen taken

Typically, blood (intermediate hosts) is tested by serology. Other samples could include abortion material (e.g. sheep) or feaces (e.g. cats)..

Case definition/definition of a positive sample

- **Positive animal—**animal with a positive test result for *Toxoplasma*.

Diagnostic/analytical methods typically used

Serological methods (describe or include reference): ELISA. If other methods are used, they should be specified. Other methods are MAT, LAT, immunoblotting (IB) and immunofluorescence antibody test (IFAT).

Preventative methods in place

These measures can typically include vaccination policy (e.g. in sheep) and specific recommendations/guidelines given to pregnant women.

Reporting the results in the prevalence data model

Specific guidelines for reporting data

- **Matrix—**the relevant animal species and category.
- **Sampling stage—**where the samples have been collected (e.g. 'farm') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'animal sample—blood').
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring' or 'clinical investigations') should be reported.
- **Sampler—**who performed the sampling (e.g. 'official sampling').
- **Sampling strategy—**the type of sampling (e.g. 'objective sampling', 'suspect sampling').
- **Sampling details—**free text to be used for further information on samples. The animal age is an important parameter to report. For pigs it is important to mention the type of farming.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Sampling unit—**use 'herd', 'holding', 'slaughter batch' or 'animal'.
- **Analytical methods—**the diagnostic or analytical method used in testing of the sample should be reported here (e.g. ELISA, MAT or LAT).
- **Total units tested—**the number of sampling units that are analysed in total, and for which results are available.
- **Total units positive—**the total number of sampling units considered positive for the *Toxoplasma* based on the results reported. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of units tested positive for the *Toxoplasma* species (e.g. *T. gondii*). A clear indication should be made in order to differentiate clinical investigations from those resulting from monitoring or surveillance. In order to facilitate the analysis of the reported results, the type of diagnostic method used is mandatory to be reported in the analytical method data element, e.g. serology (ELISA, MAT, etc.) or direct methods (PCR).

5.10. *Cysticercus* in animals

Relevant animal species to be reported on

- **Cattle**, **pigs** and wild boar.

For cattle, data should be reported separately for the different types of animals (dairy cows, meat production animals or calves), if available.

Relevant agent species to be reported

- Cysticerci of *Taenia saginata* (*T. saginata*) (metacestode stage of the human tapeworm *T. saginata*, called *Cysticercus bovis* in cattle).
- Cysticerci of *Taenia solium* (*T. solium*) (metacestode stage of the human tapeworm *T. solium*, called *Cysticercus cellulosae* in pigs).

Type of specimen taken

Typically, the masseter muscle, tongue and heart are incised and examined and the intercostal muscles and diaphragm inspected. The triceps muscle is also incised in many countries.

Case definition/definition of a positive sample

- **Positive animal—**animal in which cysticerci have been detected.

Diagnostic/analytical methods typically used

By visual inspection, in the context of meat inspection procedures established in Regulation (EC) No 854/2004, including the last amendments laid down in Regulation (EU) No 218/2014. Microscopic examination is also used for diagnosis/confirmatory purposes. Confirmatory testing is done by PCR.

It is recommended that the diagnostic method used is always reported or that reference is made to visual post-mortem inspection.

Preventative measures in place

For control of cysticercosis, these measures typically include a high standard of human sanitation, following the good general practice of cooking meat thoroughly (the thermal point of death of cysticerci is 57°C) and compulsory meat inspection.

Analyses of the results

In the analyses of results, it is preferable to address:

- the results of meat inspection for the presence of cysticerci;
- an estimation of level of infection and whether or not the carcase is condemned.

Reporting the results in the tables in the prevalence data model

Specific guidelines for reporting data

- **Matrix—**the relevant animal species and category.
- **Sampling stage—**where the samples have been collected (e.g. 'slaughterhouse') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**use 'animal sample-organ/tissue'.
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring') should be reported.
- **Sampler—**use 'official sampling'.

- **Sampling strategy—**use 'census'.
- **Sampling details—**free text to be used for further information on samples. For pigs it is important to mention the type of farming.
- **Sampling unit—**the sampling unit is typically 'animal'.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the 'comment' data element.
- **Total units tested—**the number of sampling units that are analysed in total, and for which results are available.
- **Total units positive—**the total number of sampling units considered positive for the *Taenia* based on the analyses results reported. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the total number of units tested positive for the *Taenia* species (e.g. *Taenia saginata, Taenia solium.*

It is important to report species information on cysticercus (e.g. *T. solium* in pigs, *T. saginata* in bovine) to facilitate the analyses of the data.

5.11. Rabies in animals

Relevant animal species to be reported on

All domestic animal species, including pets and farm animals and wildlife animals, especially **dogs** and **cats**, including stray dogs and stray cats. Typically, the domestic farm animals to be reported on are species kept in free-range production systems, such as sheep, goats or bovine animals. Wildlife species are **foxes**, raccoon dogs, wolves and badgers. **Bats** that are known to harbour bat-type *Lyssavirus* should also be reported on.

Relevant agent species to be reported

Information on the *Lyssavirus* species is of particular interest. It is recommended that, whenever possible, the differentiation between European bat *Lyssavirus* (EBLV-1 or EBLV-2) and rabies virus (RABV) is made. If no information is available on the virus species, '*Lyssavirus* (unspecified virus)' should be used for reporting data.

Description of the monitoring and control system

It is recommended that national control strategy and vaccination programmes be reported.

Reporting on the status as free

A country may be recognised as 'free from rabies' by the OIE or by the World Health Organization (WHO), in accordance with their specific criteria. There are no officially free regions or MSs according to EU legislation.

A country may be considered free from rabies in accordance with the OIE *Terrestrial Animal Health Code* conditions, when:

- the disease is notifiable;
- an effective system of disease surveillance is in operation;
- all regulatory measures for the prevention and control of rabies have been implemented, including effective importation procedures;
- no case of indigenously acquired rabies infection has been confirmed in man or in any animal species during the past two years (however, this status will not be affected by the isolation of EBLV-1 or EBLV-2);

- no imported cases in carnivores have been confirmed outside a quarantine station for the past 6 months.

Note that, for WHO, detection of EBLV-1 or EBLV-2 will prevent countries from being considered free from rabies.

Case definition

A case is any animal infected with the rabies virus species (OIE, 2013a).

Diagnostic methods typically used

The only way to undertake a reliable diagnosis of rabies is to identify the virus or some of its specific components using laboratory tests (OIE, 2013b).

Agent identification is preferably done using the fluorescent antibody test (FAT). For a large number of samples, the immunoenzyme technique can provide rapid results; however, at present, such a test is not commercially available. As a single negative test on fresh material does not rule out the possibility of infection, inoculation tests (performed on neuroblastoma cells or upon intracranial inoculation of mice) should be carried out simultaneously.

The identification of the agent can be supplemented in specialised laboratories by identifying any variant virus strains through the use of monoclonal antibodies, specific nucleic acid probes or PCR followed by DNA sequencing of genomic areas. Typing of rabies virus isolates should be performed for any isolated cases of rabies and in cases in which attenuated oral rabies vaccines are used.

Analyses of the results

In the analyses of results, it is preferable to address:

- The number of confirmed rabies cases in animals and the sources of infection. The number of investigated animals should be recorded as well as the species tested.
- The results and effectiveness of the vaccination programmes in domestic and wildlife animals.
- A clear distinction between sylvatic and bat rabies cases when describing rabies in wildlife.
- *Lyssavirus* type and subtypes, and distinction of virus isolates from terrestrial animal species (rabies virus) from those circulating in European bats (EBLV-1 or EBLV-2).

Reporting the results in prevalence data model

Specific guidelines for reporting data

- **Matrix—**the relevant animal species and category.
- **Sampling stage—**where the samples have been collected (e.g. 'farm') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'animal sample—brain 'animal sample—organ/tissue').
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring') should be reported.
- **Sampler—**who performed the sampling should be reported here (e.g. 'official sampling').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling', 'suspect sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Area of sampling—**information on the region from which the data originate must be reported; the NUTS standards are made available in the specific catalogue.

- MSs are asked to report data at the lowest level of granularity available, following the rule that the **total units tested**, **total units positive** and **units positive** for the selected NUTS level should be reported.

  Depending on the available data the following scenarios of reporting are possible:

  - If only country-level data are available, select the NUTS level corresponding to the whole country and report the total at national level.
  - If data are available at both country level and from all regions, select the NUTS level corresponding to the whole country and report the total at national level, and then report data for each region.
  - If data are available at country level and **only partially** at regional level, select the NUTS level corresponding to the whole country and report the total at national level, and then report data for each region for which you have data.

  In case that MSs have data at a finer level of detail (province/city level), report also the data available the requested NUTS level.

  Please refer to Appendix H for practical examples on regional reporting.
- **Sampling unit—**in rabies, this is typically 'animal'.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Total units tested—**the number of sampling units that are analysed in total and for which results are available.
- **Total units positive—** the total number of animals found positive for rabies should be reported. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the total number of units considered positive for the Rabies virus positive for the Rabies virus species (e.g. EBLV-1, EBLV-2).

It is highly recommended that for positive samples the species is clearly identified (e.g. RABV, or EBLV-1 or EBLV2).

5.12. West Nile virus in animals

Relevant animal species to be reported on

- **Equids, wild birds*** (including synanthropic birds), and **domestic birds** (including poultry and birds other than poultry).

*Wild birds such as corvids, crows, jays, magpies, pigeons, doves, *Passeriformes* and *Passeriformes* other than corvids.

Relevant agent species to be reported

West Nile virus (WNV).

Description of the monitoring and control system

It is relevant to define whether the data derive from active or passive monitoring (including clinical investigations).

Type of specimen taken

- **Equids**: blood serum (used for indirect diagnosis).
- **Wild birds**: blood serum (used for indirect diagnosis), quills and feathers, whole blood, pool of organs (kidney, spleen, brain, heart) (used for direct diagnosis).

Definition of a positive sample

- **Positive animal**: animal with a positive test result for WNV.

In the context of this reporting, the definition of positive animal does not take into account the occurrence of clinical signs.[32]

The use of equine WNV vaccine may decrease the incidence of WNV disease, but influences also results in serological assays used for WNV. For this reason, information on whether or not the horses were vaccinated is recommended for the correct interpretation of positive test results.

Diagnostic methods typically used

- **Horses:**

  Serology: ELISA test based on detection of IgM (recommended method to detect acute infection), ELISA test based on IgG detection.

  Confirmatory sero-neutralisation (sero-neutralisation tests allow discrimination between infections by different flaviviruses; information on the use of these confirmatory tests is to be provided, when available, in addition to the serological test).

Data from reverse transcription PCR (RT-PCR) on blood can also be reported, where available. It is, however, to be noted that equine tissues generally contain lower concentrations of the virus than birds, and the duration of viraemia is very short.

- **Wild birds:**

  RT-PCR, ELISA tests (same consideration as above for horses);

  confirmatory sero-neutralisation.

Reporting the results in the prevalence data model

- **Specific guidelines for data reporting Matrix—**the relevant animal species and category.
- **Sampling stage—**where the samples have been collected (e.g. 'farm', 'slaughterhouse') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'animal sample-blood').
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring- active').
- **Sampler—**who performed the sampling (e.g. 'official sampling').
- **Sampling strategy—**the type of sampling (e.g. 'objective sampling', 'suspect sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Area of sampling—**information on the region from which the data originate must be reported; the NUTS standards are made available in the specific catalogue.

  NUTS is a geographical nomenclature subdividing the territory of the EU into regions at three different levels (NUTS 1, 2 and 3, respectively, moving from larger to smaller territorial units).

  MSs are asked to report data at the lowest level of granularity available, following the rule that the **total units tested**, **total units positive** and **units positive** for the selected NUTS level should be reported.

  Depending on the available data the following scenarios of reporting are possible:

  – If only country-level data are available, select the NUTS level corresponding to the whole country and report the total at national level.

[32] Refer to Chapter 8.16 of the OIE *Terrestrial Animal Health Code* (Volume II) for the detailed criteria that define the occurrence of West Nile fever (OIE, 2009b).

  - If data are available at both country level and from all regions, select the NUTS level corresponding to the whole country and report the total at national level, and then report the data for each region.
  - If data are available at country level and **only partially** at regional level, select the NUTS level corresponding to the whole country and report the total at national level, and then report data for which you have data.

  In case that MSs have data at a finer level of detail (province/city level), report also the data available at the requested NUTS level.

- **Sampling unit—**use 'herd', 'holding', 'slaughter batch' or 'animal'.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Analytical methods—**the diagnostic or analytical method used in testing of the sample should be reported here.
- **Vaccination status—**use 'yes', 'no', 'unknown'.
- **Total units tested—**the number of sampling units that are analysed in total and for which results are available.
- **Total units positive—**the total number of sampling units considered infected with WNV, based on the results of the analyses, should be reported. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of units tested positive for the West Nile virus.

Further details on the proposal for data collection on vector-borne zoonoses in animals can be found in the external scientific report by Mannelli et al. (2012).[33]

6. Reporting on zoonotic agents in foodstuffs

6.1. General recommendations

Typical information to be reported on zoonotic agents in foodstuffs includes:

Description of the monitoring and control system

It is highly recommended to describe the sampling strategy in terms of:

- The place or stage where the sample was taken, where available, e.g. farm, slaughterhouse, processing plant, retail, border inspection post. For *Salmonella*, *Campylobacter*, *Yersinia* and VTEC it is highly recommended to report data derived from the slaughterhouse, as a minimum. For all zoonotic agents in foodstuffs, data derived from the retail level are also recommended.
- The control, surveillance and monitoring programmes in place.
- Who performs the sampling (competent authority (official sampling) or industry (own checks)).
- The sampling strategy, i.e. objective, census, selective, convenience or suspect sampling or unspecified.

Type of specimen taken

A description of the specimen taken that further elaborates on the description provided in the reporting tables should be provided, e.g. surface of carcase/fresh meat, meat juice or surface of eggshell.

[33] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/234e.pdf

Diagnostic/analytical methods typically used

Reference methods standardised by the European Committee for Standardization (CEN) and/or ISO or the Nordic Committee on Food Analysis (NMKL) are often available. Where other methods are used, the performance characteristics of the methods should be given in comparison with the EN/ISO or ISO standard reference methods or other reference methods. Modifications to standard methods should be detailed and evidence of validation against the standard method or against other reference methods should be given.

Preventative and control measures in place

National microbiological criteria or guidelines for foodstuffs should be described, as well as provisions or recommendations concerning the use of certain foodstuffs containing potentially hazardous agents, such as raw eggs, unpasteurised milk, etc., or special recommendations for susceptible populations of consumers.

Note that, even though data reported in the context of own checks or HACCP activities are useful, they are not currently analysed for the purpose of the EU Summary Report, as the associated sampling strategy is considered to be targeted, process related and, thus, open to subjective interpretation.

In the following chapters the food categories specifically recommended to be reported are highlighted by **bold text.**

6.2. *Salmonella* spp. in foodstuffs

For the purpose of following trends the information to be reported each year or at regular intervals (e.g. every two or three years) is:

—*Salmonella* spp. in fresh broiler meat;

—*Salmonella* spp. in fresh pig meat.

It is recommended that this information is provided at the retail level.

Other relevant food categories to be reported

- **Meat and products thereof—**information should be provided on the animal species from which the meat is derived and the nature of the meat, e.g. carcase, **fresh meat**, **minced meat**, **meat preparations**, meat products. The reporting of data on **bovine meat, pig meat**, **broiler meat** and **turkey meat** is recommended. More detailed information on the status of the meat at the point of sampling (e.g. frozen, cooked) and how it is intended to be consumed (e.g. intended to be eaten raw, intended to be eaten cooked) should be provided where relevant and available.
- **Milk and dairy products—**information should be provided on the nature of the food, e.g. milk, cheese or other dairy products. For milk and cheese, it is useful to report the animal species from which the food is derived, e.g. cow, sheep, goat. More detailed information on **milk** (e.g. pasteurised or **raw**/low heat-treated milk), on **cheese** (e.g. hard or soft and semi-soft cheese) and on other dairy products (e.g. **made from** pasteurised or **raw/low heat-treated milk**) should be provided where available.
- **Egg and egg products—**information should be provided on the nature of the food, i.e. eggs or egg products. More detailed information on eggs (e.g. table eggs or liquid egg to be used for egg products) and on egg products (e.g. liquid, dried, pasteurised, frozen) should be provided where available.
- **Fish and fishery products, live bivalve molluscs, frogs' legs and snails—**information should be provided on the nature of the food, e.g. crustaceans, molluscan shellfish, live bivalve molluscs, other fish and frog's legs. More detailed information on the specific type of food (e.g. shrimps, lobsters, oysters) and the status of the food at the point of sampling (e.g. raw, cooked, smoked and frozen) should be provided where relevant and available.

- **Fruit and vegetables—**information should be provided on the nature of the food (e.g. fruit, vegetables, sprouted seeds, salad) and the status of the food at the point of sampling (e.g. pre-cut/non-pre-cut fruit and vegetables, ready-to-eat/non-ready-to-eat sprouted seeds).
- **Juices—**information should be provided on the nature of the food (e.g. fruit or vegetable juice) and the status of the food at the point of sampling (e.g. pasteurised/non-pasteurised).
- **Other foods—**e.g. ready-to-eat foods containing raw egg, infant formulae, formulae for special medical purposes and follow-on formulae.

Of particular interest are the food categories for which harmonised food safety criteria are set in Regulation (EC) No 2073/2005, Regulation (EC) No 1441/2007, Regulation (EU) No 1086/201, Commission Regulation (EU) No 209/2013 and Commission Regulation (EU) No 217/2014.

For compliance with the new criteria laid down in Regulation (EU) No 1086/2011, the following information has to be reported: *S*. Typhimurium, monophasic *S*. Typhimurium only 1,4,[5],12:i:-[22] and *S*. Enteritidis in **fresh poultry meat** (fresh meat from breeding flocks of *Gallus gallus*, laying hens, broilers and breeding and fattening flocks of turkeys).

Based on the requirements laid down in Commission Regulation (EU) No 218/2014, MSs are requested to report the total number and the number of *Salmonella*-positive samples, differentiating between samples taken under the points listed below, when applied, in order to verify the correct implementation by food business operators of the process hygiene criterion for *Salmonella* on pig carcases:

- Official sampling using the same method and sampling area as food business operators. At least 49[34] random samples shall be taken in each slaughterhouse each year. This number of samples may be reduced in small slaughterhouses based on a risk evaluation. These samples should be reported by completing the following information: sampler, 'Official, based on Regulation 218/2014', and sampling context, 'Control and eradication programmes'.
- Collecting all information on the total number and the number of *Salmonella*-positive samples taken by food business operators in accordance with Article 5(5) of Regulation (EC) No 2073/2005, within the frame of point 2.1.4 of Annex I thereof. These samples should be reported by completing the following information: sampler, 'HACCP and own checks', and sampling context, 'Control and eradication programmes'.
- Collecting all information on the total number and the number of *Salmonella*-positive samples taken within the frame of national control programmes in MSs or regions of MSs for which special guarantees have been approved in accordance with Article 8 of Regulation (EC) No 853/2004 as regards pork production. These samples should be reported by completing the following information: sampler, 'Official', and sampling context, 'Control and eradication programmes'.

Relevant agent species/serovars/phagetypes to be reported

Salmonella serovars and where available phagetypes in foodstuffs should be reported..

Case definition/definition of a positive sample

- ***Salmonella*-positive sample—**a sample in which *Salmonella* spp. have been isolated.
- ***Salmonella*-positive batch—**a batch in which *Salmonella* spp. have been isolated from at least one single sample taken out of the batch.

Diagnostic/analytical methods typically used

The recommended method is ISO 6579:2002 (ISO, 2002), in accordance with Regulations (EC) No 2073/2005, No 1441/2007, No 1086/2011, No 209/2013 and No 217/2014 on microbiological criteria for foodstuffs.

Reporting the results in the prevalence data model

[34] If all negative, 95% statistical certainty is provided that the prevalence is below 6%.

Specific guidelines for reporting data

- **Matrix—**the relevant food category and subcategory.
- **Sampling stage—**where the samples have been collected (e.g. 'processing plant', 'retail') should be reported.
- **Sample origin—**is used to report the country of origin of the food.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'food sample—meat').
- **Sampling context—**information on the context of the sampling (e.g. 'surveillance')reported.
- **Sampler—**who performed the sampling (e.g. 'official sampling' or 'HACCP and own checks').
- **Sampling strategy—**the type of sampling (e.g. 'objective sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'single' or 'batch' should be used as the terms to be reported.
- **Sample weight—**the weight or volume of the specimen used in the laboratory for analysis, e.g. 10, etc.; for carcase swabs the area sampled could be reported (e.g. 100).
- **Sample weight unit**—the unit of the indicated sample weight e.g. gram, millilitre, square centimetre.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Total units tested—**the number of sampling units that are analysed in total and for which results are available.
- **Total units positive—**the total number of units positive for *Salmonella* spp. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of units tested positive for a specific *Salmonella* serovar (e.g. *Salmonella* Typhimurium, *Salmonella* Infantis) or phagetype (e.g. *Salmonella* Enteritidis-PT 1).

Data on monophasic *S.* Typhimurium should be reported as follows: this group comprises *S.* Typhimurium strains lacking the second phase H antigen (1,4,[5],12:i:- [22]). Whenever feasible, as much detail as possible of the antigenic formula as determined by testing should be reported (e.g. 1,4,[5],12:i:- or 1,4,12:i:-). If the full antigenic formula is not available, but a phagetype that is consistent with *S.* Typhimurium lacking phase 2 flagellar antigen has been confirmed, and the lack of the second flagellar antigen has been verified by PCR, then it is recommended that the term 'monophasic *S.* Typhimurium' be used.

6.3. *Campylobacter* spp. in foodstuffs

For the purpose of following trends the information to be reported each year or at regular intervals (e.g. every two or three years) is:

—*Campylobacter* spp. in fresh broiler meat, preferably at slaughterhouse.

Other relevant food categories to be reported

- **Meat and products thereof—**information should be provided on the animal species from which the meat is derived and the nature of the meat, e.g. carcase, fresh meat, minced meat, meat products, meat preparations. The reporting of data on **broiler meat, turkey meat, bovine meat** and **pig meat** is recommended. More detailed information on the status of the meat at the point of sampling (e.g. frozen, cooked) and how it is intended to be consumed (e.g. intended to be eaten raw, intended to be eaten cooked) should be provided where available.

- **Milk and dairy products—**information should be provided on the nature of the food, i.e. milk, cheese or other dairy products. For milk and cheese, it is useful to report the animal species from which the food is derived, e.g. cow, sheep, goat. More detailed information on **milk** (e.g. pasteurised or **raw**/low heat**-**treated milk), on cheese (e.g. hard or soft and semi-soft cheese) and on other dairy products (e.g. made from pasteurised or raw/low heat-treated milk) should be provided where available.
- **Fish and fishery products, live bivalve molluscs, frogs' legs and snails—**information should be provided on the nature of the food, e.g. crustaceans, molluscan shellfish, **live bivalve molluscs**, other fish, frogs' legs. More detailed information on the specific type of food (e.g. shrimps, lobsters, oysters) and the status of the food at the point of sampling (e.g. raw, cooked, smoked, frozen) should be provided where available.
- **Other foods**, e.g. fresh fruit and vegetables—information should be provided on the status of the food at the point of sampling (e.g. pre-cut/non-pre-cut).

Relevant agent species to be reported

Thermotolerant *Campylobacter* spp. differentiation to species level is recommended and should be provided. The major agents of interest are *C. jejuni* and *C. coli*; however, *C. lari* and *C. upsaliensis* may also be reported.

Case definition/definition of a positive sample

- ***Campylobacter*-positive sample—**a sample in which thermotolerant *Campylobacter* spp. have been isolated.
- ***Campylobacter* positive batch—**a batch in which thermotolerant *Campylobacter* spp. have been isolated from at least one single sample taken out of the batch.

Diagnostic/analytical methods typically used

For detection and enumeration of *Campylobacter* the methods ISO 10272-1:2006 (ISO, 2006a), ISO/TS 10272-2:2006 (ISO, 2006b) and ISO/TS 10272-3:2010 (ISO, 2010) are used. Speciation of *Campylobacter* by the use of recognised DNA-based methods, i.e. validated and published PCR methods, is recommended. The method used shall be indicated. PCR is the preferred method for *Campylobacter* speciation, as phenotypical methods (e.g. detection of hippurate hydrolysis) have a certain risk of giving intermediate or incorrect test results.

Reporting the results in the prevalence data model

Specific guidelines for data reporting

- **Matrix—**the relevant food category and subcategory.
- **Sampling stage—**where the samples have been collected (e.g. 'processing plant', 'retail') should be reported.
- **Sample origin—**is used to report the country of origin of the food.
- **Sample type—**the sample category and sample type should be reported(e.g. 'food sample-meat').
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring') should be reported.
- **Sampler—**who performed the sampling should be reported here (e.g. 'official sampling' or 'HACCP and own checks').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'single' or 'batch' should be used as the terms to be reported.

- **Sample weight—**the weight or volume of the specimen used in the laboratory for analysis, e.g. 10, etc.; for carcase swabs the area sampled could be reported (e.g. 100).
- **Sample weight unit**—the unit of the indicated sample weight e.g. gram, millilitre, square centimetre.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Total units tested—**the number of sampling units that are analysed in total and for which results are available.
- **Total units positive —**the number of units positive for *Campylobacter* spp. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive**—the number of units tested positive for *Campylobacter* species (e.g. *C. coli, C. jejuni*).

6.4. *Listeria* spp. in foodstuffs

For the purpose of following trends the information to be reported each year or at regular intervals (e.g. every two or three years) is:

—*L. monocytogenes* in ready-to-eat foods (fishery products, meat products and cheeses). It is recommended that this information is provided at the retail level.

Other relevant food categories to be reported

- **Minced meat and meat preparations intended to be eaten raw—**information should be provided on the animal species from which the meat is derived, e.g. bovine animals, pigs, and on the nature of the meat, e.g. minced meat, meat preparation.
- **Ready-to-eat meat products—**and meat preparations—detailed information (e.g. frozen, pâté) should be provided where relevant and available.
- **Milk and dairy products—**information should be provided on the nature of the food, i.e. milk, cheese or other dairy product. For milk and cheese, it is useful to report the animal species from which the product is derived, e.g. cow, sheep, goat. More detailed information on milk (e.g. pasteurised or raw/low heat-treated milk), on cheese (e.g. hard or **soft and semi-soft cheese**) and on other dairy products (e.g. made from pasteurised or **raw/low heat-treated milk**) should be provided where available.
- **Ready-to-eat fishery products—**information on the nature of the product, e.g. crustaceans, molluscan shellfish, other fish. More detailed information (e.g. crab, hot and cold smoked, and dry-cured fish) should be provided where relevant and available.
- **Other ready-to-eat foods—**e.g. fruit and vegetables, infant formulae, formulae for special medicinal purposes and follow-on formulae. More detailed information on fruit and vegetables (e.g. pre-cut, non-pre-cut) should be provided where available.

Of particular interest are the food categories for which harmonised food safety criteria are set in Regulation (EC) No 2073/2005.

Relevant agent species to be reported

The information provided should concentrate on *L. monocytogenes*.

Absence/presence of *L. monocytogenes* as well as **quantitative** results obtained from the enumeration (≤ 100 or > 100 colony-forming units (cfu)/g) of *L. monocytogenes* should be reported, where available. It is strongly recommended to provide enumeration information for those food categories for which the criterion ≤ 100 cfu/g has been set.

Case definition/definition of a positive sample

- **Positive sample—**a sample is positive for *L. monocytogenes* where *L. monocytogenes* has been isolated from that sample. When using qualitative analysis, it is recommended that the weight of the sample tested be indicated. When using quantitative analysis, it is recommended that the limit of detection of the method used be indicated.
- **Positive batch—**a batch is positive for *L. monocytogenes* where *L. monocytogenes* has been isolated from at least one of the samples in the batch. When using qualitative analysis, it is recommended that the weight of the sample tested be indicated. When using quantitative analysis, it is recommended that the limit of detection of the method used be indicated.

Diagnostic/analytical methods typically used

The recommended methods are ISO 11290-1 for detecting *L. monocytogenes* (ISO, 1996) and ISO 11290-2 for enumeration of *L. monocytogenes* (ISO, 1998), in accordance with Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

Preventative and control measures in place

National guidelines for pregnant women or other susceptible population groups concerning the consumption of food with a high risk of contamination with *L. monocytogenes*.

Reporting the results in the prevalence data model

Specific guidelines for data reporting

- **Matrix—**the relevant food category and subcategory.
- **Sampling stage—**where the samples have been collected (e.g. 'processing plant', 'retail') should be reported.
- **Sample origin—**is used to report the country of origin of the food.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'food sample—meat').
- **Sampling context—**information on the context of the sampling (e.g. 'surveillance').
- **Sampler—**who performed the sampling should be reported here (e.g. 'official sampling' or 'HACCP and own checks').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'single' or 'batch' should be used.
- **Sample weight—**the weight or volume of the specimen used in the laboratory for analysis, e.g. 10, etc.; for carcase swabs the area sampled could be reported (e.g. 100).
- **Sample weight unit**—the unit of the indicated sample weight e.g. gram, millilitre, square centimetre.
- **Source of information** the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Analytical methods—**the diagnostic or analytical method used in testing of the sample must be reported for *L. monocytogenes.* Results from different methods for the same samples can only be reported for *L. monocytogenes* in food where the code F145A (corresponding to the term Detection method—presence in x g) is used to indicate the results from detection method (qualitative) analyses. The code F141A (corresponding to the term Enumeration/Quantitative method) is used to indicate the results from enumeration method (quantitative) analyses.
- **Total units tested—**the total number of units (belonging to the same investigation) tested for *L. monocytogenes* using qualitative and/or quantitative methods, for which results are

reported. A sample tested using both qualitative and quantitative analysis should be reported as one unit tested.

- **Total units positive—**the total number of units positive for *L. monocytogenes* based on the results of qualitative and/or quantitative analysis. Where both qualitative and quantitative analyses are used, a unit is considered to be positive if it was shown to be positive in either a qualitative and/or a quantitative test (either positive < 100 cfu/g or positive ≥ 100 cfu/g). In such cases it should be reported as a positive unit only once. It is important to note that, when reporting the total positive units detected using quantitative methods, both units positive < 100 cfu/g and ≥ 100 cfu/g are to be considered. It is important that the definition of a positive sample is provided in the narrative section of the report. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units tested—**numbers of units tested for *L. monocytogenes* by the detection method or by the enumeration method. This data element is mandatory when reporting data on *L. monocytogenes* in food.
- **Number of units positive—**the number of units positive for *L. monocytogenes.* This data element must be used to report the number of units found to be positive for *L. monocytogenes* by the detection method and found to be <=100 or > 100 cfu/g by the enumeration method. Information on this data element must be reported also when no positive units were detected, meaning that also the negative results '0' should be reported when appropriate.

Quantity—the quantity measured by the test. This data element is mandatory when reporting on enumeration method results of *Listeria* in food (in colony-forming units (cfu)/g). For the data reported on *Listeria* in food, the code R073A (corresponding to the term <=100) is used to report results where *Listeria monocytogenes* was found in numbers over the quantification limit but less than or equal to 100 cfu/g. On the other hand, the code R077A (corresponding to the term > 100) is used to report results where *Listeria monocytogenes* was found in numbers greater than 100 cfu/g.In the event that *L. monocytogenes* enumeration analysis is carried out only for the samples that have already been found positive by the *L. monocytogenes* detection method, this should be explained in the comment data element.

6.5. *Yersinia* spp. in foodstuffs

Relevant food categories to be reported on

- **Meat and products thereof—**information should be provided on the animal species from which the meat is derived, e.g. bovine animals, **pigs**, and the nature of the meat, e.g. carcase, fresh meat, minced meat, meat products, meat preparations. More detailed information on the status of the meat at the point of sampling (e.g. frozen, cooked) and how it is intended to be consumed (e.g. intended to be eaten raw, intended to be eaten cooked) should be provided where available.
- **Milk—**for milk, it is useful to report the animal species from which the product is derived, e.g. cow, sheep, goat. More detailed information on milk (e.g. pasteurised or raw/low heat-treated milk) should be provided where available.
- **Fruit and vegetables—**information on the nature of the product (e.g. fruit, **vegetables**, sprouted seeds, salad) and the status of the product at the point of sampling (e.g. pre-cut/non-pre-cut fruits and vegetables, ready-to-eat/non-ready-to-eat sprouted seeds) is to be provided.

Relevant agent species/serotypes/biotypes to be reported

Yersinia spp.

Differentiation at species level should be provided (e.g. *Y. enterocolitica*, *Y. pseudotuberculosis*). Main pathogenic serotypes of *Y. enterocolitica* (O:3, O:9, O:5,27) and/or biotypes (1B, 2, 3, 4, 5) should be reported, when the information is available. If information on both serotype and biotype is available,

the results should be reported as the biotype/serotype combinations, as recommended in the report 'Technical specifications for harmonised national surveys of *Y. enterocolitica* in slaughter pigs' (EFSA, 2009b), for example biotype 4/O:3.

Case definition/definition of a positive sample

- ***Yersinia* positive sample—**a sample in which *Yersinia* spp. have been isolated.
- ***Yersinia* positive batch—**a batch in which *Yersinia* spp. have been isolated from at least one single sample taken out of the batch.

Diagnostic/analytical methods typically used

The reference method for the detection of *Y. enterocolitica* in food is ISO 10273:2003 (ISO, 2003).

Preventative measures in place

Special provisions or guidelines concerning slaughter techniques or hygiene when slaughtering pigs.

Reporting the results in the prevalence data model

Specific guidelines for data reporting

- **Matrix—**the relevant food category and subcategory.
- **Sampling stage—**where the samples have been collected (e.g. 'processing plant', 'retail') should be reported.
- **Sample origin—**is used to report the country of origin of the animal.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'food sample-meat').
- **Sampling context—**information on the context of the sampling (e.g. 'monitoring') should be reported.
- **Sampler—**who performed the sampling should be reported (e.g. 'official sampling' or 'HACCP and own checks').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'single' or 'batch' should be used as the terms to be reported.
- **Sample weight—**the weight or volume of the specimen used in the laboratory for analysis, e.g. 10, etc.; for carcase swabs the area sampled could be reported (e.g. 100).
- **Sample weight unit**—the unit of the indicated sample weight e.g. gram, millilitre, square centimetre.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Analytical methods—**the diagnostic or analytical method used in testing of the sample should be reported here.
- **Total units tested—**the number of sampling units that are analysed in total, and for which results are available.
- **Total units positive—**the total number of units positive for *Yersinia* spp. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive**—the number of units tested positive for *Yersinia* species (e.g. *Y. enterocolitica*, *Y. pseudotuberculosis*) or serotype (e.g. O:3, O:9, O:5,27), or biotype (e.g. 1B, 2, 3, 4, 5). If information on both serotype and biotype is available, the results should be reported as the biotype/serotype combinations (available in the catalogue), for example biotype 4/O:3.

It is recommended that the presence of human pathogenic *Y. enterocolitica* biotypes/serotypes (e.g. biotype 4/O:3, biotype 2/O:9, biotype 3/O:3, biotype 1B/O:7) be reported.

6.6. Verotoxigenic *Escherichia coli* in foodstuffs

Relevant food categories to be reported on

- **Meat and products thereof—**information should be provided on the animal species from which the meat is derived, e.g. broiler**, bovine animals**, **sheep**, **goat, game,** and the nature of the meat, e.g. **carcase, fresh meat, minced meat**, **ready-to-eat fermented meat products**, meat preparations. More detailed information on the status of the meat at the point of sampling (e.g. frozen, cooked) and how it is intended to be consumed (e.g. intended to be eaten raw, intended to be eaten cooked) should be provided where available.
- **Milk and dairy products—unpasteurised milk and products thereof—**information should be provided on the nature of the food, i.e. milk, cheese or other dairy product. For milk and cheese, it is useful to report the animal species from which the product is derived, e.g. cow, sheep, goat. More detailed information on **milk** (e.g. pasteurised or **raw/**low heat-treated milk), on cheese (e.g. hard or soft and semi-soft cheese) and on other dairy products (e.g. made from pasteurised or raw/low heat-treated milk) should be provided, where available.
- **Fruit and vegetables—**information should be provided on the nature of the product (e.g. fruit, vegetables, sprouted seeds, salad) and the status of the product at the point of sampling (e.g. pre-cut/non-pre-cut fruit and vegetables, ready-to-eat/non-ready-to-eat sprouted seeds).
- **Juices—**information should be provided on the nature of the product (e.g. fruit or vegetable juice, pasteurised/**unpasteurised**).

Relevant agent species/serotypes to be reported

Strains of *E. coli* which are capable of producing VT/Stx (VTEC or STEC). Information on the serogroup (O antigen) is to be reported. Serogroups of particular interest are: O157, O111, O103, O26 and O145.

MSs are strongly invited to report information on the STEC/VTEC serogroup, when available.

It is recommended that information on genes encoding verocytotoxin 1 (*vtx1*), verocytotoxin 2 (*vtx2*) or intimin (*eae*) be reported, where available, as stated in the report 'Technical specifications for the monitoring and reporting of verotoxigenic *Escherichia coli* (VTEC) on animals and food' (EFSA, 2009a); for example VTEC O157 *eae* positive *vtx1* positive.

For serogroup O104, it is recommended that the virulence characters are reported, including presence of verocytotoxin VT2 (*vtx2*+) and enteroaggregative virulence plasmid (*EAgg*+).

The serogroups non-O157 should be differentiated based on the presence/absence of the gene for intimin (*eae*), which is considered a marker of potentially high virulence.

For compliance with the new criteria laid down in Regulation (EU) No 209/2013 the following information has to be reported: VTEC (STEC) O157, O26, O111, O103, O145 and O104:H4—in **sprouts** (excluding sprouts that have received a treatment effective to eliminate *Salmonella* spp. and STEC).

Case definition/definition of a positive sample

- **VTEC-positive sample/batch—**a sample/batch from which any VTEC has been isolated using a method specified below.
- **VTEC O157 or other serogroup positive sample/batch—**a sample/batch from which VTEC O157 or other serogroup has been isolated using a method specified below.

MSs are strongly encouraged to only report data on STEC/VTEC as indicated in the Directive 2003/99/EC.

It is important to note that the positive result to be reported, according to the EFSA Data dictionaries' guideline, is an *E. coli* strain producing VT or possessing the *vtx* genes. The correct reporting of the positive results is strongly recommended.

To make the data reporting easier and harmonized across the MSs, the following proposal for data reporting at the Zoonosis L3 level is made. Values for Zoonosis L3 reporting should include the following:

- *VTEC, serogroup identified*: to be used when a strain carrying the *vtx* genes or producing VT is isolated, and information on the STEC serogroup is available. The VTEC serogroup identified to be selected from the whole list of VTEC serogroups (From O1 to O…).
- *VTEC non-O157*: to be used only when a strain carrying the *vtx* genes is isolated but its serogroup belongs neither to O157 nor to any of the other serogroups the laboratory is able to detect.
- *VTEC non* O157, O26, O111, O103, O145: to be used only when a strain carrying the *vtx* genes is isolated but its serogroup belongs neither to O157, O26, O111, O103, O145 (the serogroups identified by the ISO/TS13136:2012) nor to any of the other serogroups the laboratory is able to detect.
- *VTEC unspecified*: to be used only when a strain carrying the *vtx* genes or producing VT is isolated, but no information on the STEC serogroup is available.

Algorithm for reporting VTEC serogroup detection at the Zoonosis L3 level

1. Isolation of an *E. coli* strain producing VT or carrying the *vtx1* or *vtx2* or both genes.
2. Was an attempt to identify the serogroup of the VTEC strain performed?
   - Yes → go to point 3
   - No→ report as **VTEC, unspecified**.
3. Did the isolated VTEC strain belong to O157?
   - Yes → to be reported as **VTEC, O157**
   - No → go to point 4
4. Was the identification of the VTEC serogroup obtained?
   - Yes → to be reported as **VTEC, serogroup identified** (detailing the information on the specific serogroup)
   - No → to be reported as:
     - **VTEC, non-O157**
       or
     - **VTEC non O157, O26, O111, O103, O145** if the typing attempt included not only O157 but also the serogroups O26, O111, O103, O145

Please consider the following **REMARKS**

- Double reporting is no longer required/allowed for VTEC. Please note that the results should be reported only once.
- Since the list of values for Zoonosis L3 would now be exhaustive, missing values should not be reported for records with 'Total Units Positive' > 0.
- The *VTEC, NT (Non Typeable*) value should not be accepted. This information strongly depends on the panel of serotyping reagents available in the laboratories. As a result, the information provided by the MSs with this value is not homogeneous and cannot be analysed, because its merging would be meaningless.

Reporting countries are strongly encouraged to submit information on the presence of virulence genes in the VTEC strains using the Zoonosis level 4 term.

Diagnostic/analytical methods typically used

Two main categories of analytical methods are typically used:

a) Methods aiming at detecting any VTEC, regardless of the serotype. These methods are usually based on PCR screening of sample enrichment cultures and isolation of colonies harbouring *vtx* genes, followed by the characterisation of the isolated VTEC strains. This category includes the method ISO/TS 13136:2012 (ISO, 2012), other PCR-based methods, and also methods based on the detection of verocytotoxin production by immunoassays.

b) Methods designed to detect only VTEC O157, such as the method ISO 16654:2001 (ISO, 2001) and the equivalent NMKL 164:2005 (NMKL, 2005). VTEC O157 is the serotype most commonly reported in the EU as a cause of both outbreaks and sporadic cases in humans and has also been identified as the major cause of HUS in children. The focus has therefore traditionally been on this serotype in many of the MS surveillance programmes.

The recommended method for the detection of VTEC O104:H4 is the method 'EU-RL_Method_food_2. Rev.2-O104:H4'.[35]

Details should be provided on the diagnostic method used, including how verification of VTEC is carried out and the serogroups for which screening is carried out.

Reporting the results in the prevalence data model

Specific guidelines for data reporting

- **Matrix—**the relevant food category and subcategory.
- **Sampling stage—**where the samples have been collected (e.g. 'processing plant', 'retail') should be reported.
- **Sample origin—**is used to report the country of origin of the food.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'food sample—meat').
- **Sampling context—**information on the context of the sampling (e.g. 'surveillance') should be reported.
- **Sampler—**who performed the sampling should be reported here (e.g. 'official sampling' or 'HACCP and own checks').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—'**single' or 'batch' should be used as the terms to be reported.
- **Sample weight—**the weight or volume of the specimen used in the laboratory for analysis, e.g. 10, etc.; for carcase swabs the area sampled could be reported (e.g. 100).
- **Sample weight unit—**the unit of the indicated sample weight e.g. gram, millilitre, square centimetre.
- **Source of information** the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Analytical methods—**the diagnostic or analytical method used in testing of the sample must be reported.

Please use the available **analytical methods to report on VTEC**:

- ISO 16654:2001 or NMKL 164:2005 or DIN 10167 or any alternative method validated against these methods, according to the ISO 16140[23]
- ISO/TS 13136:2012 (including the EU-RL adaptation for O104:H4) or any alternative method validated against this method, according to the ISO 16140[24]
- In house real time PCR methods based on ISO/TS 13136:2012[24]
- Other methods based on PCR detection of vtx genes[24]
- DIN 10118:2004 or any alternative method validated against this method, according to the ISO 16140[25]
- Other methods based on the immunochemical detection of VT[25]
- Other methods. In this case, basic details on the method should be specified in the 'comment' data element.

MSs are strongly invited to report information on methods in the proper data element for analytical method.

- **Total units tested—**the number of sampling units that are analysed in total, and for which results are available.
- **Total units positive—**the total number of units positive for specific VTEC serogroup. Information on genes encoding for verocytotoxins or intimin should be reported if available, for example VTEC O157 *eae* positive *vtx1* positive *vtx2* negative. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of units tested positive for VTEC.

The type of diagnostic method used is mandatory to be reported in the analytical method, in order to facilitate the correct interpretation of the results**.**

6.7. *Brucella* spp. in foodstuffs

Relevant food categories to be reported

- **Milk and dairy products—**information on the nature of the food, e.g. milk, cheese or other dairy products. For milk and cheese, it is useful to report the animal species from which the product is derived, e.g. cow's, **sheep's, goat's** or mixed milk. More detailed information on milk (e.g. pasteurised or raw/low heat-treated milk), on **cheese** (e.g. hard or soft and semi-soft cheese) and on other dairy products (e.g. made from pasteurised or **raw/low heat-treated milk**) should be provided where available.

Relevant agent species to be reported

Detection of *Brucella* spp. to be reported. Differentiation at species level should be provided, where available, e.g. *B. abortus*, *B. melitensis* and the biovar.

Case definition/definition of a positive sample

- ***Brucella*-positive sample—**a sample from which *Brucella* spp. have been isolated.
- ***Brucella*-positive batch—**a batch from which *Brucella* spp. have been isolated from at least one single sample taken out of the batch.

Diagnostic/analytical methods typically used

There is no standard method for food examination.

Details of the detection method used should be provided.

Preventative measures in place

Report provisions or recommendations concerning the use and marketing of raw milk and cheeses made of raw or low heat-treated milk, with reference to the relevant EC legislation, when appropriate.

Reporting the results in the prevalence data model

Specific guidelines for data reporting

- **Matrix—**the relevant food category and subcategory.
- **Sampling stage—**where the samples have been collected (e.g. 'processing plant', 'retail') should be reported.
- **Sample origin—**is used to report the country of origin of the food.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'food sample—meat').
- **Sampling context—**information on the context of the sampling (e.g. 'surveillance').
- **Sampler—**who performed the sampling should be reported here (e.g. 'official sampling' or 'HACCP and own checks').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'single' or 'batch' should be used as the terms to be reported.
- **Sample weight—**the weight or volume of the specimen used in the laboratory for analysis, e.g. 10, etc.; for carcase swabs the area sampled could be reported (e.g. 100).
- **Sample weight unit**—the unit of the indicated sample weight e.g. gram, millilitre, square centimetre.
- **Source of information** the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Analytical methods—**the diagnostic or analytical method used in testing of the sample should be reported here.
- **Total units tested—**the number of sampling units that are analysed in total and for which results are available.
- **Total units positive—**the number of units positive for *Brucella* spp. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive**—the number of units tested positive for specific *Brucella* species (e.g. *B. abortus, B. melitensis*).

7. Reporting of zoonotic agents in feedingstuffs

7.1. *Salmonella* spp. in feedingstuffs

Relevant feed categories to be reported

- **Feed material of animal origin**, e.g. meat and bone meal, fish meal, animal fat, fish oil or compound (both of land and marine sources).
- **Feed material of vegetable origin**, either of cereal (e.g. barley, wheat, maize) or **oil seed**/fruit/vegetable source (e.g. groundnut, soya, cotton, sunflower) or compound vegetable source.
- **Compound feedingstuffs** (from both animal and vegetable origin), subcategorised according the animal species of destiny—cattle, pigs, poultry (subcategorised as for breeders, laying hens, broilers, if possible, or not specified) and pets.

Relevant agent species/serovars/phagetypes to be reported

Salmonella serovars and phagetypes, where available.

Case definition/definition of a positive sample

- ***Salmonella*-positive sample—**a sample in which *Salmonella* spp. have been isolated.
- ***Salmonella*-positive batch—**a batch in which *Salmonella* spp. have been isolated from at least one single sample taken out of the batch.

Diagnostic/analytical methods typically used

ISO 6579:2002 (ISO, 2002) and NMKL 71 (NMKL, 1999).

Reporting the results in the prevalence data model

- **Specific guidelines for data reporting Matrix—**the relevant feed category and subcategory.
- **Sampling stage—**where the samples have been collected (e.g. 'feed mill') should be reported.
- **Sample origin—**is used to report the country of origin of the food.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'feed sample').
- **Sampling context—**information on the context of the sampling (e.g. 'surveillance') should be reported.
- **Sampler—**who performed the sampling should be reported here (e.g. 'official sampling' or 'HACCP and own checks').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**use 'batch' or 'single'.
- **Sample weight—**the weight or volume of the specimen used in the laboratory for analysis, e.g. 10, etc.; for carcase swabs the area sampled could be reported (e.g. 100).
- **Sample weight unit—**the unit of the indicated sample weight e.g. gram, millilitre, square centimetre.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Total units tested—**the number of sampling units that are analysed in total and for which results are available.
- **Total units positive—**the total number of units positive for *Salmonella* spp. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of units tested positive for a specific *Salmonella* serovar (e.g. *Salmonella* Typhimurium, *Salmonella* Infantis) or phagetype (e.g. *Salmonella* Enteritidis-PT 1).

Data on monophasic *S.* Typhimurium should be reported as following: this group comprises *S.* Typhimurium strains lacking the second phase H antigen (1,4,[5],12:i:- [22]). Whenever feasible, as much detail as possible of the antigenic formula as determined by testing should be reported (e.g. 1,4,[5],12:i:- or 1,4,12:i:-). If the full antigenic formula is not available, but a phagetype that is consistent with *S.* Typhimurium lacking phase 2 flagellar antigen has been confirmed, and the lack of the second flagellar antigen has been verified by PCR, then it is recommended that the term 'monophasic *S.* Typhimurium' be used.

8. Reporting on other pathogenic microbiological agents in foodstuffs

8.1. Staphylococcal enterotoxins in foodstuffs

Relevant food categories to be reported on

Food categories for which staphylococcal enterotoxins food safety criterion is laid down in Regulation (EC) No 2073/2005:

- cheeses made from raw milk or milk that has undergone treatment with heat at a temperature lower than that of pasteurisation;
- ripened cheeses made from milk or whey that have undergone pasteurisation or treatment at a higher temperature;
- unripened soft cheeses (fresh cheeses) made from milk or whey that have undergone pasteurisation or treatment at a higher temperature;
- milk powder and whey powder not intended for further processing in the food industry.

Case definition/definition of a positive sample

- **Positive sample—**a sample in which staphylococcal enterotoxins have been detected. It is recommended that the weight of the sample tested be indicated.
- **Positive batch—**a batch in which staphylococcal enterotoxins have been detected in at least one of the samples in the batch. It is recommended that the weight of the sample tested be indicated. When using quantitative analysis, it is also recommended that the limit of detection of the method used be indicated.

Diagnostic/analytical methods typically used

The recommended method is the European screening method of the European Union Reference Laboratory (EURL) for staphylococci (ANSES-Lerqap, Maison-Alfort) in accordance with Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

Reporting the results in the prevalence data model

Specific guidelines for data reporting

- **Matrix—**the relevant food category and subcategory.
- **Sampling stage—**where the samples have been collected (e.g. 'processing plant') should be reported.
- **Sample origin—**is used to report the country of origin of the food.
- **Sample type—**the sample category and sample type should be reported (e.g. 'food sample').
- **Sampling context—**information on the context of the sampling (e.g. 'HACCP and own checks') should be reported.
- **Sampler—**who performed the sampling should be reported here (e.g. 'official sampling' or 'HACCP and own checks').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling').

- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'single' or 'batch' should be used as the terms to be reported.
- **Sample weight—**the weight or volume of the specimen used in the laboratory for analysis, e.g. 10, etc.; for carcase swabs the area sampled could be reported (e.g. 100).
- **Sample weight unit**—the unit of the indicated sample weight e.g. gram, millilitre, square centimetre.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Total units tested—**the total number of sample units tested in the laboratory.
- **Total units positive—**the number of sample units in which staphylococcal enterotoxins have been detected. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive—**the number of units tested positive for staphylococcal enterotoxins.

8.2. *Cronobacter* spp. in foodstuffs

Relevant food categories to be reported

Food categories for which a *Cronobacter* spp. (previously named *Enterobacter sakazakii*) food safety criterion is laid down in Regulation (EC) No 2073/2005:

- **Dried infant formulae—**where available, information should be provided on the animal species from which the product is derived, e.g. cow, sheep, goat.
- **Dried dietary foods for special medical purposes intended for infants below six months of age—**where available, information should be provided on the nature of the food, e.g. milk, fruit and cereals. For milk-derived products, it is useful to report the animal species from which the product is derived, e.g. cow, sheep, goat.

Relevant agent species to be reported

Cronobacter spp. differentiation to species level is recommended, e.g. *Cronobacter sakazakii* (*C. sakazakii*).

Case definition/definition of a positive sample

***Cronobacter* spp.-positive sample—**a sample in which *Cronobacter* spp. have been isolated.

***Cronobacter* spp.-positive batch—**a batch in which *Cronobacter* spp. have been isolated from at least one single sample taken out of the batch.

Diagnostic/analytical methods typically used

The recommended method for the detection of *Cronobacter* in milk products is ISO/TS 22964:2006 (ISO, 2006c) in accordance with Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

Reporting the results in the prevalence data model

Specific guidelines for data reporting

- **Matrix—**the relevant food category and subcategory.
- **Sampling stage—**where the samples have been collected (e.g. 'retail') should be reported.
- **Sample origin—**is used to report the country of origin of the food.
- **Sample type—**the sample category and sample type should be reported (e.g. 'food sample').

- **Sampling context—**information on the context of the sampling (e.g. 'HACCP and own checks') should be reported.
- **Sampler—**who performed the sampling should be reported (e.g. 'official sampling' or 'HACCP and own checks').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'single' or 'batch' should be used as the terms to be reported.
- **Sample weight—**the weight or volume of the specimen used in the laboratory for analysis, e.g. 10, etc.; for carcase swabs the area sampled could be reported (e.g. 100).
- **Sample weight unit**—the unit of the indicated sample weight e.g. gram, millilitre, square centimetre.
- **Source of information—**the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Total units tested—**the total number of sample units tested in the laboratory.
- **Total units positive—**the number of sample units in which *Cronobacter* spp. have been detected. In case that no positive units were detected, a '0' (zero) should be reported.
- **Number of units positive**—the number of units tested positive for *Cronobacter* spp. (e.g. *C. sakazakii*).

8.3. Histamine in foodstuffs

Relevant food categories to be reported

Food categories for which a histamine food safety criterion is laid down in Regulation (EC) No 2073/2005:

- **Fishery products from fish species associated with large amounts of histidine** (e.g. fish species of the families *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae* and *Scombresosidae*), **which are not enzyme matured in brine** (category 1). This typically includes raw fish flesh and canned products from these fish species. It is recommended that a detailed description of the product examined is given (raw product, canned, matured, etc.).
- **Fishery products from fish species associated with large amounts of histidine** (e.g. fish species of the families *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae* and *Scombresosidae*), **which have undergone enzyme maturation treatment in brine** (category 2). It is recommended that a detailed description of the product examined is given (raw product, canned, matured, etc.).

Relevant agent species to be reported

Histamine, categorised according to the quantity of the histamine detected in the sampling unit.

Case definition/definition of a positive sample

The microbiological criteria set for the fishery products prescribes that a sample taken from a batch should include nine sample units, out of which two sample units are allowed to have values between the given two limits (*m* and *M*).

- **Sample in non-conformity—**a single sample that contains histamine with more than 100 mg/kg (category 1) or 200 mg/kg (category 2).
- **Batch in non-conformity—**a batch for which the mean value of the sample units exceeds 100 mg/kg (category 1) or 200 mg/kg (category 2); or a batch in which out of the *n* sample units taken more than *c* contain histamine over 100 mg/kg (category 1) or 200 mg/kg

(category 2); or a batch in which one or more sample units contain histamine with more than 200 mg/kg (category 1) or more than 400 mg/kg (category 2).

Diagnostic/analytical methods typically used

High-performance liquid chromatography (HPLC) in accordance with Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs (Malle et al., 1996; Duflos et al., 1999).

Reporting the results in the prevalence data model

Please note that in the case of batch sampling, where a set of sample units (usually nine) is taken from the batch (= sampling unit), the breakdown of the sampling units (batches) in different result value categories is done on the basis of the maximum value detected for the unit (batch).

Specific guidelines for data reporting

- **Matrix—**the relevant food category and subcategory.
- **Sampling stage—**where the samples have been collected (e.g. 'retail') should be reported.
- **Sample origin—**is used to report the country of origin of the food.
- **Sample type—**the sample category and sample type should be reported here (e.g. 'food sample').
- **Sampling context—**information on the context of the sampling (e.g. 'HACCP and own checks') should be reported.
- **Sampler—**who performed the sampling should be reported here (e.g. 'official sampling' or 'HACCP and own checks').
- **Sampling strategy—**the type of sampling should be reported (e.g. 'objective sampling').
- **Sampling details—**free text to be used for further information on samples.
- **Sampling unit—**'single' or 'batch' should be used as the terms to be reported.
- **Sample weight—**the weight or volume of the specimen used in the laboratory for analysis, e.g. 10, etc.; for carcase swabs the area sampled could be reported (e.g. 100).
- **Sample weight unit**—the unit of the indicated sample weight e.g. gram, millilitre, square centimetre.
- **Source of information** the institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comment data element.
- **Analytical methods—**the diagnostic or analytical method used in testing of the sample shall be reported for Histamine.
- **Total units tested—**the total number of sample units tested in the laboratory.
- **Total units positive —**the total number of sampling units that are in non-conformity with the microbiological criterion based on the analytical results should be reported.
- **Number of units positive—**the number of units tested positive for Histamine. This data element must be used to report the number of units found in the six categories <=100, > 100 to <=200, <=200, > 200 > 200 to <=400, and > 400 mg/kg. This data element must be reported also when no positive units were detected.
- **Quantity—**the quantity measured by the test. In histamine in food, the codes 'R073A' to 'R076A' and 'R106A' and 'R107A'are used to report the numbers of units where histamine was found in quantities in the following ranges:
    - less than or equal to 100 mg/kg ('<=100' code 'R073A');
    - more than 100 mg/kg but below or equal to 200 mg/kg ('> 100 to <=200' code 'R075A');
    - less than or equal to 200 mg/kg ('<=200' code 'R106A');

- more than 200 mg/kg ('> 200' code 'R107A');
- more than 200 mg/kg but below or equal to 400 mg/kg ('> 200 to <=400' code 'R076A');
- more than 400 mg/kg ('> 400' code 'R074A').

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Appendix A – Guidelines for reporting analytical methods

Laboratories can use international standard methods such as ISO and CEN but also national standard methods (such as the Netherlands Standardization Institute (NEN) and Deutsches Institut für Normung (DIN), etc.), or even their own (laboratory-developed) methods.

When comparing data it will be necessary to have sufficient detailed information on the methods, for example:

For conventional ('classic') methods

1) If a CEN or ISO method is followed, the number of the CEN/ISO method and the year of publication of the procedure used.
2) If a CEN/ISO method is used with modifications, the information in point 1 will be needed, as well as information on the modifications.
3) If a national standard method is followed, it may be sufficient if the laboratory gives the number of the national standard method (and the year of publication), depending on whether or not EFSA is able to obtain these methods from the national standardisation bodies. If this last is a problem (the language might also be a problem) and if the method is also not published in the international literature, then it may be necessary to ask for a more detailed description of the method (such as the media used, incubation temperatures and times, method of confirmation).
4) If an 'own' method is used, it may be sufficient to ask for the reference in the literature. If this is not available, it may be necessary to ask for more details (see point 3).
5) If neither an ISO nor a CEN method is used, is the method validated against and/or compared with the relevant ISO/CEN method?

If molecular (PCR) methods are used

1) Name of the test and manufacturer of the commercially available test.
2) Use of the PCR in combination with a conventional method. Which step of the conventional method is replaced by the PCR (e.g. the confirmation step)?
3) Is the test validated? If so, by which organisation (Association Française de Normalisation (AFNOR), Association of Official Agricultural Chemists (AOAC), MICROVAL (a European validation and certification organisation) or other)?

If immunological (serological) methods are used

1) Name of the test and manufacturer of commercially available tests.
2) Use of the test in combination with a conventional method. Which step of the conventional method is replaced by the test (e.g. confirmation step)?
3) Type of test.
4) Is the test validated? If so, by which organisation (AFNOR, AOAC, MICROVAL or other)?

Appendix B – General definitions

Case definition—definition stating when the sample is considered to be positive for the zoonotic agent or when the person, animal, herd or flock is considered to be infected with the zoonotic agent.

Microorganism—bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, microscopic parasitic helminths and their toxins and metabolites (Regulation (EC) No 2073/2005).

Notification system—a system whereby the disease or infection has to be reported to the competent authority based on a legal obligation.

NUTS—is a geographical nomenclature subdividing the territory of the EU into regions at three different levels (NUTS 1, 2 and 3, respectively, moving from larger to smaller territorial units).

Positive finding—situation stating when the sample (a foodstuff, feedingstuff or a batch of them) is considered to be positive for the zoonotic agent.

Prevalence—the proportion of existing positive cases in a population at that specified time.

Region—part of a MS's territory which is at least 2 000 km^2 in area and includes at least one of the following administrative regions:

- Belgium: province/provincie;
- Germany: laender;
- Denmark: amt or island;
- France: département;
- Italy: provincia;
- Luxembourg: not applicable;
- Netherlands: RVV-kring;
- United Kingdom (England, Wales, Scotland and Northern Ireland): county;
- Scotland: district or island area;
- Ireland: county;
- Greece: *νομός*;
- Spain: provincia;
- Portugal continental: distrito; other parts of Portugal's territory: região autónoma;
- Austria: bezirk;
- Sweden: län;
- Finland: lääni/län;
- Czech Republic: kraj;
- Estonia: maakond;
- Cyprus: *επαρχία* (district);
- Latvia: rajons;
- Lithuania: apskritis;
- Hungary: megye;
- Malta: not applicable;
- Poland: powiat;
- Slovenia: območje;
- Slovakia: kraj;

- Bulgaria: oblast;
- Romania: counties.

Source of information—the institute (or laboratory or other organisation) that provided the data.

Zoonosis—any disease and/or infection that is naturally transmissible directly or indirectly between animals and humans (Directive 2003/99/EC).

Zoonotic agent—any virus, bacteria, fungus, parasite or other biological entity that is likely to cause a zoonosis (Directive 2003/99/EC).

Appendix C – Sampling definitions

Batch—group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period (Regulation (EC) No 853/2004,[36] No 2074/2005,[37] No 2076/2005,[38] No 208/2013[39]).

Population—the entire set of subjects (items, batches) to which the findings of a study are to be extrapolated or from which information is required.

Random sample—sample in which the characteristics of the batch from which it is drawn are maintained (Codex General Guidelines on Sampling—CAC/GL 50, 2004). It is a sample that is taken under statistical consideration to provide representative data (Decision 98/179/EC[40]).

Sample—set composed of one or several units or a portion of matter selected by different means in a population, or in an important quantity of matter, that is intended to provide information on a given characteristic of the studied population or matter and to provide a basis for a decision concerning the population or matter in question or concerning the process that produced it (Regulation (EC) No 2073/2005).

Sample origin—information on where the sample originated from (i.e. domestic, imported from outside EU, intra-EU trade).

Sample size—the number of units randomly chosen from the sampling frame.

Sample type—represents the characterisation of the sample category (e.g. animal, food, feed or environmental sample) and the sample type (e.g. faeces, lymph nodes).

Sample weight—the weight (in grams or millilitres or cm^2) of the specimen used for analysis in the laboratory. The sample weight should be reported as a number + space + unit of measure. Appropriate units of measure are g, ml and cm^2. Multiple weights should not be reported in the same row. If results for specific weights are not known, the sample weight should be set to unknown.

Sampling frame—complete list of all units of the population, which can be sampled.

Sampling strategy—planned procedure for selecting samples from a population and for conducting the sampling in order to obtain the information needed.

Sampling unit—the unit which the specimens taken represent and which is considered either infected (contaminated) or not, based on the analyses result. For animal data, the sampling unit may be 'animal', 'flock', 'herd', 'holding' or 'slaughter batch'; for food and feed data, the sampling unit might be 'single' or 'batch'.

Single—means a foodstuff or a feedingstuff comprising one unit or a portion of matter, e.g. a package, a carcase, a piece of cheese. It does not represent the entire batch (of production or consignment).

Specimen—unit or portion of a matter that is sampled and intended to be analysed.

[36] Commission Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. OJ L 139, 30.4.2004, p. 55–205.

[37] Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (Text with EEA relevance). OJ L 338, 22/12/2005, p. 27–59.

[38] Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (Text with EEA relevance). OJ L 338, 22/12/2005, p. 83–88.

[39] Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts (Text with EEA relevance). OJ L 68, 12.3.2013, p. 16–18.

[40] Commission Decision 98/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products. OJ L 65, 5.3.1998, p. 31–34.

Appendix D – Definitions regarding the sampling context

Clinical investigation—clinical investigation in animals is considered as a selective way of sampling and results in a number of samples obtained in a passive way. The samples obtained and analysed via clinical investigations are heterogeneous with relation to the species (matrix) as well as type of samples. The reason for the analysis of the samples is very often a clinical examination of (diseased) animals by a veterinarian and/or specific clinical signs observed by the farmer and/or veterinarian.

Control programme—programme applying measures designed to reduce the frequency of existing infection or contamination to levels biologically and/or economically justifiable or otherwise of little consequence.

Eradication programme—programme applying measures aimed at eliminating selected zoonotic agents from a defined area. In the context of Directive 77/391/EEC[41] the eradication programmes are so devised that, on their completion, herds are classified as officially free of brucellosis/tuberculosis.

HACCP (Hazard Analysis and Critical Control Point)—programme designed to effectively control processes by identifying critical control points (CCPs), establishing critical limits for each CCP, monitoring CCPs, gathering data, keeping records, and implementing corrective actions and verification procedures. HACCP is applied by the food or feed business operators (Codex Alimentarius).

Monitoring—system of collecting, analysing and disseminating data on the occurrence of zoonoses, zoonotic agents and antimicrobial resistance related thereto. As opposed to surveillance, no active control measures are taken when positive cases are detected (Directive 2003/99/EC).

Monitoring—active—active monitoring programme of zoonotic agents or antimicrobial resistance in food and animals, based on random sampling strategies of the population of interest, stratified according to the relevant subcategories of the population. The sampling strategy should ensure that the sample is representative of the population of interest and that the sampling method is robust. A planned monitoring of wild life for e.g *Trichinella or Echinococcus* via organised hunting schemes should be considered as active monitoring.

Monitoring—passive—passive monitoring programme of zoonotic agents or antimicrobial resistance that includes information from diagnostic testing, or a representative selection of this information. Data on the prevalence of the zoonotic agents and on antimicrobial resistance provided by passive monitoring programmes are typically derived from diseased animals (clinical investigations, observed syndromes, etc).

Monitoring—EFSA specifications—a monitoring system following harmonised technical specifications prepared by EFSA.

Official control—any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules (Regulation (EC) No 882/2004[42])

Official sampling—sampling performed under the control of the competent authority.

Objective sampling—planned strategy based on the selection of a random sample, which is statistically representative of the population to be analysed. Each unit, within the framework population, has a specified probability of being selected. This strategy provides data from which statistical inference can be implemented. That means that the results inferred are comparable. Objective sampling is often the case in monitoring and surveillance schemes as well as in surveys.

Sampler—one who performs the sampling (e.g. competent authority ('official sampling') or 'industry' or 'HACCP or own checks').

[41] Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle. OJ L 145, 13.6.1977, p. 44–47.

[42] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. OJ L 165, 30.4.2004, p. 1–141.

Selective sampling—planned strategy whereby the selection of the sample is from previously defined 'high-risk' population groups. Samples are normally selected to either illustrate or document unsatisfactory conditions or suspected adulteration of a product. The sampling is deliberately biased and is directed at the particular products or manufacturers. The sampling procedure can be random or not. The specification of the 'high-risk' population comes from either scientific studies or previous analysis and information of other regions or countries. The comparability of the results lies on both the definition of the population to be analysed and the way the samples have been drawn.

Suspect sampling—unplanned selection of a sample whereby the individual units are selected based on the recent judgement and experience regarding the population, lot or sampling frame, e.g. earlier positive samples. The samples obtained from this procedure are not randomly extracted.

Census—strategy whereby all units of the population are sampled.

Convenience sampling—is used in exploratory research when the researcher is interested in getting an inexpensive approximation of the truth. The samples are selected because they are convenient and easy to obtain. This non-probability method is often used during preliminary research efforts to get a gross estimate of the results, without incurring the cost or time required to select a random sample. This methodology is potentially subject to serious bias.

Sampling strategy—planned procedure for selecting samples from a population and for conducting the sampling in order to obtain the information needed.

Surveillance—a careful observation of one or more food or feed businesses, food or feed business operators or their activities (in the context of the food and feed control Regulation (EC) No 882/2004). In general, it means a close and continuous observation for the purpose of control. As opposed to monitoring, active control measures are frequently taken when positive cases are detected. This type of programme does not necessarily have a defined target for reducing the occurrence of diseases/contamination.

Survey—study involving a sample of units selected from a larger, well-delineated population. This (target) population is the entire set of units to which the findings of the survey are to be extrapolated. The units to examine are to be selected randomly (Rothman, 1986; Noordhuizen et al., 2001).

Survey—EU baseline survey—a study involving a sample of units selected from a larger, well-delineated population. This (target) population is the entire set of units to which findings of the survey are to be extrapolated. The units to examine are to be selected randomly.

Appendix E – Definitions of foodstuffs

Carcase—the body of an animal after slaughter and dressing (Regulation (EC) No 853/2004).

Compliance with microbiological criteria—obtaining satisfactory or acceptable results set in Annex I when testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective actions, in accordance with food law and the instructions given by the competent authority (Regulation (EC) No 2073/2005).

Contamination—the presence or introduction of a hazard (Regulation (EC) No 852/2004).

Cutting plant—an establishment used for boning and/or cutting up meat (Regulation (EC) No 853/2004).

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

Dispatch centre (of live bivalve molluscs)—any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption (Regulation (EC) No 853/2004).

Egg products—processed products resulting from the processing of eggs, or of various components or mixtures of eggs, or from the further processing of such processed products (Regulation (EC) No 853/2004).

Eggs—eggs in shell, other than broken, incubated or cooked eggs, that are produced by farmed birds and are fit for direct human consumption or for the preparation of egg products (Regulation (EC) No 853/2004).

Dietary food for special medical purposes—category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or those with other medically determined nutrient requirements whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses or by a combination of the two (Directive 2006/141/EC[43]).

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[44]).

Food intended for infants—food specifically intended for infants (Directive 2006/141/EC).

Food intended for special medical purposes—dietary food for special medical purposes (Directive 99/21/EC[45]).

Food safety criterion—criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market (Regulation (EC) No 2073/2005).

Fishery products—all seawater or freshwater animals (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, parts and products of such animals (Regulation (EC) No 853/2004).

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

[43] Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC. OJ L 401, 30.12.2006, p. 1–33.
[44] 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.
[45] Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical OJ L 91, 7.4.1999, p. 29–36.

Frogs' legs—the posterior part of the body divided by a transverse cut behind the front limbs, eviscerated and skinned, of the species *Rana*, family *Ranidae* (Regulation (EC) No 853/2004).

Liquid egg—unprocessed egg contents after removal of the shell (Regulation (EC) No 853/2004).

Marine biotoxins (of live bivalve molluscs)—poisonous substances accumulated by bivalve molluscs, in particular as a result of feeding on plankton containing toxins (Regulation (EC) No 853/2004).

Meat—edible parts of the animals below mentioned, including blood (Regulation (EC) No 853/2004):

- 'Domestic ungulates'—domestic bovine (including *Bubalus* and *Bison* spp.), porcine, ovine and caprine animals, and domestic solipeds.
- 'Poultry'—farmed birds, including birds that are not considered to be domestic but which are farmed as domestic animals, with the exception of ratites, which are considered to be 'farmed game'.
- 'Lagomorphs'—rabbits, hares and rodents.
- 'Wild game'—wild ungulates and lagomorphs, as well as other land mammals that are hunted for human consumption and are considered to be wild game under the appropriate law in the MS concerned, including mammals living in enclosed territory under conditions of freedom similar to those of wild game and wild birds that are hunted for human consumption.
- 'Farmed game'—farmed ratites and farmed land mammals other than those referred to as 'domestic ungulates'.
- 'Small wild game'—wild game birds and lagomorphs living freely in the wild.
- 'Large wild game'—wild land mammals living freely in the wild that do not fall within the definition of small wild game.

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

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

Microbiological criterion—criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of microorganisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch (Regulation (EC) No 2073/2005).

Minced meat—boned meat that has been minced into fragments and contains less than 1% salt (Regulation (EC) No 853/2004).

Offal—fresh meat other than that of the carcase, including viscera and blood (Regulation (EC) No 853/2004).

Packing centre—establishment where eggs are graded by quality and weight (Regulation (EC) No 853/2004).

Potable water—water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption[46].

Prepared fishery products—unprocessed fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting and chopping (Regulation (EC) No 853/2004).

Process hygiene criterion—criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative

[46] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1998, p. 32–54.

contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law (Regulation (EC) No 2073/2005).

Processed fishery products—processed products resulting from the processing of fishery products or from the further processing of such processed products (Regulation (EC) No 853/2004).

Processed products—foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics (Regulation (EC) No 852/2004[47]).

Processing—any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes (Regulation (EC) No 852/2004).

Products of animal origin—food of animal origin, including honey and blood; live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption; and other animals destined to be prepared with a view to being supplied live to the final consumer (Regulation (EC) No 853/2004).

Raw milk—milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40°C or undergone any treatment that has an equivalent effect (Regulation (EC) No 853/2004).

Ready-to-eat food—food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing in order to eliminate or reduce to an acceptable level microorganisms of concern (Regulation (EC) No 2073/2005).

Shelf life—either the period preceding the 'use by' date or that preceding the minimum durability date, as defined in Article 24 of Regulation (EU) 1169/2011.[48]

Slaughterhouse—establishment used for slaughtering and dressing animals, the meat of which is intended for human consumption (Regulation (EC) No 853/2004).

Snails—terrestrial gastropods of the species *Helix pomatia* Linnaeus, *Helix aspersa* Muller, *Helix lucorum* and species of the family *Achatinidae* (Regulation (EC) No 853/2004).

Unprocessed products—foodstuffs that have not undergone processing and including products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed (Regulation (EC) No 852/2004).

Wrapping—the placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself (Regulation (EC) No 852/2004).

[47] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. OJ L 139, 30.4.2004, p. 1–54.

[48] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. OJ L 304, 22/11/2011, p. 18–63.

Appendix F – Definitions of animals

Animal—any animal of the species referred to in EU Directives (Directive 64/432/EEC, Directive 91/68/EEC and Directive 92/102/EEC[49]).

Animals for breeding or production—bovine animals (including the species *Bison bison* and *Bubalus bubalus*) and swine other than animals for slaughter, including those intended for breeding, milk or meat production, or draft purposes, shows or exhibition with the exception of animals taking part in cultural and sporting events (Directive 64/432/EEC).

Animals for slaughter—bovine animal (including the species *Bison bison* and *Bubalus bubalus*), swine or animals of the ovine or caprine species intended to be taken to a slaughterhouse or assembly centre from which it may proceed only to slaughter (Directive 64/432/EEC and Directive 91/68/EEC).

Breeding poultry—poultry 72 hours old or more, intended for the production of hatching eggs (Directive 2009/158/EC[50]).

Calves—domestic animals of the bovine species, not exceeding a live weight of 300 kg, that do not yet have their second teeth (Decision 94/433/EC[51]).

Calves for slaughter—cattle less than 12 months old intended for slaughter as calves (Decision 94/433/EC).

Cows—female bovine animals that have already calved (Decision 94/433/EC).

Cows, dairy—cows that are kept exclusively or principally to produce milk for human consumption and/or for processing into dairy products. Includes cull dairy cows (whether or not they are fattened between their last lactation and slaughter) (Decision 94/433/EC).

Day-old chicks—all poultry less than 72 hours old, not yet fed; however, Barbary ducks may be fed (Directive 2009/158/EC).

Epidemiological unit—group of animals that is of epidemiological importance in terms of the transmission and maintenance of infection.

Ewes, milk—ewes that are kept exclusively or principally to produce milk for human consumption and/or processing into dairy products. This includes cast milk sheep (whether fattened or not between their last lactation and slaughtering).

Ewes, other—ewes other than milk ewes, to be included in production animals.

Ewes and ewe lambs put to the ram—females of the ovine species that have already lambed at least once, as well as those that have been put to the ram for the first time.

Flock—all poultry of the same health status kept on the same premises or in the same enclosure and constituting a single epidemiological unit; in the case of housed poultry, this includes all birds sharing the same airspace (Regulation (EC) No 2160/2003[52]).

Goats—domestic animals of the species *Capra*.

Hatching eggs—eggs for incubation, laid by poultry (Directive 2009/158/EC).

Heifers—female non-calf bovine animals which have not yet calved (based on Decision 94/433/EC).

Heifers for breeding purposes—heifers raised for breeding and intended to replace cows.

Heifers for slaughter—heifers bred for meat production (Decision 94/433/EC).

[49] Council Directive 92/102/EEC of 27 November 1992 on the identification and registration of animals. OJ L 355, 5.12.1992, p. 32–36.
[50] Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs. OJ L 343, 22.12.2009, p. 74–113.
[51] Commission Decision 94/433/EC of 30 May 1994 laying down detailed rules for the application of Council Directive 93/24/EEC as regards the statistical surveys on cattle population and production, and amending the said Directive. OJ L 179, 13.7.1994, p. 27–32.
[52] Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of *Salmonella* and other specified food-borne zoonotic agents. OJ L 325, 12.12.2003, p. 1–15.

Herd—an animal or group of animals kept on a holding as an epidemiological unit (Regulation (EC) No 2160/2003); if more than one herd is kept on a holding, each of these herds shall form a distinct unit and shall have the same health status (Directive 64/432/EEC).

Holding—any establishment, construction or, in the case of an open-air farm, any place in which animals are held, kept or handled (Directive 92/102/EEC).

Lambs—male or female sheep under 12 months of age.

Meat production animals (bovines)—bovine animals, other than calves, kept exclusively for the production of meat and including cows, heifers and bulls.

Milk production holding—establishment where one or more farmed animals are kept to produce milk with a view to placing it on the market as food (Regulation (EC) No 853/2004).

Ovine or caprine animals for breeding—ovine and caprine animals other than animals for slaughter or animals for fattening intended to be transported to the place of destination, either directly or via an approved assembly centre, for breeding and production purposes (Directive 91/68/EEC).

Ovine or caprine animals for fattening—ovine and caprine animals other than animals for slaughter or ovine and caprine animals for breeding intended to be transported to the place of destination, either directly or via an approved assembly centre, in order to be fattened for subsequent slaughter (Directive 91/68/EEC).

Pigs—domestic animals of the species *Suis*.

Controlled housing conditions (**in integrated production systems for pigs)—**a type of animal husbandry in which swine are kept at all times under conditions controlled by the food business operator with regard to feeding and housing (Commission Regulation (EC) No 2075/2005).

Poultry—fowl, turkeys, guinea fowl, ducks, geese, quails, pigeons, pheasants and partridges reared or kept in captivity for breeding, the production of meat or eggs for consumption, or for restocking supplies of game (Directive 2009/158/EC).

Productive poultry—poultry 72 hours old or more, reared for the production of meat and/or eggs for consumption or for restocking supplies of game (Directive 2009/158/EC).

Period:

- **Rearing period—**the period in which birds are reared for production purposes. For laying hens this period starts when the chickens are one day old and ends when they enter the laying phase at 18 weeks, whereas for broilers this period starts when the chickens are one day old and ends when they are one week old.
- **Production period—**the period wherein birds are productive. For laying hens this period starts when they enter the laying phase at 18 weeks and ends 3 weeks before slaughter, whereas for broilers this period starts when the chickens are 1 week old and ends when they are slaughtered (usually at 6 weeks).
- **Before slaughter—**the period just before sending animals to slaughter (typically two or three weeks before).

Sheep—domestic animals of the species *Ovis*.

Spent hens—hens that do not adequately perform their duty of breeding or egg laying.

Steers—male bovine animals castrated before sexual maturity.

Appendix G – Definitions of feedingstuffs

Compound feedingstuffs—mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feedingstuffs (Regulation (EC) No 767/2009[53]).

Cereal grains, their products and by-products (Regulation (EC) No 767/2009)**:**

- Oats (and derived)—oats; oat flakes; oat middlings; oat hulls; oat bran.
- Barley (and derived)—barley; barley middlings; barley protein.
- Rice (and derived)—rice, broken; rice bran (brown); rice bran (white); rice bran with calcium carbonate; fodder meal of parboiled rice; ground fodder rice; rice germ expeller; rice germ, extracted; rice starch.
- Rye (and derived)—rye; rye middlings; rye feed; rye bran.
- Wheat (and derived)—wheat; wheat middlings; wheat feed; wheat bran; wheat germ; wheat gluten; wheat gluten feed; wheat starch; pre-gelatinised wheat starch.
- Maize (and derived)—maize; maize middlings; maize bran; maize germ expeller; maize germ, extracted; maize gluten feed; maize gluten; maize starch; pre-gelatinised maize starch.
- Other—millet; sorghum; spelt; triticale; malt culms; brewers' dried grains; distillers' dried grains; distillers' dark grains.

Feed (or feedingstuff)—any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals (Regulation (EC) No 178/2002).

Feed materials—various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding, either directly as such or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures (Regulation (EC) No 767/2009).

Fish, other marine animals, their products and by-products—fish meal; fish solubles, condensed; fish oil; fish oil, refined, hardened (Directive 96/25/EC).

Forages and roughage—lucerne meal; lucerne pomace; lucerne protein concentrate; clover meal; grass meal; cereal straw, treated**;** cereal straw (Regulation (EC) No 767/2009).

Land animal products—meat meal; meat and bone meal; bone meal; greaves; poultry meal; feather meal, hydrolysed; blood meal; animal fat (Regulation (EC) 767/2009)

Legume seeds, their products and by-products—chickpeas; guar meal, extracted; ervil; chickling vetch; lentils; sweet lupins; beans, toasted; peas; pea middlings; pea bran; horse beans; monantha vetch; vetches (Regulation (EC) No 767/2009).

Milk products—skimmed-milk powder; buttermilk powder; whey powder; whey protein powder; casein powder; lactose powder; whey powder, low in sugar (Regulation (EC) No 767/2009).

Oil seeds, oil fruits, their products and by-products (Regulation (EC) No 767/2009)**:**

- Groundnut derived—groundnut, partially decorticated, expeller; groundnut partially decorticated, extracted; groundnut, decorticated, expeller; groundnut decorticated, extracted.
- Rape seed derived—rape seed; rape seed expeller; rape seed, extracted; rape seed hulls.
- Cotton seed—cotton seed; cotton seed, partially decorticated extracted; cotton seed expeller.
- Copra expeller derived—copra expeller; copra, extracted.

[53] Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC. OJ L 229, 1.9.2009, p. 1–28.

- Palm kernel expeller derived—palm kernel expeller; palm kernel, extracted.
- Soya (bean), toasted—soya (bean), toasted, soya (bean), extracted, toasted; soya (bean), dehulled, extracted, toasted; soya (bean) protein concentrate; soya (bean) hulls.
- Sunflower seed—sunflower seed; sunflower seed, extracted; sunflower seed, partially decorticated, extracted.
- Linseed derived—linseed; linseed expeller; linseed, extracted.
- Other—safflower seed, partially decorticated, extracted; niger seed expeller; olive pulp; sesame seed expeller; cocoa bean, partially decorticated, extracted; vegetable oil; cocoa husks.

Other seeds and fruits, their products and by-products—carob pods; citrus pulp; fruit pulp; tomato pulp; grape pulp; grape pips, extracted; grape pips (Regulation (EC) No 767/2009).

Other plants, their products and by-products—(sugar) cane molasses; (sugar) cane vinasse; (cane) sugar; seaweed meal (Regulation (EC) No 767/2009).

Tubers, roots, their products and by-products—(sugar) beet pulp; (sugar) beet molasses; (sugar) beet pulp, molassed; (sugar) beet vinasse; (beet) sugar; sweet potato; manioc; manioc, starch, puffed; potato pulp; potato starch; potato protein; potato flakes; potato juice condensed; pre-gelatinised potato starch (Regulation (EC) No 767/2009).

Appendix H – Regional reporting scenarios

According to the level of detail available, the following scenarios are possible:

In the following examples, it is assumed that Country 'X' (NUTS_LEVEL_1) has 5 regions (NUTS_LEVEL_2) and 100 provinces (NUTS_LEVEL_3).

Scenario 1

Only data at country level are available:

		Tested	Positive
Row 1	'Country X' (from NUTS_LEVEL_1)	20	8

Scenario 2

Data at country level and data for all regions are available:

		Tested	Positive
Row 0	'Country X' (from NUTS_LEVEL_1)	20	8
Row 1	Region 1 (from NUTS_LEVEL_2)	7	2
Row 2	Region 2 (from NUTS_LEVEL_2)	5	2
Row 3	Region 3 (from NUTS_LEVEL_2)	2	2
Row 4	Region 4 (from NUTS_LEVEL_2)	4	0
Row 5	Region 5 (from NUTS_LEVEL_2)	2	2

Scenario 3

Data at country level and data for some regions and some provinces are available:

		Tested	Positive
Row 1	'Country X' (from NUTS_LEVEL_1)	20	8
Row 2	Region 1 (from NUTS_LEVEL_2)	7	2
Row 3	Region 2 (from NUTS_LEVEL_2)	5	2
Row 4	Region 3 (from NUTS_LEVEL_2)	2	2
Row 5	Province/City A (from NUTS_LEVEL_3)	2	1
Row 6	Province/City B (from NUTS_LEVEL_3)	3	1

Please note that, in scenario 3, Region 4 and Region 5 are not reported as data are not available.

Abbreviations

AFNOR	Association française de Normalisation
BSE	bovine spongiform encephalopathy
BST	brucellosis skin test
CCP	critical control points
CEN	European Committee for Standardization
CFT	complement fixation test
cfu	colony-forming unit
DCF	Data Collection Framework
DIN	Deutsches Institut für Normung
DNA	deoxyribonucleic acid
EBLV	European bat *Lyssavirus*
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EEC	European Economic Community
EFSA	European Food Safety Authority
ELISA	enzyme-linked immunosorbent assay
EMA	European Medicines Agency
EN	European Norm
EU	European Union
EURL	European Union Reference Laboratory
FAT	fluorescent antibody test
FISH	fluorescence *in situ* hybridisation
HACCP	Hazard Analysis Critical Control Point
HPLC	high-performance liquid chromatography
IB	immunoblotting
ICH	immunohistochemistry
IFA	immunofluorescence assay test
IFAT	immunofluorescence antibody test
Ig	immunoglobulin
IHA	indirect haemagglutination test
ISO	International Organization for Standardization
LAT	latex agglutination test
MAC-ELISA	IgM-capture ELISA

MAT	modified agglutination test
MICROVAL	European Validation and Certification Organisation
MRT	milk ring test
MS	Member State of the European Union
MSRV	Rappaport–Vassiliadis medium semi-solid modified
NEN	Dutch Standardization Institute
NMKL	Nordic Committee on Food Analysis
NUTS	Nomenclature of Territorial Units for Statistics
OBF	Officially Brucellosis Free
ObmF	Officially *Brucella melitensis* Free
OIE	World Organisation for Animal Health
OTF	Officially Tuberculosis Free
PCR	polymerase chain reaction
RABV	rabies virus
RBT	Rose Bengal test
RT-PCR	reverse transcription polymerase chain reaction
SAT	slow agglutination test
TSE	transmissible spongiform encephalopathies
STEC	Shiga toxin-producing *Escherichia coli*
Stx	Shiga toxin
VT	verotoxigenic
VTEC	verotoxigenic *Escherichia coli*
WHO	World Health Organization
WNV	West Nile virus
XML	Extensible Markup Language