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Manual for Reporting on Zoonoses, Zoonotic Agents and Antimicrobial Resistance in the framework of Directive 2003/99/EC and of some other pathogenic microbiological agents for information derived from the year 2010[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This Reporting Manual provides guidance for reporting on zoonoses, zoonotic agents and antimicrobial resistance in animals, food and feed under the framework of Directive 2003/99/EC. Some advice is also given on reporting on other pathogenic microbiological agents in food. The objective is to harmonise and streamline the reporting made by the Member States in a way that the data collected would be relevant and easy to be analysed at the European Union level. The manual covers all the agents and items included by the current data collection through the web-based reporting system run by the European Food Safety Authority. Detailed guidelines are provided for reporting of the data in the tables and text forms. This guidance typically applies to the agents, animal species and food categories to be reported on. Instructions are given on description of the sampling and monitoring schemes as well as analyses of the results in the national reports. Special reference is made to fields were following of trends would be desirable. This manual is specifically aimed to guide the reporting of information deriving from the year 2010.

KEY WORDS

Animal population, foodstuff, trend analysis, sample size, zoonotic agent.

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2 Correspondence: zoonoses@efsa.europa.eu

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SUMMARY

This Reporting Manual provides guidance for reporting on zoonoses, zoonotic agents and antimicrobial resistance in animals, food and feed under the framework of Directive 2003/99/EC. Some advice is also given on reporting of other pathogenic microbiological agents in food. The objective is to harmonise and streamline the reporting made by the Member States in a way that the data collected would be relevant and easy to be analysed at the European Union level. The manual is in particular intended to be used when reporting the data through the web reporting application run by the European Food Safety Authority.

The manual covers all the agents and items included by the current data collection through the web-based reporting system. This includes animal populations, antimicrobial resistance as well as bovine tuberculosis, bovine, ovine and caprine brucellosis, *Salmonella*, *Campylobacter*, *Listeria*, *Yersinia*, verotoxigenic *Escherichia coli*, MRSA, Q fever, *Trichinella*, *Echinococcus*, *Toxoplasma*, *Cysticercus,* and rabies, in animals, food and feed. Also data on some microbiological contaminants, such as staphylococcal enterotoxins, *Cronobacter sakazakii* and histamine, is covered by the manual.

Detailed guidelines are provided for reporting of the data in the tables and text forms of the web reporting application. 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 as well as on the reporting on antimicrobial resistance.

Instructions are given on description of the sampling and monitoring schemes as well as analyses of the results in the national reports. Special reference is made to fields were following of trends would be desirable at the European Union level and where Member States are encouraged to provide data on a regular basis.

This manual is specifically aimed to guide the reporting of the information deriving from the year 2010.

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1. Introduction

Monitoring of zoonoses, antimicrobial resistance and food-borne outbreaks

The European Union (EU) system for monitoring and collection of information on zoonoses is established by Directive 2003/99/EC[4] on the monitoring of zoonoses and zoonotic agents. This Directive requires Member States (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 used is based on that of the MSs, and in a few cases it is harmonised by EC legislation to the extent that the results from the monitoring are comparable between the MSs.

It should be noted that data on zoonoses cases in humans are provided through the EU network for the epidemiological surveillance and control of communicable diseases established under Decision No 2119/98/EC[5].

The MSs have to send their national report on zoonoses to the EC each year by 31st May. The EC shall submit this information to the European Food Safety Authority (EFSA), which shall examine the data and publish the EU Summary Report from the results. The Summary Report is prepared in collaboration with the European Centre for Disease Prevention and Control (ECDC) and EFSA's Zoonoses Collaboration Centre (ZCC).

For the food-borne outbreaks there is an own specific reporting manual and therefore food-borne outbreaks are not covered by this document.

Monitoring of other pathogenic microbiological agents in foodstuffs

On the request of the EC, reporting of some non-zoonotic pathogenic microbiological agents in foodstuffs should take place in connection 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 set down for these agents by Regulations (EC) No 2073/2005[6] and No 1441/2007[7] are being met.

Web-based reporting system

EFSA has established a web-based reporting system and database to streamline and harmonise the reporting under Directive 2003/99/EC. This system shall be used for the purpose of reporting and it is accessible on the following website: http://www.efsa.europa.eu/zoonoses

[4] OJ L 325, 12.12.2003, p. 31.
[5] OJ L 268, 3.10.1998, p. 1.
[6] OJ L 338, 22.12.2005, p. 1.
[7] OJ L 322, 7.12.2007, p. 12.

2. General guidelines for reporting

Structure of the zoonoses web-based reporting system

For each reporting year, a national report is created in the web-based reporting system. For each zoonoses or other subject, text forms and reporting tables are provided. The text forms are used to enter the narrative part of the report, *e.g.* description of the monitoring system and the analyses of the results. The reporting tables are used to enter the results, *e.g.* number of samples tested and number of positive results.

Detailed instructions on how to use the text forms and reporting tables as well as the entire web application are given in the user manuals on the web-based reporting system homepage (http://www.efsa.europa.eu/zoonoses).

Mandatory reporting and reporting based on 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 1) 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*;
- Antimicrobial resistance in *Salmonella* and *Campylobacter* isolates from poultry, pigs and cattle and foodstuffs derived from these species;
- Food-borne outbreaks;
- Susceptible animal populations.

Other zoonoses are to be included in the monitoring and reporting 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 in their MSs.

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

Viral zoonoses:

- Calicivirus;
- Hepatitis A virus;
- Influenza virus;

- Rabies;
- 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 in point A;
- 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 non-zoonotic pathogenic microbiological and toxicological agents in foodstuffs includes *Enterobacter sakazakii*, staphylococcal enterotoxins and histamine. The reporting of these agents is made on a voluntary basis.

At present, the web-based reporting system provides default tables and text forms for all the zoonoses to be reported on a mandatory basis and in addition for *Yersinia, Toxoplasma, Staphylococcus,* rabies and *Coxiella burnetii*, antimicrobial resistance in *E. coli* and *Enterococci*, food-borne outbreaks as well as for *Enterobacter sakazakii*, staphylococcal enterotoxins and histamine.

If any zoonoses or microbiological agent other than those mentioned above are to be reported, the necessary tables and text forms can be created in the web application by using the "*Report structure*" tool.

The requirements for the content of annual reports on zoonoses are laid down in Annex IV of Directive 2003/99/EC.

Reporting of BSE and other TSE diseases and of Avian Influenza takes place directly to the Commission on the basis of Regulation (EC) No 999/2001[8] and Commission Decision 2004/111/EC[9], respectively.

[8] OJ L 147, 31.5.2001, p. 1.
[9] OJ L 32, 5.2.2004, p. 20.

2.1. General guidelines on reporting the results in prevalence tables

General recommendations

The results (data) of investigations are reported in tables provided in the web-based reporting system. The types of data that are reported in the tables are mostly numerical, but also text type information can be requested for certain table cells.

In the tables, comments may be added to each reporting row, so as to provide additional general information. All tables have options for adding additional zoonotic agent species or serotypes, as well as additional categories of foodstuffs, animal species, feedingstuffs and antimicrobials.

When no data are available no value should be entered in the tables, not even the zero ("*0*") value. The zero value "*0*" may only be entered in instances of true zero results, *e.g.* no positive results from a number of units tested. Also, when reporting is optional and one decides not to report data, no value should be entered in the tables.
In case there is no relevant information to be reported on or if the MS wishes not to report any data, the table should be left empty and marked as complete (see the user manual for the web-based reporting system) in order to indicate that no data will be submitted.

However, when no positive units have been detected out of the units tested in the context of the investigations, a "0" (zero) should always be inserted in the column "Total units positive for Agent spp." to indicate the testing results.

In the following zoonoses/agent specific chapters the animal species/ food categories particularly recommended to be reported on are indicated by bold text.

Prevalence tables for food, animals and feedingstuffs

The prevalence tables are used to report the prevalence of zoonotic agents in food, animals and feedingstuffs.

Information requested in the rows
In the rows, data on foodstuffs, animals and feedingstuffs should be categorised using the classification system provided by the pick list. Obviously, there will be variability in the degree of detail which can be provided, however reporters are encouraged to provide as much relevant information as possible within the limits of the system.

MSs are asked to avoid a double reporting into different category levels, i.e. data reported both in the total and in the detailed categories. E.g. if out of 100 pig herds 20 are breeding herds and 60 are fattening herds and no detailed information is provided for the remaining 20

herds, data should be reported as follows: 20 breeding pig herds, 60 fattening pig herds, 20 unspecified pig herds and not as: 100 pig herds, 20 breeding pig herds, 60 fattening pig herds.

- **Food and feedingstuff categories -** for the specification of the food and feedingstuffs, the pick list categories at level 1 provide for a high level categorization of foodstuffs, while levels 2, 3 and 4 allow for the reporting of more detailed information on the foodstuff. For example:
  "Meat from bovine animals / meat preparation / raw but intended to be eaten cooked";
  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*". This '*Unspecified*' option should only be used when there is a specific need and no other option is available;
- **Animal species -** for the specification of the animal species, the categories at level 1 provide the name of the animal species, while levels 2, 3 and 4 allow for the reporting of more detailed breakdown information, such as the type of animals (wild, farmed, pet), production category (breeding, fattening animals), production period (during rearing period, adult), production system and housing conditions (outdoor, indoor, raised under controlled housing conditions in integrated production system), age (piglets, gilts, sows). For example: "*Gallus gallus* (fowl) / *laying hens / day-old chicks*".
- **Sampling stage** - to allow for comparability, data on the place or stage of sampling is reported by using the four level classification system provided in the pick list. The categories at level 1 provide a list of main "*Places*" or "*Stages*" at which samples may be taken *e.g.* at farm, slaughterhouse, retail; whereas level 2 and 3 provide the subcategories which allow for further characterization of the sample category (i.e. animal or environmental sample) and the sample type (i.e. faeces, lymph nodes), respectively. An example is: "*At farm / animal sample/ faeces*";
- **Sampling context** - The information on the context of sampling (e.g. monitoring, official controls) is reported by using the three level classification system in the pick list. Level 1 category provides a list of sampling programmes (*e.g.* control and eradication programmes, monitoring). Level 2 and 3 categories provide a list of options for reporting on who performs the sampling (*i.e.* competent authority (official sampling) or industry (HACCP or own checks)) and the type of sampling (i.e. objective, selective, suspect, convenience or census sampling);
- **Sampling details** – free text field that can be used to give further information on the sampling stage or context or other further information in brief.

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 boars (to be reported under the_level_2 of the pick list for animal species);

• The stage along the food chain where samples have been collected;

• The type of sampling carried out, under level 3 of the Sampling context pick list (e.g. objective, selective, suspect sampling), in order to make clear if samples are representative of the national population;

• The type of diagnostic/analytical test (e.g. bacteriology or serology) used and/or on the specific method used (e.g. ISO method), when relevant to the interpretation of the results. This information can be given in the comments or footnote.

Information requested in the columns

- **Source of information** - the Institute (or laboratory) that has provided the data. Abbreviations should be clarified in the comments section or in the footnote unless already described in the "*Institute and laboratory List*" under "*Edit report details*";
- **Sampling unit** - for foodstuffs and feedingstuffs the terms "S*ingle*" and "*Batch*" are used. For animals, the sampling unit may be "*Animal*", "*Flock*", "*Holding*", "*Herd*" or "*Slaughter batch*";
- **Sample weight -** the weight (in grams or millilitres) of the specimen used in the laboratory for analysis *e.g.* 25g, 10g, etc.; for carcass swabs the area sampled could be reported (e.g. 100 cm^2);
- **Units tested -** the number of sampling units that are analysed in the laboratory, or tested in other 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; the value "unknown" is to be used when the number of units is not available;
- **Total units positive for Agent spp.** - in this column the total number of sampling units considered infected (contaminated) based on the testing results should be inserted. In case no positive units were detected, a "*0*" (zero) should be inserted;
- **Agent a, Agent b, … agent species / serotypes /serovars columns** - in these columns the breakdown of the positive units for the specific agent species / serotypes / serovars is to be reported, where this information is available. In each column the number of sampling units positive for the specific agent species / serotype / serovars is indicated;
- **Agent *spp*., unspecified** - in this column one should report the number of sampling units positive for the zoonotic agent where the species / serotype / serovar is unknown for whichever reason (*e.g.* untypeable serotypes or when information is not available). If no breakdown of the positive sampling units to agent species or serotypes or

serovars is given, one should enter in the "unspecified" column the same figure as in the "total units positive" column.

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

Information that could be reported in the table columns (such as agent species) should not be reported in the comments or footnote in order not to make the data extractions difficult.

2.2. General guidelines on reporting the narrative part in the text forms

The narrative part should include the description of the monitoring and / or control system from which the data is derived. This information enables the understanding and interpretation of the results in the right framework. The description should be detailed enough to give an accurate picture of the monitoring and control activities in place and to facilitate, when 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 the trend. The sources of zoonotic agents are 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 provided in the web-based reporting system are used. The information is entered in the text fields bearing the titles listed below.

The information below is recommended to be given under each title.

A. Monitoring system

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

- First of all, it is useful to state if the sampling covered the whole MS or only parts of it;
- The target population is identified. To that end, 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 that were sampled are identified;
- If the sampling is stratified, for example, by geographical regions or other criteria, such as size of the holdings, this should be described;
- It is important to explain how the units to be sampled are chosen, whether it is a question of objective, selective, suspected, convenience or census sampling or a combination of them;
- One should specify who is performing the sampling, *e.g.* samples taken by the competent authority as part of an official sampling, samples taken by owners of animals, food or feed businesses, or by other representatives of private enterprises, in the context of HACCP / own checks;
- It is also essential to explain where the samples are taken, *e.g.* at farm, at slaughterhouse, at hatchery, at food processing plant or at retail. Equally important is the stage of sampling, which can be any step in animal rearing process or the food chain. For example, it may be animal rearing period, production period, before or after

chilling of carcase in the slaughterhouses, before or after the expiration of the shelf-life of foodstuffs;

- The framework of the sampling is an important part of the strategy, and, to this end, it should be stated if the sampling is part of a permanent or temporary monitoring programme, linked to surveillance or control programmes or if it is a question of a single survey.

Frequency of the sampling - this part is intended to explain how often samples are taken. The standard terms (*e.g.* every week, once a month, *x* times a year) provided on the pick list in the text forms should be used when possible. A more general statement can also be used, such as "*Detection of annual prevalence of xx by yy % confidence level and zz % accuracy*".

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

Methods of sampling (description of sampling techniques) - the sampling techniques, meaning the procedures how the sample is technically taken, are described. This should include information on the site of sampling (*e.g.* part of a carcase, part of the facilities for environmental sample), size of sample taken (*e.g.* in g, cm², ml), use of swabs or other instruments in the sampling, when relevant, the number of (sub)samples / sample units taken, pooling of samples when conducted (always refer the number of samples combined by pooling), the possible storage of samples and the length of this storage.

Case definition / definition of a positive sample - 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.

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 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. Annex I 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. It may also be that there is no official policy regarding vaccination. If a vaccination policy exists, it should be described and 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.

Other preventive measures than vaccination in place - other preventive 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 the foodstuffs, it may include, for example, prohibition to market unpasteurised milk and recommendations on food consumption for susceptible consumer groups.

B. 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 Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field[10]. Control programmes run by the industry / food business operators are also included. The nature of the control programmes, *e.g.* voluntary, mandatory, national, regional, EU or national approval and co-financing should be indicated. 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 in meat inspection. The relevant legislation should be mentioned.

Measures in case of the positive findings or single cases - actions required by the legislation or control programmes as a consequence of findings of positive animals, foodstuffs or feedingstuffs are 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 notifiable.

Recent actions taken to control the zoonoses - specific measures undertaken during the recent years to contain zoonoses are described. In case of measures initiated in previous years, the year in which measures started to be applied should be indicated. These actions

[10] OJ L 155, 18.6.2009, p. 30–45

can 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 at the EU level. Typically, this could involve suggestions for new EU legislation.

C. Results of the investigation

The results reported and presented in the reporting tables are summarised. The important findings and the relevant conclusions based on the results are 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 to the previous year, when there is a decreasing or increasing trend or is the situation stabilized. The important sources of infections are also discussed.

Relevance of the findings in feedingstuffs / animals / foodstuffs and to human cases (as a source of infection) - in the light of the results reported, the importance of the feedingstuffs / animals / foodstuffs as sources of the human infections is 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 are considered, as well.

History of the disease and / or infection in the MS - the history of the zoonoses cases in humans and animals in the past is reflected under this title. For example, issues such as 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

Susceptible animal population table - in this table, 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:

In the columns, one specifies:

- **Number of herds or flocks** - the number of existing herds or flocks of farm animals;
- **Number of holdings** - the number of existing holdings rearing farm animals;
- **Livestock numbers (live animals) -** the number of live animals;
- **Numbers of slaughtered animals** - the total number of slaughtered animals.

In case the information derives from previous years, the relevant year should be indicated in the specific table column named "*Year"*.

The numbers are specified for the relevant animal species and animal species categories, as indicated in the row headings. In the rows named "*in total*", the accumulated sum for the animal species subcategories may be indicated, when possible.

The nature of the data should be indicated, if 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 of the year. This can be done either in footnotes or in the text form.

In the **text form for susceptible animal populations**, one specifies:

- **Sources of information** – in this field, the origin of the reported figures is indicated, *e.g.* official statistics, institutions involved, etc.;
- **Dates the figures relate to and the content of the figures** – dates from which the information derives and what the figures represent, *e.g.* the number of animals at a certain time point of the year, an average population during the year, the number of slaughtered animals in a 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 they differ from those given in Annex II of this manual or on the web-based reporting system;
- **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 them are reflected, for example, related to the national consumption of food of animal origin;

- **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.

4. Reporting on tuberculosis and brucellosis in animals

For the purpose of following trends the information to be reported each year is:
- infected / positive herds for bovine tuberculosis
- infected / positive herds for bovine brucellosis
- infected / positive herds for ovine/caprine brucellosis

4.1. Bovine tuberculosis and tuberculosis in farmed deer

Relevant animal species to be reported on

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

Relevant agent species to be reported

The report is focused on *Mycobacterium bovis*. According to the epidemiological situation, also *M. tuberculosis, M. caprae* and *M. africanum* may be reported.

Description of the monitoring and control system

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

- For the non-Officially Tuberculosis Free (non-OTF) countries, the eradication, control and surveillance programmes in place to combat the disease;
- For Officially Tuberculosis Free (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 on regional level, if appropriate.

Reporting on the status as officially free

According to Council Directive 64/432/EEC[11], regions or MSs can be OTF and therefore MSs and regions can be classified in 3 categories for reporting purposes:

- OTF MS or region, meaning a MS or part of a MS which has been found to fulfil the conditions laid down in Annex A.I, paragraphs 4 and 5 of the amended Council Directive 64/432/EEC and has been declared OTF accordingly;
- Non-OTF with eradication programmes receiving EU co-financing;
- Non-OTF with eradication programmes that do not receive EU co-financing.

The MSs themselves fall into three categories as well:

- MS where the whole country is OTF;
- MS where part of the regions are OTF and part non-OTF;
- MS where the whole country is non-OTF.

[11] OJ 121, 29.7.1964, p. 1977.

Type of specimen taken / methods of sampling

Abnormal lymph nodes and parenchymatous organs (e.g. lungs, liver and spleen) are typically sampled in case 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 case of 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 II of Decision 2002/677/EC[12].

Positive animal - animal with positive reaction to an official diagnosis method specified in Annex B of Council Directive 64/432/EEC. In MS 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 in this period, as defined in Annex II to Decision 2002/677/EC.

Diagnostic / analytical methods used

The methods to be used are laid down in Annex B of Council Directive 64/432/EEC: gamma-interferon assay (as referred in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* from OIE) and tuberculin skin test (single or comparative). A reference to the legislation is recommendable in case these methods have been used.

If other methods have been used, these diagnostic tests should be described, including the interpretation of results applied, *e.g.* stained smears or immunoperoxidase techniques followed by cultivation of the organism on primary isolation medium, determination of cultural and biochemical properties, PCR and genetic fingerprinting (Dir. 64/432/EEC).

Analyses of the results

The analyses should be preferably made both at regional and national level, when appropriate. Long term trends are highly recommended (for the last five years) and reflection on the sources of infection is of special interest.

Tuberculosis in farmed deer is reported in a similar table that the one used for non-OTF with eradication programmes that do not receive EU co-financing.

- For reporting of data on farmed deer, use table named "*Tuberculosis in farmed deer*" and the definitions / instructions applied to bovine tuberculosis; for reporting of data on other animal species, use table named "*Tuberculosis in other animals*".

[12] OJ L 229, 27.8.2002, p. 24.

4.2. Bovine brucellosis

Relevant animal species to be reported on

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

Relevant agent species to be reported

Brucella abortus, B. melitensis, B. suis, B. canis.

Description of the monitoring and control system

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

- For the non-Officially Brucellosis Free (non-OBF) MS, the eradication, control and surveillance programmes in place to combat the disease;
- In case of Officially Brucellosis Free (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;
- Preventive 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 on a 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 MS could be classified in following 3 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 A II, paragraphs 7, 8 and 9 of Council Directive 64/432/EEC and has been declared OBF accordingly;
- MS non-OBF with eradication programmes that have received EU co-financing;
- MS non-OBF with eradication programmes that do not receive EU co-financing.

The MSs themselves fall in three categories as well:

- MS where the whole country is OBF;
- MS where part of the regions are OBF and part non-OBF;
- MS 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;
- Milk for pooled milk samples (ELISA, 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.

Positive animal - animal with positive reaction to an official diagnosis 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 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), RBT, SAT, CFT, MRT. If other complementary tests are used, such as BST, cELISA 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 recommendable in case 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.

4.3. Ovine and caprine brucellosis

Relevant animal species to be reported on

Sheep and goats.

Relevant agent species to be reported

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

Description of the monitoring and control system

It is recommendable to provide a description of eradication or surveillance systems, including:

- For the non-Officially *B. melitensis* Free (non-OBmF) MSs, the eradication, control and surveillance programmes in place to combat the disease;
- In case of Officially *B. melitensis* Free (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;
- Preventive 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 3 categories:

- OBmF MS or region - any MS or region within the meaning of Article 2 (10) of the amended Council Directive 91/68/EEC[13] may be recognized as being officially free under the procedure laid down in Article 15;
- Non-OBmF, with control and eradication programmes that receive EU co-financing;
- Non-OBmF with control and eradication programmes that do not receive EU co-financing.

The MSs themselves fall in three categories as well:

- MS where the whole country is OBmF;
- MS where part of the regions are OBmF and part non-OBmF;
- MS where the whole country is non-OBmF.

[13] OJ L 46, 19.2.1991, p. 19.

Type of specimen taken / methods of sampling

Serum for serological test (RB, 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.

Positive animal – animal with positive reaction to an official diagnosis method specified in Annex C of Council Directive 91/68/EEC. In MS 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 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 recommendable in case these methods have been used.

If other methods have been used, such as BST 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 last five years evolution and information on sources of infection are of special interest.

4.4. Brucellosis in other animal species

Relevant animal and agent species to be reported on

It would be highly desirable, according to the epidemiological situation, to get information on *Brucella* isolations (*B. abortus*, *B. melitensis*, *B. suis*, *B. canis*) in wildlife (mainly ruminants, wild boars and hares), zoo animals, marine mammals, pet animals (mainly dogs used in herds / holding's management) and other farm animals (pigs).

Typical 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). For reporting data, use table named "*Brucellosis in other animals*".

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 tables

For reporting of data, use table named "*Brucellosis in other animals*".

Specific guidelines for entering data in the prevalence tables:

- **Sampling unit** - the sampling unit is typically "*Animal*", "*Herd"* or *"Holding" or "Slaughter batch";*
- **Total units positive for *Brucella* spp. -** in this column, the total number of sampling units considered infected based on the analyses results should be inserted;
- ***B. melitensis, B. b, B. c*** - number of units positive for *Brucella melitensis, or* other *Brucella* species, respectively;
- ***Brucella* spp. unspecified -** this is the column where to report the number of sampling units positive for *Brucella,* where the species is unknown. This column is only filled in when the other species columns are not used.

4.5. Guidelines for reporting tuberculosis and brucellosis results in the disease status tables

Disease status tables are provided for reporting on tuberculosis in bovine animals and brucellosis in bovine animals as well as in sheep and goat. Four types of tables exist:

- Tables for data on herds in EU co-financed programmes;
- Tables for data on animals in EU co-financed programmes;
- Tables for data on the status of herds at the end of reporting period in EU co-financed programmes;
- 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. The other MSs and regions use the tables for "*…countries and regions that do not receive EU co-financing for eradication programme*".

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

Information for rows and columns of tables for data on herds with EU co-financed eradication programmes

- **Region** – in this column the regions of the MS for which data is reported are indicated. If no regional information exists, the results from the whole MS are reported by adding a row "*Whole Country*". In the row "*Total*", the sum of the regional results are automatically calculated. In a MS that has an approved eradication programme, the term "*Region*" should be understood as defined in the programme;
- **Total number of herds** – the total number of existing herds in the region, including both eligible and non-eligible herds for the programme. Eligible herds are those for which the programme is compulsory to be applied. Non-eligible herds are those that can be excluded from the application of the programme;
- **Total number of herds under the programme** – herds under official control (by region in non-officially free MSs) are reported in this column.

  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 which are included into the control programmes should be here reported. For so, if all herds are routinely tested, this figure will be the total number of herds. Otherwise, the number of herds under the programme should be clearly stated;

- **Number of herds checked** – herds on which tests have been performed. Herds should not be counted twice even if they have been checked more than once;
- **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, one positive animal in this period;
- **Number of herds depopulated -** positive herds for which a stamping out policy has been applied;
- **Percentage (%) of positive herds depopulated –** this value is calculated automatically by the system and refers to the percentage of number of herds depopulated / number of positive herds;
- **Percentage (%) of herd coverage** – this value is calculated automatically by the system and refers to the percentage of number of herds checked / number of herds under the programme;
- **Percentage (%) of positive herds (period herd prevalence) -** this value is calculated automatically by the system and refers to the percentage of number of positive herds / number of herds checked under the programme;
- **Percentage (%) of new positive herds (herd incidence) -** this value is calculated automatically by the system and refers to the percentage of number of new positive herds / number of herds checked.

Information for rows and columns of tables for data on animals with EU co-financed eradication programmes

- **Region** – in this column the regions of the MS for which data is reported are indicated;
- **Total number of animals** – number of animals existing in the region, including those from both eligible and non-eligible herds for the programme;
- **Number of animals to be tested under the programme** – total number of animals under official control, including animals to be tested individually or under a bulk scheme level.

In officially free MSs or regions, usually all animals are under 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 into the control programmes should be here reported. 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 milk bulk tank);

- **Number of positive animals** - total number of animals tested with a positive result;
- **Number of animals with positive result, slaughtered or culled** – 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, inconclusive and also the negative animals slaughtered under the programme;
- **Percentage (%) of coverage at animal level –** this value is calculated automatically by the system and refers to the percentage of number of animals tested / number of animals under the programme;
- **Percentage (%) of positive animals (animal prevalence)** - this value is calculated automatically by the system and refers to the percentage of number of positive animals / number of animals tested.

Information for rows and columns of tables for data on status of herds with EU co-financed eradication programmes at the end of the period

- **Region** – in this column the regions of the MS for which data is reported are indicated;
- **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 are included;
- **Unknown (status of herds/animals under the programme)** – 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 are included.

Guidelines for reporting on other columns and rows of these tables are given in the following chapters, as the information requested is specific for each zoonosis.

Specific guidelines for Bovine Tuberculosis

The following definitions are to be used when filling in the table named "*Bovine tuberculosis - data on status of herds at the end of the period - Community co-financed eradication programmes*":

- **Herds, Officially Tuberculosis Free (OTF)** - bovine herds that satisfy the conditions laid down in paragraph I. 1. and 2. of Annex A of Council Directive 64/432/EEC and that have been declared as such by the competent authority;
- **OTF herds with status suspended** - 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); 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;
- **Non-OTF herds with last check negative** - herds checked with negative results in latest check, but not being OTF;
- **Non-OTF herds with last check positive** - herds checked with at least one positive result in the latest check.

The following definitions are to be used when filling in the table named "*Bovine tuberculosis in countries and regions that do not receive Community co-financing for eradication programme*":

- **Infected herds (bovine herds infected with tuberculosis)** - all herds under control which are non-OTF at the end of the reporting period. This figure summarises the results of different activities (tuberculin testing, meat inspection, follow up investigations, tracing);
- **Interval between routine tuberculin tests (by region)** - no routine test (a); once a year (b); every two years (c); every three years (d); every three years concerning 24 month-old animals (e); every four years (f); others, please specify (g);
- **Number of animals tested (in routine tuberculin testing)** – 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 tuberculin testing is not performed yearly, only those animals tested during the reporting period should be stated;
- **Number of tuberculin tests carried out before the introduction into the herds** – detailed regional information is required, unless the officially 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** – in this column, 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 evidenced 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** - 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.

Specific guidelines for Bovine Brucellosis

The following definitions are to be used when filling in the table named "*Bovine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes*":

- **Officially Brucellosis Free (OBF) bovine herds – bovine herds that satisfy the conditions lay down in Annex A II, paragraphs 1 and 2 of Council Directive 64/432/EEC, and that have been declared as such by the competent authority;**
- **Free bovine herds** - bovine herds that satisfy the conditions laid down in Annex A II, paragraphs 4 and 5 of Council Directive 64/432/EEC and that have been declared as such by the competent authority;
- **Free or OBF bovine herds with status suspended** - bovine herds that fall under the conditions lay down in Annex A. II. Paragraphs 3A (Officially Free) and 6A (Free) of Council Directive 64/432/EEC and that have been declared as such by the competent authority;
- **Non-free or non-OBF herds with last check negative** - herds checked with negative results in latest check, but not being free or OBF;
- **Non-free or non-OBF herds with last check positive** - herds checked with at least one positive result in the last check.

The following definitions are used when filling in the table named "*Bovine Brucellosis data from countries and regions that do not receive Community co-financing*":

- **Numbers of (infected) herds** - in this column, report the total number of bovine herds under control which are non-free or non-OBF at the end of the reporting year. This figure summarises the results of different activities (notification of clinical cases, including abortions, routine testing, follow up investigations and tracing).

Under "*Surveillance*" column:

- **Number of bovine herds tested by serological tests** – total number of herds with animals tested individually with serological tests, as mentioned in Annex C of Council Directive 64/432/EEC performed;
- **Number of bovine herds tested (by examination of bulk milk samples)** – 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.

Under "*Investigations of suspect cases*" column:

- **Suspect case (herd / animal)** - herd in which, as a result of laboratory tests, clinical grounds or on official epidemiological investigations, one or more bovine animals are suspected of having brucellosis and the suspected animals have been slaughtered or isolated in a way to avoid any direct or indirect contact with the other animals;
- **Number of notified abortions whatever the cause** - abortions notified mandatory 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** – total number of isolations, species and serotypes of *Brucella* spp. resulting from abortions, according the proper identification methods as foreseen in Annex C of Council Directive 64/432/EEC;
- **Number of abortions due to *Brucella* infection**– total number of abortions from which *Brucella* spp. has been isolated;

- **Epidemiological investigation -** official investigation for brucellosis, comprising at least two serological blood tests, including the complement fixation test and a microbiological examination of appropriate samples;
- **Number of animals tested with serological blood test** – 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** – total number of OBF herds of origin or of transit of a suspected bovine animal, and herds linked epidemiologically to it;
- **(Number of positive animals for) BST** – total number of animals with positive results on the brucellosis skin test, as specified in paragraph 3 of Annex C of Council Directive 64/432/EEC;
- **(Number of positive animals) serologically –** 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 positive microbiologically** – total number of animals with a positive result on the exam described in paragraph 1 of Annex C of Council Directive 64/432/EEC for identification of the agent.

Specific guidelines for Ovine and Caprine Brucellosis

The following definitions are to be used when filling in the table named "*Ovine or Caprine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes*":

- **Officially *Brucella melitensis* Free (OBmF) ovine or caprine herds** - 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;
- **Free ovine or caprine herds** - ovine or caprine herds that satisfy the conditions laid down Chapter 2 of Annex A of Council Directive 91/68/EEC;
- **Free or OBmF ovine or caprine herds with status suspended** - 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;
- **Non-free or non-OBmF herds with last check negative** - herds checked with negative results in latest check, but not being free or OBF;
- **Non-free or non-OBmF herds with last check positive** - herds checked with at least one positive result in the last check.

The following definitions are used when filling in the table named "*Ovine or Caprine Brucellosis non co-financed*":

- **Number of animals in infected herds** - in this column, report total number of animals on herds under control that are non free or non OBF at the end of the reporting year. This figure summarises the results of different activities (notification

of clinical cases, including abortions, routine testing, follow up investigations, tracing).

Under "Surveillance" column:

- **Number of herds tested –** total number of herds on which animals over six months were tested in accordance with paragraph II 2 of Annex A of Council Directive 91/68/EEC;
- **Number of infected herds** – total number of herds tested with, at least, one animal with a positive result.

Under "*Investigations of suspect cases*" column:

- **Suspected case** - herd where one or more ovine or caprine animals are suspected of having brucellosis by clinical or any other signs (including serology), or herd on which appropriate epidemiological examinations are carried out following a finding of a confirmed case in another herd;
- **Number of animals positive serologically** – total number of investigated animals positive to a serological test;
- **Number of animals positive microbiologically** – total number of animals where the presence of *Brucella* has been confirmed following microbiological examination;
- **Number of suspended herds** – total number of herds for which an epidemiological investigation is being carried out.

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 2. or 3. years) is:

- *Salmonella* spp. and *S.* Enteritidis, *S.* Typhimurium, *S.* Hadar, *S.* Infantis, and *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 the mononophasic *Salmonella* Typhimurium strains should also be reported for the 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 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 if the EU *Salmonella* reduction target set by Commission Regulation (EC) No 1003/2005[14] for breeding flocks of *Gallus gallus* is met, one shall report the results separately at least for adult flocks, because the target is set for adult breeding flocks.

[14] OJ L 170, 1.7.2005, p. 12.

Please note that for the purpose of verifying if the EU *Salmonella* reduction target set by Commission Regulation (EC) No 1168/2006[15] for laying hen flocks of *Gallus gallus* is met, one shall report the results separately at least for adult flocks, because the target is set for adult laying hen flocks. Also, if results from other flocks 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 if the EU *Salmonella* reduction target set by Commission Regulation (EC) No 646/2007[16] for broiler flocks of *Gallus gallus* is met, one shall report separately the results from sampling within three weeks before the birds are moved to the slaughterhouse (=before slaughter), because the target is set for this period.

Please note that for the purpose of verifying if the EU *Salmonella* reduction target set by Commission Regulation (EC) No 584/2008[17] for turkey flocks is met, one shall report separately the results from breeding turkey flocks during production (adult flocks) and in case of the fattening turkey flocks the results from sampling within 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 spp. 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 ones covered by the target. Also monophasic *Salmonella* Typhimurium strains should be included.

For flocks of laying hens *S.* Enteritidis and *S.* Typhimurium should be reported separately due to the target set for these serovars. In addition it is recommended to report the 5 most frequent serovars and also always *S.* Infantis, *S.* Hadar and *S.* Virchow, even though these serovars may not be included in the top five serovars. Also monophasic *Salmonella* Typhimurium strains should be included.

In case of broiler flocks *S.* Enteritidis and *S.* Typhimurium should be reported separately due to the target set for these serovars. In addition it is recommended to report the 5 most frequent serovars and also always *S.* Infantis, *S.* Hadar and *S.* Virchow, even though these serovars may not be included in the top five serovars. Also monophasic *Salmonella* Typhimurium strains should be included.

[15] OJ L 211, 1.8.2006, p. 4.
[16] OJ L 151, 13.6.2007, p. 21.
[17] OJ L 162, 21.6.2008, p. 3.

In case of turkey breeding flocks and turkey fattening flocks *S.* Enteritidis and *S.* Typhimurium should be reported separately due to the target set for these serovars. Also monophasic *Salmonella* Typhimurium strains should be included. In addition, all other *Salmonella* serovars isolated from turkey flocks should be reported

When reporting the serovar distrubution in the table "*Salmonella* serovars in animals", the strains isolated in the context of "monitoring", "clinical", "surveillance" and "control programme" could be reported separately.

Data on monophasic *Salmonella* Typhimurium should be reported as following: this group comprises *Salmonella* Typhimurium strains lacking the second phase H antigen (1,4,[5],12:i:-). Whenever possible as much detail 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 phage type that is consistent with *S.* Typhimurium lacking phase two flagellar antigen has been confirmed, and the lack of the second flagellar antigen has been verified by PCR, then the term "monophasic *Salmonella* Typhimurium" is recommended to be used.

Information on the serovars covered by the EU reduction target for the specific animal populations should be always reported in the relative prevalence tables for the purpose of verifying the achievement of the reduction target. Please note that in case of turkeys, the target Regulation (EC) No 584/2008 request all serovars to be reported.

For the more general analysis of serovar distribution the table "*Salmonella* serovars in animals" is to be used. **Please note** that for the purpose of evaluating the distribution of *Salmonella* serovars along the food chain, mainly the data from the tables "*Salmonella* serovars in animals" and "*Salmonella* serovars in food" will be used.

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 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, hatched eggs, hatching eggs, meconium, and organs. Blood or eggs are collected in 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 the Commission Regulation (EC) No 1003/2005.
For laying hens it should be described whether the sampling was in accordance with the Annex of the Commission Regulation (EC) No 1168/2006.
For broilers, it should be indicated if the sampling was in accordance with the Annex of the Commission Regulation (EC) No 646/2007.
For turkeys, it should be indicated if the sampling was in accordance with the Annex of the Commission Regulation (EC) No 584/2008.

Case definition / definition of a positive sample

Positive flock / unit - flock which has had a positive result in a test performed under the programme or monitoring, *e.g.* where *Salmonella* spp. has been isolated or where the results of serological test indicate *Salmonella* infection of the flock. Each flock should be reported positive only once, irrespective how many positive samples were received.

Diagnostic / analytical methods typically used

Method recommended by EU Reference Laboratory for *Salmonella* in Bilthoven Netherlands: a modification of ISO 6579:2002, where a semisolid medium (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 the corresponding serovars distribution, 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 tables

For reporting data on breeding flocks of *Gallus gallus*, use the table named "*Salmonella in breeding flocks of Gallus gallus"*. Data on laying hens, broilers and turkeys are reported on the table named "*Salmonella in other poultry*".

Specific guidelines for entering data on samples collected in breeding flocks of *Gallus gallus* according to the Commission Regulation (EC) No 1003/2005 (target Regulation):

Information requested in the rows

- **Animal species** – for level 1 use "*Gallus gallus (fowl)*"; for level 2 "*parent breeding flocks", "grandparent breeding flocks"* or *"elite breeding flocks"*; for level 3 use "*day-old chicks*", "*during rearing period*" or "*adult*".
- **Sampling stage** – for level 1 use "*at farm*".
- **Sampling context**
  - for level 1 use "*control or eradication programme*" for all data;
  - then for level 2 use "*official and industry sampling*", combining the results both from the sampling carried out by competent authorities and from the

samples by food business operators. This information is the most important, because it is used to evaluate whether the target was met.

- In addition the results from sampling carried out by competent authorities and from sampling by food business operators could be reported separately. Then use level 2 terms "official sampling" and "sampling by industry".

Information requested in the columns

- **Sampling unit** – use "*Flock*";
- **Number of existing flocks** - the number of all breeding flocks in the country during the year.
- **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 irrespectively of the number of times it is tested;
- **Total units positive for *Salmonella* spp.** - the total number of flocks considered infected based on the analyses results. This total should be distributed according to the following columns, when possible;
- ***S.* serovar a, *S.* serovar b, …-** in these columns, the number of positive flocks should be categorized according to the serovar, when this information is available;
- ***Salmonella* spp. unspecified** - this is the column where one should report the number of flocks positive for *Salmonella* where the serovar is unknown.

For rows, 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, productive period, unspecified). If results for the different type of breeding flocks are not available, use the "*Breeding flock*" line.

Use the "*Unspecified*" line only when it is not known whether the results are derived from testing during day old chicks, rearing period or productive period.

Number of flocks where *Salmonella* vaccine strains were detected may be reported in the footnote below the prevalence table regarding the specific animal population. However, these flocks are not counted as *Salmonella* positives.

Specific guidelines for entering data on samples collected in laying hens according to the Commission Regulation (EC) No 1168/2006 (target Regulation):

Information requested in the rows

- **Animal species** – for level 1 use "*Gallus gallus (fowl)*"; for level 2 "*laying hens*"; for level 3 use "*adult*"; and if needed add "flocks under control programme".
- **Sampling stage** – for level 1 use "*at farm*".
  One may also report the data divided according to the type of samples taken. In this case for level 2 use "*animal sample*" or "*environmental sample*"; for level 3 use "*faeces*" (animal sample), "*boot/ sock swabs*" (environmental sample) or "*dust*" (environmental sample). If several types of samples were taken use separate rows to report the data.
- **Sampling context**
  - for level 1 use "*control or eradication programme*" for all data;
  - then for level 2:
    - under "*official and industry sampling*" report all the sampling information in summarised format. This information is the most important, because it is used to evaluate whether the target was met,
    - under "*official sampling*" - "*objective sampling*" report the sampling done by the competent authorities according to point 2.1 (a) of the Annex = sampling of one flock per holding having at least 1,000 birds,
    - under "*official sampling*" - "*suspect sampling*" report the sampling carried out according to point 2.1 (b) to (e) of the Annex,
    - under "*sampling by industry*" report the sampling carried out by the food business operators in accordance with point 2.1, second paragraph of the Annex = sampling of all flocks every 15 weeks.

Information requested in the columns

- **Sampling unit** – use "*Flock*";
- **Number of existing flocks** - the number of all laying hen flocks in the country that were in production (laying) during the year.
- **Units tested** - the number of flocks under investigation. Each flock should be counted only once irrespectively of the number of times it is tested;
- **Total units positive for *Salmonella* spp.** - the total number of flocks considered infected based on the analyses results. This total should be distributed according to the following columns, when possible;
- ***S.* serovar a, *S.* serovar b, …-** in these columns, the number of positive flocks should be categorized according to the serovar, when this information is available;
- ***Salmonella* spp. unspecified** - this is the column where one should report the number of sampling flocks positive for *Salmonella* where the serovar is unknown.

Specific guidelines for entering data on samples collected in broiler flocks according to the Commission Regulation (EC) No 646/2007 (target Regulation):

Information requested in the rows

- **Animal species** – for level 1 use "*Gallus gallus (fowl)*"; for level 2 "*broilers*"; for level 3 use "*before slaughter"*.
- **Sampling stage** – for level 1 use "*at farm*".
- **Sampling context**
  - for level 1 use "*control or eradication programme*" for all data;
  - then for level 2 use "*official and industry sampling*", combining the results both from the sampling carried out by competent authorities and from the samples by food business operators. This information is the most important, because it is used to evaluate whether the target was met.
  - In addition, the results from sampling carried out by competent authorities and from sampling by food business operators may be reported separately. Then use level 2 terms "official sampling" and "sampling by industry".

Information requested in the columns

- **Sampling unit** – use "*Flock*";
- **Number of existing flocks** - the number of all broiler flocks in the country during the year.
- **Units tested** - the number of flocks under investigation. Each flock should be counted only once irrespectively of the number of times it is tested;
- **Total units positive for *Salmonella* spp.** - the total number of flocks considered infected based on the analyses results. This total should be distributed according to the following columns, when possible;
- ***S.* serovar a, *S.* serovar b, …-** in these columns, the number of positive flocks should be categorized according to the serovar, when this information is available;
- ***Salmonella* spp. unspecified** - this is the column where one should report the number of sampling flocks positive for *Salmonella* where the serovar is unknown.

Specific guidelines for entering data on samples collected in turkeys according to the Commission Regulation (EC) No 584/2008 (target Regulation):

For breeding flocks of turkeys
Information requested in the rows

- **Animal species** – for level 1 use "*Turkeys*"; for level 2 "*breeding flocks, unspecified*"; for level 3 use "*day-old chicks*", "*during rearing period*" or "*adult*".
- **Sampling stage** – for level 1 use "*at farm*".

- **Sampling context**
  - for level 1 use "*control or eradication programme*" for all data;
  - then for level 2 use "*official and industry sampling*", combining the results both from the sampling carried out by competent authorities and from the samples by food business operators. This information is the most important, because it is used to evaluate whether the target was met.
  - It would be beneficial, whenever this information is available, to report the results from sampling carried out by competent authorities and from sampling by food business operators separately. Then use level 2 terms "official sampling" and "sampling by industry".

Information requested in the columns

- **Sampling unit** – use "*Flock*";
- **Number of existing flocks** - the number of all turkey breeding flocks in the country during the year.
- **Units tested** - the number of breeding flocks under investigation. Each flock should be counted only once irrespectively of the number of times it is tested;
- **Total units positive for *Salmonella* spp.** - the total number of flocks considered infected based on the analyses results. This total should be distributed according to the following columns, when possible;
- ***S.* serovar a, *S.* serovar b, …-** in these columns, the number of positive flocks should be categorized according to the serovar, when this information is available;
- ***Salmonella* spp. unspecified** - this is the column where one should report the number of flocks positive for *Salmonella* where the serovar is unknown.

For fattening flocks of turkeys
Information requested in the rows

- **Animal species** – for level 1 use "Turkeys"; for level 2 "*Fattening flocks, unspecified*"; for level 3 use "*before slaughter*".
- **Sampling stage** – for level 1 use "*at farm*".
- **Sampling context**
  - for level 1 use "*control or eradication programme*" for all data;
  - then for level 2 use "*official and industry sampling*", combining the results both from the sampling carried out by competent authorities and from the samples by food business operators. This information is the most important, because it is used to evaluate whether the target was met.
  - It would be beneficial, whenever this information is available, to report the results from sampling carried out by competent authorities and from sampling by food business operators separately. Then use level 2 terms "official sampling" and "sampling by industry".

Information requested in the columns

- **Sampling unit** – use "*Flock*";
- **Number of existing flocks** - the number of all fattening turkey flocks in the country during the year.
- **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 for *Salmonella* spp.** - the total number of flocks considered infected based on the analyses results. This total should be distributed according to the following columns, when possible;
- ***S.* serovar a, *S.* serovar b, …-** in these columns, the number of positive flocks should be categorized according to the serovar, when this information is available;
- ***Salmonella* spp. unspecified** - this is the column where one should report the number of flocks positive for *Salmonella* where the serovar is unknown.

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, meat production, and egg production) and stage of sampling (*e.g.* day-old chicks, production period).
Pigeons, guinea fowls, pheasants, partridges and ostriches: indicate, when possible, the type of birds (*e.g.* farmed, wild, pets) and, in case of wild birds, the animal species.
Pigs (both fattening and breeding pigs), cattle, sheep, goats, domestic solipeds.
Pet animals (dogs, cats).
Wildlife species are also interesting, such as hedgehog.

Relevant agent species / serotypes / phage types to be reported

Salmonella spp.; The 5 most prevalent serovars should be reported, where available.

As regards pigs, the serovars *S.* Enteritidis, *S.* Typhimurium and *S.* Infantis should all be reported separately. Also monophasic *Salmonella* Typhimurium strains should be included.
As regard the table "*Salmonella* serovars in animals", the strains isolated in the context of "monitoring", "clinical", "surveillance" and "control programme" could be reported separately.

Data on monophasic *Salmonella* Typhimurium should be reported as following: this group comprises *Salmonella* Typhimurium strains lacking the second phase H antigen (1,4,[5],12:i:-). Whenever possible as much detail 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 phage type that is consistent with *S.* Typhimurium lacking phase two flagellar antigen has been confirmed, and the lack of the second flagellar antigen has been verified by PCR, then the term "monophasic *Salmonella* Typhimurium" is recommended to be used.

Please note that for the purpose of evaluating the distribution of *Salmonella* serovars along the food chain, mainly the data from the tables "*Salmonella* serovars in animals" and "*Salmonella* serovars in food" will be used.

Type of specimen taken

In 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 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 Netherlands: a modification of ISO 6579:2002 where a semisolid medium (MSRV) is used as the single selective enrichment medium. This method is described in Annex D of ISO 6579:2002 (ISO, 2007).
Blood, meat juice: ELISA, serological method.

Analyses of the results

The analyses of results from different animal species, as well as the corresponding serovars distribution 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 tables

For reporting of data, use prevalence tables named "*Salmonella in other poultry*" (for ducks and geese), "*Salmonella in other birds*" and "*Salmonella in other animals*".

Specific guidelines for entering data in the prevalence tables:

- **Animal species** – the relevant animal species and category;
- **Sampling stage** – where the samples have been collected (e.g. at farm / at slaughterhouse) and the sample type (e.g. animal sample/ faeces) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. monitoring), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;
- **Number of existing flocks** (only in "*Salmonella in other poultry*") - the number of flocks present at the sampling year should be counted;
- **Sampling unit** – use "*Flock*", "*Herd*", "*Holding*", "*Slaughter batch*" or "*Animal*";
- **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 irrespectively of the number of times it is tested;

- **Total units positive for *Salmonella* spp.** - in this column, the total number of sampling units considered infected based on the analyses results should be inserted. This total should be distributed according to the following columns;
- ***S.* serovar a, *S.* serovar b, …-** in these columns, the number of positive units should be categorized according to the serovar, when this information is available;
- ***Salmonella* spp. unspecified** - this is the column where one should report the number of sampling units positive for *Salmonella* where the serovar is unknown.

Information to be reported in rows:

As regard 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, rearing flocks, productive period, unspecified);

Also when possible give the breakdown of the results by different types of cattle (*e.g.* calves, adults etc.) and pigs (breeding and fattening pigs);

Use the "*Unspecified*" line only when it is not known whether the results are derived from testing on day-old chicks, rearing period or productive period.

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 2. or 3. 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

Thermophilic *Campylobacter* spp. Differentiation at species level should be provided, where available. The major agents of interest are *C. jejuni* and *C. coli*; however *C. lari*, *C. fetus*, *C. upsaliensis* and *C. helveticus*, which are known to cause human infections, 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;
- Drinking water, surface water, environmental water;
- Feed.

Case definition / definition of a positive sample

Positive holding / herd / flock / batch / animal - a holding, herd, flock, batch, animal in which thermophilic *Campylobacter* spp. has been detected.

Positive slaughter batch - a batch where thermophilic *Campylobacter* spp. has 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) bear a certain risk to give intermediate or incorrect test results.

Reporting the results in the tables

For the reporting of data, use the table named "*Campylobacter in animals*".

Specific guidelines for reporting data in the prevalence tables:

- **Sampling stage** – where the samples have been collected (e.g. at farm / at slaughterhouse) and the sample type (e.g. animal sample/ faeces) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. control and eradication programme), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;
- **Sampling unit** – "*Flock*", "*Herd*", "*Holding*", "*Slaughter batch*" or "*Animal*" should be used as the terms to be reported;
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Campylobacter* spp**. - in this column, the total number of sampling units considered infected (contaminated) based on the analytical results should be inserted. This total should be distributed according to the following columns, when possible;
- ***Campylobacter a*, *Campylobacter b*, …** - in these columns the number of positive units is categorised according to the *Campylobacter* species, where this information is available;
- ***Campylobacter* spp., unspecified** - in this column the number of sampling units positive for *Campylobacter* where the (sub)species is unknown should be reported.

The prevalence can 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.

5.3. *Listeria* spp. in animals

Relevant animal species to be reported on

A wide variety of animal species can be infected with *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 *Listeria monocytogenes*.

Type of specimen taken

Typically the types of specimen 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 on which *Listeria monocytogenes* has been detected.

Diagnostic / Analytical methods typically used

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

Preventive 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 bodies of dead animals.

Reporting the results in the tables

For the reporting of data, use the table named "*Listeria spp. in animals*".

Specific guidelines for reporting data in the prevalence tables:

- **Sampling stage** – where the samples have been collected (e.g. at farm / at slaughterhouse) and the sample type (e.g. animal sample/ faeces) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. control and eradication programme), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;
- **Sampling unit –** "*Flock*", "*Herd*", "*Holding*", "*Slaughter batch*" or "*Animal*" should be used as the terms to be reported;
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;

- **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;
- **Total units positive for *Listeria monocytogenes, Listeria b, Listeria c* -** in these columns, the number of units positive for *Listeria monocytogenes* and other *Listeria* species should be inserted, respectively;
- ***Listeria* spp., unspecified** - in this column, the number of sampling units positive for *Listeria,* where the species is unknown, should be reported.

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 cases in individual animals should be clearly distinguished from those resulting from survey, control or monitoring schemes.

Listeria monocytogenes serotypes can also be reported on by inserting them from the specific pick-list.

5.4. *Yersinia* spp. in animals

Relevant animal species to be reported on

Pigs, **bovines**, **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, Yersinia pseudotuberculosis)*. Main pathogenic *Yersinia 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 *Yersinia 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. has been isolated.

Diagnostic / analytical methods typically used

Information on the analytical and diagnostic methods used should 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 main pathogenic serotypes. The reference method for the detection of *Yersinia enterocolitica* in food (ISO 10273:2003 (ISO, 2003)) is also applicable for examination of tonsils and lymph nodes.

Reporting the results in the tables

For reporting of data, use the table named "*Yersinia spp. in animals*".

Specific guidelines for reporting data in the prevalence table:

- **Sampling stage** – where the samples have been collected (e.g. at farm / at slaughterhouse) and the sample type (e.g. animal sample/ faeces) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. control and eradication programme), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **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;

- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Yersinia* spp. -** in this column, the total number of sampling units considered infected based on the analytical results should be inserted. This total is distributed according to the following columns, when possible;
- ***Yersinia enterocolitica* -** number of units positive for *Yersinia enterocolitica*, This total should be distributed according to the following columns, when possible;
- ***Yersinia enterocolitica* O:3, O:5, O:9, and the biotypes 1B, 2, 3, 4** - number of units positive for each *Yersinia enterocolitica* serotypes, or biotypes respectively. If information on both serotype and biotype is available, the results should be reported as the biotype/ serotype combinations (available in the pick list); for example biotype 4/O:3;
- ***Yersinia pseudotuberculosis* -** number of units positive for *Yersinia pseudotuberculosis*;
- ***Yersinia enterocolitica,* unspecified –** the number of sampling units positive for *Yersinia enterocolitica,* where serotype/ biotype is unknown;
- ***Yersinia* spp., unspecified -** in this column, the number of sampling units positive for *Yersinia* spp. where the species is unknown should be reported.

Note that, in this table, the "*Total units positive for Yersinia spp."* is the sum of units positive for *Yersinia* species (*Y. enterocolitica, Y. pseudotuberculosis*) and for "*Yersinia spp., unspecified*" (excluding the serotypes/ biotypes). *Y. enterocolitica* count should also include the positive units where the serotype/ biotype information is reported.

5.5. Verotoxigenic *Escherichia coli* (VTEC) in animals

Relevant animal species to be reported on

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

Relevant agent species / serotypes to be reported

Strains of *E. coli* that are capable of producing verocytotoxin (VT)/ shigatoxins (*Stx*) . Information on the serogroup (O antigen) should be reported. Serogroups of particular interest are: O157, O111, O103, O26, O145 and O91.

Information on genes encoding for verocytotoxin 1 (*vtx1*), verocytotoxin 2 (*vtx2*) or intimin (*eae*) should be reported, where available, as recommended 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.

Type of specimen taken

Rectal faeces samples, coat, ears, hide and fleece swabs.

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.

Diagnostic / analytical methods typically used

For detection of VTEC O157 in animals, the standard methods developed for food may be used (NMKL No 164 (NMKL, 2005) and ISO 16654:2001 (ISO, 2001)). 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.

Currently, there is no internationally recognised standard method for detection of VTEC non-O157.

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.

Reporting the results in the tables

For reporting of data, use the table named "*VT E. coli in animals*".

Specific guidelines for reporting data in the prevalence table:

- **Sampling stage** – where the samples have been collected (e.g. at farm / at slaughterhouse) and the sample type (e.g. animal sample/ faeces) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. control and eradication programme), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;

- **Sampling unit –** "*Herd*", "*Holding*" or "*Slaughter batch*" or "*Animal*" should be used as the terms to be reported;
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *VTEC*** - in this column, the total number of sampling units positive for Verotoxigenic *E. coli*, should be inserted;
- **Verotoxigenic *E. coli* (VTEC) O157 and other serogroups -** number of units positive for the specific serogroup. Information on genes encoding for verocytotoxins or intimin should be reported if available; for example VTEC O157 *eae* positive *vtx1* positive;
- **Verotoxigenic *E. coli* (VTEC), unspecified** – number of units positive for VTEC, where the serogroup is unknown.

5.6. *Mycobacteria* in other animal species than bovines and farmed deer

Relevant animal and agent species to be monitored and reported on

It would be highly desirable, according to the epidemiological situation, to get information on *Mycobacteria* isolations (*M. tuberculosis*, *M. bovis*, *M. caprae*, *M. africanum, M. avium*) in sheep, goats, pigs and wild deer, zoo animals, pet animals, wildlife (wild ruminants, badgers, wild boars, and wild birds).

Typical interesting information to be reported

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

Reporting the results in the tables

For reporting of data, use table named "*Tuberculosis in other animals*".
Also data for *Mycobacteria* other than *M. tuberculosis* and *M. bovis* should be reported in this table.

Specific guidelines for entering data in the prevalence tables:

- **Sampling unit** - the sampling unit is typically "*Animal*", "*Herd"* or *"Holding" or "Slaughter batch";*
- **Total units positive for *Mycobacterium* spp. -** in this column, the total number of sampling units considered infected based on the analyses results should be inserted;
- ***M. bovis, M. b, M. c*** - number of units positive for *Mycobacterium bovis*, or other *Mycobacterium* species, respectively;
- ***Mycobacterium* spp., unspecified -** this is the column where to report the number of sampling units positive for *Mycobacterium,* where the species is unknown. This column is only filled in when the other species columns are not used.

Please pay attention that the number of units sampled is correctly reported, for example representing the number of animals inspected in slaughterhouse. In case of reporting of testing animals having suspected lesions, please report the right sampling context "suspect sampling".

5.7. *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

Coxiella 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 which tested positive for *Coxiella burnetii* on the test carried out, by a serological test or PCR according the *Manual of Diagnostic Test and Vaccines for Terrestrial Animals* from OIE (OIE, 2009b) or by isolation of the agent, staining, or immunofluorescence assay test (IFA)

A herd should be considered as clinically affected in case of:

- Clinical pattern of coxiellosis: mainly abortion, stillbirth;
- Confirmation of agent presence (PCR-positive); and
- Positive serology.

Diagnostic / analytical methods typically used

Serologic testing: ELISA or complement fixation test (CFT) in animals.

Isolation of the agent by cell culture or identification by PCR or IFA.

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 *e.g.* 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, 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 tables

For reporting data, use the table ”*Coxiella burnetii (Q fever) in animals*”.

Specific guidelines for reporting data in the prevalence table:

- **Sampling stage** – where the samples have been collected (e.g. at farm / at slaughterhouse) and the sample type (e.g. animal sample/ faeces) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. control and eradication programme), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples; this can be used to report the type of diagnostic method used, e.g. serological or PCR.
- **Sampling unit –** "*Herd*", "*Holdings*", or "*Slaughter batch*" or "*Animal*" should be used as the terms to be reported;
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for C. burnetii (Q fever)** - in this column, the total number of sampling units considered infected based on the analytical results is reported.

Information if the herd was found to be clinically affected by Q fever (according to the definition) can be added in the comment or footnote.

Please report the type of diagnostic method used, e.g. serology, PCR, direct isolation, in the comments or footnote field, in order to facilitate the right interpretation of the results.

5.8. *Trichinella* spp. in animals

Other relevant animal species to be reported on

Pigs and **horses**, carnivorous game animals, *e.g.* **wild boar**, **bears**, **foxes**, **raccoon dogs**, lynxes, rats, badgers, wolves and stone martens.

Relevant agent species to be reported

Trichinella spiralis and other zoonotic species, such as *T. britovi*, *T. nativa* and *T. pseudospiralis*. *T. nativa* is a cold-resistant species and circulates only among carnivores living in cold regions (in arctic and subarctic regions of some Northern 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 if all slaughtered pigs and horses are investigated or not;
- Monitoring and surveillance schemes or programmes in farmed wild boars, horses, breeding pigs and other indicator animals, especially in wildlife, *e.g.* foxes, raccoon dogs;
- **Information if pigs are raised under controlled housing conditions in integrated production system or have outdoor access or are raised organically;**

In the text forms, the information on monitoring and control systems in place is asked for 4 different categories:

- General;
- *Trichinella* free holdings;
- Categories of holdings officially recognised *Trichinella*-free;
- Regions with negligible *Trichinella* risk.

If free holdings or regions with negligible risk do not exist in the MS, only the "*General*" part is used.

Reporting on the status as officially free/ negligible risk

According Commission Regulation (EC) No 2075/2005[18], there are currently provisions for approval of holdings officially recognised free and regions presenting a negligible *Trichinella* risk. Information on this status would be welcome.

Type of specimen taken

Diaphragm muscles or tongue are typically taken during meat inspection.

[18] OJ L 338, 22.12.2005, p. 60.

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) 2075/2005.

Case definition / definition of a positive sample

Positive animal - animal where *Trichinella* spp. larvae has been detected.

Diagnostic / analytical methods typically used

Methods for detection of *Trichinella* in fresh meat are specified in Commission Regulation (EC) 2075/2005:

- Magnetic stirrer method for pooled sample digestion;
- Equivalent methods to pooled sample digestion methods:
  a. Mechanically assisted pooled sample digestion method / sedimentation technique;
  b. Mechanically assisted pooled sample digestion method / on filter isolation technique;
  c. Automatic digestion method for pooled samples of up to 35 g.
- Trichinoscopic examination.

Other available tests include: ELISA tests, serological methods (serological methods cannot be regarded as diagnostic tests) - describe or include reference.
For horses and other animal species than pigs the prescribed method is digestive method with some changes. The method used should be described in detail (*e.g.* sample size and type of sample used).

Preventive measures in place

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

Analyses of the results

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

- Results of meat inspection for *Trichinella* spp.;
- 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:

- description of positive cases and of the *Trichinella* species identified, as well as the age and sex of the affected animals,
- the type of management system they originated from,
- the diagnostic method used,
- the degree of infestation,

- outdoor access during lifetime,
- feeding practices
- and any other relevant information.

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

- Fattening pigs raised under controlled housing conditions in integrated production system;
- Fattening pigs not raised under controlled housing conditions in integrated production system;
- Fattening pigs raised under organic farming conditions;
- Backyard and free-range farms;
- Wildlife (farmed and wild);
- Breeding sows and boars.

Reporting the results in the tables

For reporting of data, use the table named "*Trichinella in animals*".

It would be beneficial to report whenever the information is available, whether the pigs tested were raised under controlled housing conditions or not. Furthermore, the information whether it was question of fattening or breeding pigs, would be important. These options are available on the animal species pick list.

Specific guidelines for entering data in the prevalence tables:

- **Sampling stage** – where the samples have been collected (e.g. at slaughterhouse) and the sample type (e.g. animal sample/ meat) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. monitoring), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;
- **Sampling unit** - the sampling unit is typically "*Animal*";
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Trichinella* spp. -** in this column, the total number of sampling units considered infected (contaminated) based on the analyses results should be inserted;
- ***Trichinella spiralis, Trichinella b, Trichinella c*** - number of units positive for *Trichinella spiralis* or other *Trichinella* species, respectively;
- ***Trichinella* spp., unspecified -** this is the column where to report the number of sampling units positive for *Trichinella,* where the species is unknown.

5.9. *Echinococcus* spp. in animals

For the purpose of following trends the information to be reported each year or at regular intervals (*e.g.* every 2. or 3. years) is:
- *Echinococcus multilocularis* in red foxes

Other relevant animal species to be reported on

For *E. granulosus* - sheep, **goats**, **cattle**, **pigs** and horses, other animals, such as camels, reindeer, deer, moose, wild boars.

For *E. multilocularis* – foxes, dogs, cats and other wild animal species, such as **raccoon dogs**, voles, musk rats and other rodents.

The distribution of *Echinococcus* in animal species varies between the 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 the proper analyses of the data. Also reporting of the zoonotic strains/ (sub)species most prevalent in Europe (G1, G4, G5, G7) is encouraged.

Description of the monitoring and control system

- Monitoring, surveillance schemes or strategies 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 (meat inspection based on national and EU legal requirements) for intermediate hosts;
- 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

Positive animal - animal with a positive test result in the diagnostic test used or where *Echinococcus* cysts have been detected.

Diagnostic / analytical methods typically used

For *E. granulosus* and *E. multilocularis*: post mortem visual examination of intermediate hosts, in the context of meat inspection procedures established in the Regulation (EC) No. 854/2004[19]; and the diagnostic method for the identification of the strain/ subspecies
For *E. multilocularis*: faecal examination and post-mortem intestine analysis for definitive hosts and the diagnostic method for the identification of the strain/ subspecies.

Preventive measures in place

These measures may include anti-parasitic clinical treatments in pets (dogs) and wildlife, targeted meat inspection procedures in slaughterhouses, good practices for viscera of infected animals (in order to avoid consumption by dogs), recommendations concerning collecting berries and mushrooms, effective management of stray dogs, and education / training of food handlers.

Analyses of the results

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

Reporting the results in the tables

For reporting of data, the table named "*Echinococcus spp. in animals*" is used.

Specific guidelines for reporting of data in the prevalence table:

- **Sampling stage** – where the samples have been collected (e.g. at slaughterhouse) and the sample type (e.g. animal sample/ faeces) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. monitoring), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;
- **Region (NUTS)** – information on the region where the data are originating from should be reported; the NUTS standards are made available in the specific pick list;

  MSs are asked to report data at the lowest level of granularity available, following the rule that in each line the **total** number of unit tested and unit positives for the selected NUTS level should be reported.

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

  - When only data at national are available, select the NUTS level corresponding to the all country and report the totals at national level.

[19] OJ L 139, 30.4.2004, p. 206.

- When both data at national level and data at regional level for all the regions are available, select the NUTS level corresponding to the all country and report the total at national level and then add as many rows as needed in order to report for each region its total.
- When data at national level are available and **only <u>partial</u>** data are available at regional level, select the NUTS level corresponding to the all country and report the total at national level and add as many rows as you need, one row for each region you have data for, and then report the total for each region as well.

In case you have data at lower details (province/city level) you can also report the available data by adding additional rows at the requested NUTS level.

Please refer to Annex IV for practical examples on regional reporting.

- **Sampling unit** – use "*Herd*", "*Slaughter batch*" or "*Animal*";
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Echinococcus* spp. -** in this column, the total number of sampling units considered infected based on the results, should be inserted. The total figure should be distributed according to the following columns;
- ***Echinococcus multilocularis* and *Echinococcus granulosus* -** in these columns, the number of positive units should be categorised according to the *Echinococcus* species, where this information is available. <u>The reporting of the species is highly recommended.</u>
- ***Echinococcus* spp., unspecified -** this is the column where one should report the number of sampling units positive for *Echinococcus*, where the species is unknown.

5.10. *Toxoplasma* spp. in animals

Relevant animal species to be reported on

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

Relevant agent species to be reported

Toxoplasma gondii.

Description of the monitoring and control system

It is relevant for domestic cats and sheep.

Type of specimen taken

Typically blood is sampled for serology. Other samples could include abortion material.

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.

Preventive methods in place

These measures can typically include vaccination policy in cats to reduce their role as reservoirs of *Toxoplasma gondii* and specific recommendations / guidelines given to pregnant women.

Reporting the results in the tables

For reporting of data, use the table named "*Toxoplasma in animals*".

Specific guidelines for reporting of data in the prevalence table:

- **Sampling stage** – where the samples have been collected (e.g. at farm) and the sample type (e.g. animal sample/ blood) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. monitoring), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;
- **Sampling unit** – use "*Herd*", "*Holding*", "*Slaughter batch*" or "*Animal*";
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Toxoplasma gondii*** - in this column, the total number of sampling units considered infected with *Toxoplasma gondii*, based on the analyses results, should be inserted.

A clear indication should be made in order to differentiate clinical investigations from those resulting from monitoring programmes or surveillance.

Please report the type of diagnostic method used, e.g. serology, in the comments or footnote field, in order to facilitate the right interpretation of the results.

5.11. *Cysticercus* spp. 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* (metacestode stage of the human tapeworm *Taenia saginata,* called *Cysticercus bovis* in cattle).
- *Cysticerci* of *Taenia solium* (metacestode stage of the human tapeworm *Taenia 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 where *Cysticerci* have been detected.

Diagnostic / analytical methods typically used

By visual inspection, in the context of meat inspection procedures established in the Regulation (EC) 854/2004. Microscopic examination is also used for diagnosis / confirmatory purposes. Confirmatory test is made by PCR.

It is recommended to report always the diagnostic method used or to make a reference to visual post mortem inspection.

Preventive measures in place

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

Analyses of the results

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

- Results of meat inspection for presence of *Cysticerci*;
- Estimation of level of infection and whether carcase is condemned.

Reporting the results in the tables

For reporting data, use prevalence table for animals from the web-based reporting system. This table can be created under the "*Report structure*".

Specific guidelines for entering data in the prevalence tables:

- **Sampling stage** – where the samples have been collected (e.g. at slaughterhouse) and the sample type (e.g. animal sample/ tongue) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. monitoring), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;
- **Sampling unit** - the sampling unit is typically "*Animal*";
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Cysticerci* -** in this column, the total number of sampling units considered infected (contaminated) based on the analyses results should be inserted;
- ***Cysticerci* of *Taenia saginata*** and ***Cysticerci* of *Taenia solium*** - in these columns, the number of positive units should be categorised according to the *Taenia* species found, where this information is available;
- ***Cysticerci* spp., unspecified -** this is the column where to report the number of sampling units positive for *Cysticercus,* but where the species is unknown.

It is important to report the *Cysticerci* species information, whenever possible, to facilitate the proper analyses of the data.

5.12. Rabies in animals

Relevant animal species to be tested and reported

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

Relevant agent species of *Lyssavirus* to be tested and reported

Information on the *Lyssavirus* species is of particular interest. Whenever possible, the differentiation between European Bat *Lyssavirus* (unspecified, EBL1 or EBL2) and the classical rabies virus (genotype 1) should be made.

Description of the monitoring and control system

It is recommended to report national control strategy and vaccination programmes.

Reporting on the status as free

A country may be recognised "free from rabies" by OIE or by WHO, according to 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 2 years (however, this status will not be affected by the isolation of the European Bat *Lyssavirus* - EBL 1 or EBL 2);
- no imported cases in carnivores have been confirmed outside a quarantine station for the past 6 months.

Note that for WHO, detection of the European Bat *Lyssavirus* (EBL 1 or EBL 2) will prevent countries from being considered free from rabies.

Diagnostic methods typically used

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 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 Polymerase Chain Reaction followed by DNA sequencing of genomic areas. Typing of rabies virus isolates should be performed for any isolated cases of rabies and in case attenuated oral rabies vaccines are used.

Analyses of the results

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

- Number of confirmed rabies cases in animals and the sources of infection. The number of investigated animals should be recorded as well as 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 (classical rabies virus) from those circulating in European bats (European Bat *Lyssavirus*, EBL 1 or EBL 2).

Reporting the results in tables

For reporting of data, use the table named "*Rabies in animals*".

Specific guidelines for entering data in the prevalence tables:

- **Sampling stage** – where the samples have been collected (e.g. at farm) and the sample type (e.g. animal sample/ blood) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. monitoring), who collected the samples (e.g. competent authority) and the sample strategy (e.g. suspect sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;
- **Region (NUTS)** – information on the region where the data are originating from should be reported; the NUTS standards are made available in the specific pick list;

  MSs are asked to report data at the lowest level of granularity available, following the rule that in each line the **total** number of unit tested and unit positives for the selected NUTS level should be reported.

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

  - When only data at national are available, select the NUTS level corresponding to the all country and report the totals at national level
  - When both data at national level and data at regional level for all the regions are available, select the NUTS level corresponding to the all country and report the total at national level and then add as many rows as needed in order to report for each region its total.
  - When data at national level are available and **only partial** data are available at regional level, select the NUTS level corresponding to the all country and report

the total at national level and add as many rows as you need, one row for each region you have data for, and then report the total for each region as well.

In case you have data at lower details (province/city level) you can also report the available data by adding additional rows at the requested NUTS level.

Please refer to Annex IV for practical examples on regional reporting.

- **Sampling Unit** – in rabies, this is typically the "*Animal*".
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Lyssavirus* (rabies)** - in this column, the total number of animals found positive for rabies should be inserted. The information about occurrence of European Bat *Lyssavirus* should be provided as a comment or footnote.
- **Classical rabies virus (genotype 1)** – in this column the number of animals found positive for classical rabies virus is reported.
- **European Bat *Lyssavirus*, unspecified** – in this column the number of animals positive for European bat virus are reported. If the bat virus type is known (EBL 1 or EBL 2), these specific columns can be added from the picklist.
- **Unspecified *Lyssavirus*** –this column is used to indicate the number of sampling units where the subspecies of the virus is unknown.

It is highly recommended to report whether the virus found was the classical rabies virus or the European Bat *Lyssavirus*.

5.13. *Staphylococcus* spp. in animals

Relevant animal species to be reported on

Sheep, goats, pigs, fowl (*Gallus gallus*), turkeys, cattle.

Relevant agent species to be reported

MRSA: Strains of *S. aureus* resistant to virtually all available beta-lactam antimicrobials including methicillin (methicillin-resistant *S. aureus* (MRSA)) should be reported.
Information on the MRSA *spa*-typesmay also be reported if availalbe.

Type of specimen taken

Typically swabs from the lesions, biopsy, blood, dust, nasal swabs, milk samples.

Case definition / definition of a positive sample

***Staphylococcus* positive animal / sample / herd / flock / batch** – an animal / sample / herd / flock from which *Staphylococcus* has been isolated.
MRSA positive animal / sample / herd / flock / batch – an animal / sample / herd / flock from which MRSA has been isolated.

Diagnostic / analytical methods typically used

Currently, there is no internationally recognised standard method for detection of MRSA in animals.
Details should be provided on the diagnostic method used, including how verification of MRSA is carried; in particular whether MRSA was detected by resistance testing of isolated *S. aureus* or by the use of selective media for MRSA.

Reporting the results in the tables

For reporting of data, use the table named "*Staphylococcus in animals*".

Specific guidelines for reporting of data in the prevalence table:

- **Sampling stage** – where the samples have been collected (e.g. at farm) and the sample type (e.g. animal sample/ blood) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. monitoring), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;
- **Sampling unit** – use "*Herd*", "*Holding*", "*Slaughter batch*" or "*Animal*";
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Staphylococcus*** - in this column, the total number of sampling units considered infected or colonised with *Staphylococcus,* based on the analyses results, should be inserted.

- **Total units positive for *S. aureus*, methicillin resistant (MRSA)** - in this column, the total number of sampling units considered infected or colonised with MRSA, based on the analyses results, should be inserted.
- ***Spa*-type ….** – in this column the number of animals found positive for the specific *spa*-type is reported.
- **MRSA, unspecified** – this column is used to indicate the number of sampling units where the *spa*-type is unknown.

6. Reporting on zoonotic agents in foodstuffs

6.1. General recommendations

Typical interesting information to be reported on zoonotic agents in foodstuffs is:

Description of the monitoring and control system

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

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

Type of specimen taken

A description of the specimen taken, which 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 egg shell.

Diagnostic / analytical methods typically used

Reference methods standardized by CEN and/or ISO or NMKL are often available. Where other methods are used, the performance characteristics of the methods should be given in comparison to 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 to other reference methods should be given.

Preventive and control measures in place

National microbiological criteria or guidelines for foodstuffs should be described, as well as provisions or recommendations concerning 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 is welcome, it is not currently being analysed for the purpose of the EU Summary Report, as the associated sampling strategy is considered to be targeted, process related and, thus, of 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 2. or 3. year) is:

- *Salmonella* spp. in fresh broiler meat;
- *Salmonella* spp. in fresh pig meat;

It is recommendable to provide this information from 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, frog's 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 fruits 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 (*i.e.* 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 Regulations (EC) No 2073/2005 and No 1441/2007.

Relevant agent species / serovars / phagetypes to be reported

The five most prevalent serovars of *Salmonella* in foodstuffs. Phagetype information should be reported, where available.

As regard the table "*Salmonella* serovars in food", the strains isolated in the context of "monitoring" and "surveillance" could be reported.

Please note that for the purpose of evaluating the distribution of *Salmonella* serovars along the food chain, mainly the data from the tables "*Salmonella* serovars in animals" and "*Salmonella* serovars in food" will be used.

Case definition / definition of a positive sample

***Salmonella* positive sample** – a sample where *Salmonella* spp. has been isolated.

***Salmonella* positive batch** – a batch where *Salmonella* spp. has 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 and No 1441/2007 on microbiological criteria for foodstuffs.

Reporting the results in the tables

For reporting of data, use tables named:

- *Salmonella spp. in poultry meat and products thereof;*
- *Salmonella spp. in red meat and products thereof;*
- *Salmonella spp. in milk and dairy products;*
- *Salmonella spp. in other food.*

Specific guidance for reporting data in the prevalence tables:

- **Sampling stage** – where the samples have been collected (e.g. at processing plants / at retail);
- **Sampling context** – information on the context of the sampling (e.g. control and eradication programme), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **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 (in grams or millilitres) of the specimen used for analysis in the laboratory, *e.g.* 25g;
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;

- **Total units positive for *Salmonella* spp. –** the number of units positive for *Salmonella* spp. This total is derived from the summation of the following columns:
- ***Salmonella* a., *Salmonella* b., … -** the number of positive units categorised according to the *Salmonella* serovar, where this information is available;
- ***Salmonella* spp., unspecified** – the number of units positive for *Salmonella* where the serovar is unknown.

Information on the *Salmonella* serovars and phagetypes in food should also be reported in the relevant tables.

Data on monophasic *Salmonella* Typhimurium should be reported as following: this group comprises *Salmonella* Typhimurium strains lacking the second phase H antigen (1,4,[5],12:i:-). Whenever possible as much detail 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 phage type that is consistent with *S.* Typhimurium lacking phase two flagellar antigen has been confirmed, and the lack of the second flagellar antigen has been verified by PCR, then the term "monophasic *Salmonella* Typhimurium" is recommended to 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 2. or 3. year) is:
- *Campylobacter* spp. in fresh broiler meat.
  It is recommendable to provide this information from 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 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 product. 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 pasteurized or raw/low heat-treated milk) should be provided where available.

- ***Fish and fishery products, live bivalve molluscs, frog's legs and snails*** -information should be provided on the nature of the food *e.g.* crustaceans, molluscan shellfish, **live bivalve molluscs**, other fish, frog 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

Thermophilic *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 where thermophilic *Campylobacter* spp. has been isolated.

***Campylobacter* positive batch** - a batch where thermophilic *Campylobacter* spp. has 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 (2006a, ISO/TS 10272-2:2006 (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) bear a certain risk to give intermediate or incorrect test results.

Reporting the results in the tables

For reporting of data, use the tables named:

- *Campylobacter spp. in poultry meat;*
- *Campylobacter spp. in other food.*

Specific guidelines for reporting data in the prevalence tables:

- **Sampling stage** – where the samples have been collected (e.g. at processing plants / at retail);
- **Sampling context** – information on the context of the sampling (e.g. control and eradication programme), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **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 (in grams or millilitres) of the specimen used for analysis in the laboratory, *e.g.* 25g;
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Campylobacter* spp.** - the number of units positive for *Campylobacter* spp. This total is derived from the summation of the following columns:
- ***Campylobacter* a., *Campylobacter* b., … -** the number of positive units categorised according to the *Campylobacter* species, where this information is available;
- ***Campylobacter* spp., unspecified** - the number of units positive for *Campylobacter* where the species is unknown.

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 2. or 3. year) is:

- *Listeria monocytogenes* in ready-to-eat smoked fish. It is recommendable to provide this information from 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, pig and on the nature of the meat *i.e.* 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 "*gravad"* 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, not 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 *Listeria monocytogenes*. Absence / presence of *Listeria monocytogenes* as well as results from the enumeration (≤100 or >100 cfu/g) of *Listeria monocytogenes*, should be reported, where available. It is strongly recommended to provide the enumeration information for those food categories for which the criterion ≤ 100 cfu/g has been set down.

Case definition / definition of a positive sample

Positive sample - a sample is positive for *Listeria monocytogenes* where *L. monocytogenes* has been isolated from that sample. When using qualitative analysis, it is recommended to indicate the weight of the sample tested. When using quantitative analysis, it is recommended to indicate the limit of detection of the method used.

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

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.

Preventive and control measures in place

National guidelines for pregnant women or other susceptible population groups concerning consumption of food having high risk for *Listeria monocytogenes*.

Reporting the result in the tables

For reporting of data, use tables named:

- *Listeria monocytogenes in milk and dairy products;*
- *Listeria monocytogenes in other foods.*

Specific guidelines for reporting data in the prevalence tables:

- **Sampling stage** – where the samples have been collected (e.g. at processing plants / at retail);
- **Sampling context** – information on the context of the sampling (e.g. control and eradication programme), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;
- **Sampling unit -** "*Single*" or "*Batch*" should be used;
- **Sample weight** – the weight (in grams or millilitres) of the specimen used for analysis in the laboratory, *e.g.* 25g;
- **Units tested -** the number of units tested for *Listeria monocytogenes* for which results are available. A sample tested using both qualitative and quantitative analysis should be reported as 1 unit tested;
- **Total units positive for *L. monocytogenes*** - the 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 quantitative test. In such

cases it should be reported as a positive unit only once. It is important that the definition of a positive sample is provided in the narrative section of the report;

- **Units tested with detection method –** the number of units tested with the detection (qualitative) method for the presence or absence of *L. monocytogenes*;
- ***Listeria monocytogenes* presence in *x* g –** the positive results from the qualitative analysis (detection method for presence / absence) are reported. The number of units where *Listeria monocytogenes* was detected in *x* g, where *x* is the weight of the sample (as specified in the "*Sample weight*" column (in g or ml));
- **Units tested with enumeration method -** the number of units tested with the enumeration (quantitative) method for the quantification of the number of *L. monocytogenes* in the sample;
- **> detection limit but ≤100 cfu/g -** the positive results (number of positive units) from the enumeration method (quantitative analysis) where the number of detected *L. monocytogenes* colonies were more than the detection limit of the enumeration method but less or equal to 100 cfu/g;
- **>100 cfu/g -** the positive results (number of positive units) from the quantitative (enumeration) analysis, where the number of detected *L. monocytogenes* colonies were >100 cfu/g.

In case when the *L. monocytogenes* enumeration analysis is only carried out for the samples, which have already been found positive by the *L. monocytogenes* detection method, this should be explained in the comment field or in the footnote.

6.5. *Yersinia* spp. in foodstuffs

Relevant food categories to be reported

- ***Meat and products thereof*** – information should be provided on the animal species from which the meat is derived *e.g.* bovine, **pig**, 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).
- ***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. Yersinia enterocolitica, Yersinia pseudotuberculosis)*. Main pathogenic serotypes of *Yersinia 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 *Yersinia enterocolitica* in slaughter pigs" (EFSA; 2009b); for example biotype 4/O:3.

Case definition / definition of a positive sample

***Yersinia* positive sample** - a sample where *Yersinia* spp. has been isolated.

***Yersinia* positive batch** - a batch where *Yersinia* spp. has 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 *Yersinia enterocolitica* in food is ISO 10273:2003 (ISO, 2003).

Preventive measures in place

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

Reporting the results in tables

For reporting of data, use the table named "*Yersinia spp. in food*".

Specific guidelines for reporting data in the prevalence table:

- **Sampling stage** – where the samples have been collected (e.g. at processing plants / at retail);
- **Sampling context** – information on the context of the sampling (e.g. control and eradication programme), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;
- **Sampling unit –** "S*ingle*" or "*Batch*" should be used as the terms to be reported;
- **Sample weight** – the weight (in grams or millilitres) of the specimen used for analysis in the laboratory, *e.g.* 25g;
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Yersinia* spp. -** the total number of units positive for *Yersinia* spp.;
- ***Yersinia enterocolitica* –** the number of units positive for *Yersinia enterocolitica*, (including the units positive for *Yersinia enterocolitica* serotypes);
- ***Yersinia enterocolitica* O:3, O:5, O:9, and other serotypes and biotypes 1B, 2, 3, 4 -** number of units positive for the specific *Yersinia enterocolitica* serotype, or biotype respectively. If information on both serotype and biotype is available, the results should be reported as the biotype/ serotype combinations (available in the pick list); for example biotype 4/O:3;
- ***Yersinia enterocolitica,* unspecified -** the number of units positive for *Yersinia enterocolitica* where the serotype is unknown;
- ***Yersinia pseudotuberculosis* –** the number of units positive for *Yersinia pseudotuberculosis;*
- ***Yersinia* spp., unspecified -** the number of units positive for *Yersinia* spp. where the species is unknown.

Note that, in this table, the value in the column "Total units positive for *Yersinia* spp." is the sum of the values contained in the columns "*Y. enterocolitica"*, "*Y. pseudotuberculosis"* and "*Yersinia* spp*.,* unspecified" and that the value in the column "*Y. enterocolitica"* is the sum of the values in the columns "*Y. enterocolitica* O:3", "*Y. enterocolitica* O:9" etc. and "*Y. enterocolitica*, unspecified".

6.6. Verotoxigenic *Escherichia coli* (VTEC) in foodstuffs

Relevant food categories to be reported

- ***Meat and products thereof*** – information should be provided on the animal species from which the meat is derived *e.g.* broiler**, bovine**, **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 fruits 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* that are capable of producing verocytotoxin (VT)/ shigatoxins (*Stx*). Information on the serogroup (O antigen) should be reported. Serogroups of particular interest are: O157, O111, O103, O26, O145, and O91.

Information on genes encoding for verocytotoxin 1 (*vtx1*), verocytotoxin 2 (*vtx2*) or intimin (*eae*) should be reported, where available, as recommended 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.

Case definition / definition of a positive sample

VTEC positive sample / batch – a sample / batch from which 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.

Diagnostic / analytical methods typically used

There are standard methods for the detection of VTEC O157 in foods: ISO 16654:2001 (ISO, 2001) and NMKL 164 (NMKL, 2005).

Currently, there is no internationally recognised standard method for detection of VTEC non-O157.

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 tables

For reporting of data, use the table named "*VT E. coli in food*".

Specific guidelines for reporting data in the prevalence table:

- **Sampling stage** – where the samples have been collected (e.g. at processing plants / at retail);
- **Sampling context** – information on the context of the sampling (e.g. control and eradication programme), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **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 (in grams or millilitres) of the specimen used for analysis in the laboratory, *e.g.* 25g;
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for Verotoxigenic *E. coli* (VTEC)** - the total number of units positive for Verotoxigenic *E. coli* (VTEC);
- **VTEC O157 and other serogroup** – the number of units positive for the specific VTEC serogroup. Information on genes encoding for verocytotoxins or intimin should be reported if available; for example VTEC O157 *eae* positive *vtx1* positive;
- **VTEC, unspecified -** the number of units positive for VTEC where the serogroup is unknown.

6.7. *Brucella* spp. in foodstuffs

Relevant food categories to be reported

Milk and dairy products – information 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** 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.*

Case definition / definition of a positive sample

***Brucella* positive sample** - a sample where *Brucella* spp. has been isolated.

***Brucella* positive batch** - a batch where *Brucella* spp. has 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.

Preventive 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 tables

For reporting of data, use the table named "*Brucella in food*".

Specific guidelines for reporting data in the prevalence table:

- **Sampling stage** – where the samples have been collected (e.g. at processing plants / at retail);
- **Sampling context** – information on the context of the sampling (e.g. control and eradication programme), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **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 (in grams or millilitres) of the specimen used for analysis in the laboratory, *e.g.* 25g;

- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Brucella* spp.** - the number of units positive for *Brucella* spp. This total is derived from the summation of the following columns;
- ***Brucella* a., *Brucella* b., … -** the number of positive units categorised according to the *Brucella species*, where this information is available;
- ***Brucella* spp., unspecified** - the number of units positive for *Brucella* where the species is unknown.

6.8. *Staphylococcus* spp. in foodstuffs

Relevant food categories to be reported

- ***Meat and products thereof*** – information should be provided on the animal species from which the meat is derived *e.g.* **pig**, **broiler, turkey, bovine**, **sheep**, and the nature of the meat *e.g.* **carcase, fresh meat, minced meat**, **meat preparations, meat products**. 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 fruits and vegetables, ready-to-eat / non-ready-to-eat sprouted seeds).

Relevant agent species to be reported

MRSA: Strains of *S. aureus* resistant to virtually all available beta-lactam antimicrobials including methicillin (methicillin-resistant *S. aureus* (MRSA)) should be reported.
Information on the MRSA *spa*-types may also be reported.

Case definition / definition of a positive sample

***Staphylococcus* positive sample / batch** – a sample / batch from which *Staphylococcus* has been isolated.
MRSA positive sample / batch – a sample / batch from which MRSA has been isolated.

Diagnostic / analytical methods typically used

Currently, there is no internationally recognised standard method for detection of MRSA in food.
Details should be provided on the diagnostic method used, including how verification of MRSA is carried; in particular whether MRSA was detected by resistance testing of isolated *S. aureus* or by the use of selective media for MRSA.

Reporting the results in the tables

For reporting of data, use the table named "*Staphylococcus in food*".

Specific guidelines for reporting of data in the prevalence table:

- **Sampling stage** – where the samples have been collected (e.g. at processing plants / at retail) should be reported;
- **Sampling context** – information on the context of the sampling (e.g. control and eradication programme), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **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 (in grams or millilitres) of the specimen used for analysis in the laboratory, *e.g.* 25g;
- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Staphylococcus*** - in this column, the total number of sampling units considered contaminated with *Staphylococcus,* based on the analyses results, should be inserted;
- **Total units positive for *S. aureus*, methicillin resistant (MRSA) -** in this column, the total number of sampling units considered contaminated with MRSA, based on the analyses results, should be inserted;
- ***Spa*-type ….** – in this column the number of samples found positive for the specific *spa*-type is reported;
- **MRSA, unspecified** – this column is used to indicate the number of sampling units where the *spa*-type is unknown.

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, and cotton, sunflower) or compound vegetable source.

Compound feedingstuffs (from both animal and vegetable origin), subcategorized according the animal species of destiny – cattle, pigs, poultry (subcategorized as for breeders, laying hens, broilers, if possible, or not specified) and pets.

Relevant agent species / serovars / phagetypes to be reported

Salmonella spp.

The 5 most frequent serovars in the country should be reported. Phagetype information should be reported, where available.

Case definition / definition of a positive sample

***Salmonella* positive sample** – a sample where *Salmonella* spp. has been isolated.

***Salmonella* positive batch** – a batch where *Salmonella* spp. has 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 No. 71 (NMKL, 1999).

Reporting the results in the tables

For reporting of data, use tables named "*Salmonella in compound feedingstuffs*", "*Salmonella in feed material of animal origin*" and "*Salmonella in other feed matter*".

Specific guidelines for entering data in the prevalence tables:

- **Sampling stage** – where the samples have been collected (e.g. at feed mill);
- **Sampling context** – information on the context of the sampling (e.g. monitoring), who collected the samples (e.g. competent authority) and the sample strategy (e.g. objective sampling) should be inserted;
- **Sampling details** – free text to be used for further information on samples;
- **Sampling unit** – use "*Batch*" or "*Single*";
- **Sample weight** – the weight (in grams or millilitres) of the specimen used for analysis in the laboratory, *e.g.* 25g;

- **Units tested -** the number of sampling units that are analysed in total, and for which results are available;
- **Total units positive for *Salmonella* spp. -** in this column, the total number of positive sampling units, based on the analyses results, should be inserted. This total should be distributed according to the following columns;
- ***Salmonella* a, *Salmonella* b, … -** in these columns, the number of positive units should be categorised according to the (sub)species (serovar) found, where this information is available;

***Salmonella* spp., unspecified -** in this column, the number of sampling units positive for *Salmonella* where the (sub)species (serovar) is unknown, should be reported.

Information on the *Salmonella* serovars in feedingstuffs should also be reported in the relevant tables.

Data on monophasic *Salmonella* Typhimurium should be reported as following: this group comprises *Salmonella* Typhimurium strains lacking the second phase H antigen (1,4,[5],12:i:-). Whenever possible as much detail 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 phage type that is consistent with *S.* Typhimurium lacking phase two flagellar antigen has been confirmed, and the lack of the second flagellar antigen has been verified by PCR, then the term "monophasic *Salmonella* Typhimurium" is recommended to be used.

8. Reporting on antimicrobial resistance

Antimicrobial resistance monitoring in *Salmonella* spp.

Relevant animal species / food categories to be reported

Laying hens and broilers (*Gallus gallus*), turkeys, pigs and cattle.
Broiler meat, pig meat, bovine meat, turkey meat.

Relevant agent species / serovars to be reported

In the qualitative antimicrobial susceptibility tables: *S.* Enteritidis and *S.* Typhimurium and the next 5 most prevalent serovars in the country and the other serovars grouped together as "*Salmonella,* other serovars".

In the quantitative antimicrobial susceptibility tables: *S.* Enteritidis and *S.* Typhimurium for poultry species and meat thereof*; S.* Typhimurium and *S.* Derby for pigs and pig meat, *S.* Typhimurium and *S.* Dublin for cattle and bovine meat, and the other *Salmonella* serovars grouped together for all species as "other serovars".

Recommended antimicrobials to be reported

- Ampicillin;
- Cefotaxime;
- Chloramphenicol;
- Ciprofloxacin;
- Gentamicin
- Nalidixic acid;
- Streptomycin;
- Sulphonamides;
- Tetracycline;
- Trimethoprim*

* Trimethoprim and sulphonamides should be reported separately.

Antimicrobial resistance monitoring in *Campylobacter* spp.

Relevant animal species / food categories to be reported

Broilers (*Gallus gallus*), turkeys, pigs, cattle.
Broiler meat, turkey meat.

Relevant agent species / serovars to be reported

C. jejuni and *C. coli* separately. Reporting of susceptibility data for *Campylobacter* spp. overall is discouraged because resistance patterns vary for different species.

Recommended antimicrobials to be reported

For *C. jejuni* and *C. coli* it is recommended that results are reported for:

- Erythromycin;

- Ciprofloxacin;
- Tetracycline;
- Streptomycin;
- Gentamicin.

Antimicrobial resistance monitoring in indicator *E. coli* (non-pathogenic commensal)

Relevant animal species / food categories to be reported

Laying hen, broilers (*Gallus gallus*), turkeys, pigs, cattle.
Broiler meat, pig meat, bovine meat and turkey meat.

Recommended antimicrobials to be reported

- Ampicillin;
- Cefotaxime;
- Chloramphenicol;
- Ciprofloxacin;
- Gentamicin;
- Nalidixic acid;
- Streptomycin;
- Sulphonamides;
- Tetracycline;
- Trimethoprim*

* Trimethoprim and sulphonamides should be reported separately.

Antimicrobial resistance monitoring in indicator *Enterococcus* spp. (non-pathogenic commensal)

Relevant animal species / food categories to be reported

Broilers (*Gallus gallus*), pigs, cattle, turkeys.
Broiler meat, pig meat, bovine meat, turkey meat.

Relevant agent species to be reported

E. faecium and *E. faecalis* separately.

Recommended antimicrobials to be reported

- Ampicillin;
- Chloramphenicol;
- Erythromycin;
- Gentamicin;
- Linezolid;
- Quinopristin/dalfopristin;

- Streptomycin;
- Tetracycline;
- Vancomycin.

Diagnostic/analytical methods typically used

Different types of methods are used in antimicrobial resistance testing for *Salmonella* and indicator bacteria: disk diffusion, agar dilution, broth dilution and E-test ®. For *Campylobacter*, only dilution methods are considered reproducible.

Standard methods for antimicrobial susceptibility testing are given by the Clinical and Laboratory Standards Institute (CLSI) (CLSI standard M31-A3 (CSLI, 2008)) and European Committee on Antimicrobial Susceptibility Testing (EUCAST).

For *Salmonella* the dilution method is to be used according to the methods described by the CLSI, accepted as international reference method (ISO standard 20776-1:2006 (ISO, 2006c)), as stated in the Decision 2007/407/EC[20].

For *Campylobacter* dilution methods is to be used according to the NCCLS M45-A (CLSI, 2006), M100-S17 (CLSI, 2007), or the methods described in the CLSI guidelines M31-A3 (CSLI, 2008).

For indicator bacteria (*E. coli* and *Enterococci*) the international reference standard ISO 20776-1:2006 (ISO, 2006c) shall be used.

The cut-off values should be reported.

In the present manual the term “cut-off value” is used to be consistent with the EFSA reports on the technical specifications for harmonised monitoring and reporting as well as with the Decision 2007/407/EC, which recommends or requirse the use the epidemiologic cut-off values for monitoring purposes.

[20] OJ L 153, 14.6.2007, p. 26.

8.1. Reporting the antimicrobial susceptibility results in the tables

Antimicrobial susceptibility tables are provided for *Salmonella* and *Campylobacter*, as well as for *E. coli* and *Enterococcus* indicators as related to foodstuffs, animals and feedingstuffs. There are breakpoint tables and quantitative and qualitative antimicrobial susceptibility tables.

Cut-off value tables for antimicrobial resistance

The cut-off tables are provided to report cut-off values used in the antimicrobial susceptibility testing. The information to be reported is:

- **Test method used** - test used: disc diffusion method, agar dilution, broth dilution or E-test®;
- **Standards used for testing** - specify whether the methods used for testing were defined according to NCCLS/ CLSI standard or according to other standards;
- **The methods are used for investigation of isolates from -** information entered in the table can be copied to other cut-off value tables under the same zoonosis section by clicking the relevant categories (food, animals and feedingstuffs) in the box "*The methods are used for investigation of isolates from*". The information will then be copied to the relevant table;
- **Standard** - specify which standard for cut-off value has been used for each susceptibility category (e.g. Decision 2007/407/EC, EUCAST, EFSA's recommendations, NCCLS);
- **Concentration (microg/ml)/ Resistant >** (Dilution method) - is used to report broth and agar dilution cut-off values;
- **Zone diameter (mm) /Resistant <=** (Diffusion method) - is used to report agar diffusion cut-off values.

Please note that, when creating a new annual Report, you are able to choose the possibility to automatically import into the cut-off value tables the cut-off values specified in the EFSA's recommendation "Report of the Task Force on Zoonoses Data Collection including a proposal for a harmonized monitoring scheme of antimicrobial resistance in *Salmonella* in fowl (*Gallus gallus*), turkeys, and pigs and *Campylobacter jejuni* and *C. coli* in broilers" (EFSA, 2007) and in the EFSA's recommendation "Report from the Task Force on Zoonoses Data Collection including guidance for harmonized monitoring and reporting of antimicrobial resistance in commensal *Escherichia coli* and *Enterococcus* spp. from food animals" (EFSA, 2008).
The cut-off values specified in these EFSA's recommendations are imported automatically into the cut-off value tables for dilution methods for isolates from animals, food and feedingstuffs.
Two different cut-off value tables are available for *C. jejuni* and *C. coli* as well as for *E. faecalis* and *E. faecium*.

Please note that you can copy the cut-off value table information for the other sectors (food, animals, humans).

Quantitative antimicrobial resistance tables

These tables are used to report quantitative results from testing of bacterial isolates for antimicrobial resistance. The results are reported as the number of isolates with the given concentration/ inhibition zone.

Please note that due to the automatic calculations made by the web application, the cut-off value table has to be filled in first to allow the calculations of the values of "N" and "n" in the quantitative tables. The cut-off values can be still manually changed in the quantitative tables.

The information that should be reported includes:

- **Isolates out of a monitoring programme (yes / no) -** indicate whether the isolates in the table originate from a monitoring programme or not;
- **Number of isolates available in the laboratory -** report the total number of isolates that are tested and reported on in this table;
- **Column 'N' –** this column refers the number of isolates tested for susceptibility vis-à-vis the antimicrobial mentioned in the row heading; it is calculated automatically;
- **Column 'n' –** this column refers the number of resistant isolates (out of the N isolates tested) and is calculated automatically on the basis of the information provided concerning the corresponding breakpoints;
- **Dilution method (concentration (mg/L)), number of isolates with a concentration of inhibition equal to** - in every one of these cells, report the number of isolates with the concentration (mg/L) of inhibition equal to the column heading figure;
- **Agar diffusion method (Zone diameter (mm)), number of isolates with a zone of inhibition equal to** - in every one of these cells, report the number of isolates with the diameter (mm) of inhibition equal to the column heading figure.

Qualitative antimicrobial resistance tables

The qualitative tables are used to summarise the number of resistance strains for each antimicrobial substance for different food, animal species and feedingstuff categories. The number of multiresistant isolates is also reported in this table.

The Antimicrobial Qualitative Tables will be created by specifying first the food, feed or animal category and then, within the table, the agent serovars/ species.

Specific guidelines for reporting data in the qualitative table:

- **Isolates out of a monitoring programme (yes / no) -** indicate whether the isolates in the table originate from a monitoring programme or not;
- **Number of isolates available in the laboratory** - total number of isolates that are tested and reported on in this table;
- **Column 'N' -** number of isolates that are tested for susceptibility vis-à-vis the antimicrobial mentioned in the row heading, and for the animal species mentioned in column heading;
- **Column 'n' -** number of resistant isolates;
- For the rows **'Fully sensitive'** and **'Resistant to 1 to >4 antimicrobials'** the number of isolates tested is reported in the **'N'** column and in the **'n'** column the number of isolates found fully resistant or resistant to the specified number of antimicrobials is indicated.

Please note that due to a new function (ad hoc button) in the web reporting application, you will be able to choose the possibility to automatic import the values entered in the Antimicrobial Quantitative Tables into the Antimicrobial Qualitative Table. If you choose this option, the sum of the values reported in the corresponding Antimicrobial Quantitative tables, both for diffusion and dilution method, will be copied into the Antimicrobial Qualitative Table.
In case the data to be reported in the qualitative tables are exactly the same as reported in the quantitative tables, there is no need to fill in the qualitative tables.

9. Reporting on other pathogenic microbiological agents in foodstuffs

9.1. Staphylococcal enterotoxins in foodstuffs

Relevant food categories to be reported

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 a lower heat treatment than pasteurisation;
- ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment;
- unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment;
- 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 to indicate the weight of the sample tested.

Positive batch - a batch where staphylococcal enterotoxins have been detected in at least one of the samples in the batch. It is recommended to indicate the weight of the sample tested. When using quantitative analysis, it is also recommended to indicate the limit of detection of the method used.

Diagnostic / analytical methods typically used

The recommended method is the European screening method of the EU-RL for S*taphylococci* (ANSES–Lerqap, Maison-Alfort) in accordance with Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

Reporting the results in the tables

For reporting of data, use the table named "*Staphylococcal enterotoxins in food"*.

Specific guidelines for reporting data in the prevalence table:

- **Sampling stage** – where the samples have been collected (e.g. at processing plant);
- **Sampling context** – information on the context of the sampling (e.g. own check), who collected the samples (e.g. sampling by industry) and the sample strategy (e.g. objective sampling) should be inserted;
- **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 (in grams) of the specimen used for analysis in the laboratory, *e.g.* 10g;
- **Units tested –** the total number of sample units tested in the laboratory;

- **Total units positive for Staphylococcal enterotoxins** – the number of sample units in which staphylococcal enterotoxins have been detected.

9.2. *Enterobacter (Cronobacter) sakazakii* in foodstuffs

Relevant food categories to be reported

Food categories for which *Enterobacter (*currently *Cronobacter) 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 *i.e.* 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.

Case definition / definition of a positive sample

***Enterobacter sakazakii* positive sample** - a sample where *Enterobacter sakazakii* has been isolated.

***Enterobacter sakazakii* positive batch** - a batch where *Enterobacter sakazakii* has 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 *Enterobacter sakazakii* in milk products is ISO/TS 22964:2006 (ISO, 2006d) in accordance with Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

Reporting the results in the tables

For reporting of data, use the table named "*Enterobacter sakazakii in food*".

Specific guidelines for reporting data in the prevalence table:

- **Sampling stage** – where the samples have been collected (e.g. at retail);
- **Sampling context** – information on the context of the sampling (e.g. own check), who collected the samples (i.e. sampling by industry) and the sample strategy (e.g. objective sampling) should be inserted;
- **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 (in grams) of the specimen used for analysis in the laboratory, *e.g.* 10g;
- **Units tested –** the total number of sample units tested in the laboratory;
- **Total units positive for *E. sakazakii*** – the number of sample units in which *E. sakazakii* have been detected.

9.3. Histamine in foodstuffs

Relevant food categories to be reported

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

- **Fishery products from fish species associated with a high amount of histidine** (*e.g.* fish species of the family *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae*, *Scombresosidae*), **which are not enzyme maturated in brine** (category 1). This typically includes raw fish flesh and canned products from these fish species. A detailed description of the product examined is recommended to be given (raw product, canned, maturated, etc.).

- **Fishery products from fish species associated with a high amount of histidine** (*e.g.* fish species of the family *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae*, *Scombresosidae*), **which have undergone enzyme maturation treatment in brine** (category 2). A detailed description of the product examined is recommended to be given (raw product, canned, maturated, 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 9 sample units out of which 2 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 (cat. 1) or 200 mg/kg (cat. 2).

Batch in non-conformity - a batch for which the mean value of the sample units exceeds 100 mg/kg (cat. 1) or 200 mg/kg (cat. 2); or a batch where out of the "n" sample units taken more than "c" contains histamine over 100 mg/kg (cat. 1) or 200 mg/kg (cat. 2); or a batch where one or more sample units contain histamine with more than 200 mg/kg (cat. 1) or more than 400 mg/kg (cat. 2).

Diagnostic / analytical methods typically used

HPLC in accordance with Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs[21].

[21] References - 1. Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49. 2. Duflos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination of biogenic amines in plaice (*Pleuronectes platessa*) and whiting (*Merlangus merlangus*). J. AOAC Internat. 1999, 82, 1097-1101.

Reporting the results in the tables

For reporting of data, use the table named "*Histamine in food*".

Please note that in case of batch sampling, where a set of sample units (usually 9) are 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 reporting data in the prevalence tables:

- **Sampling stage** – where the samples have been collected (e.g. at retail);
- **Sampling context** – information on the context of the sampling (e.g. own check), who collected the samples (e.g. sampling by industry) and the sample strategy (e.g. objective sampling) should be inserted;
- **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 (in grams) of the specimen used for analysis in the laboratory, *e.g.* 10g;
- **Units tested –** the total number of sample units tested in the laboratory;
- **Total units in non-conformity** - in this column, the total number of sampling units which are in non-conformity with the microbiological criterion based on the analytical results should be inserted;
- **≤100 mg/kg -** in this column the number of single samples with values below the limit is reported. In case of batch sampling, the number of sampling units (= batches) having the maximum value below this limit is reported;
- **> 100 – ≤ 200 mg/kg –** in this column the number of single samples with values between the 2 limits is reported. In case of batch sampling, the number of sampling units (= batches) having the maximum value between the limits is given;
- **> 200 - ≤400 mg/kg -** in this column the number of single samples with values between the 2 limits is reported. In case of batch sampling, the number of sampling units (= batches) having the maximum value between the limits is given;
- **>400 mg/kg -** in this column the number of single samples with values over the limit is reported. In case of batch sampling, the number of sampling units (= batches) having the maximum value over the limit is reported.

10. References

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Annex I. Guidelines for reporting analytical methods

The laboratories can use international standard methods such as ISO and CEN, but also national standard methods (such as NEN in the Netherlands and DIN in Germany, etc.), or even own (laboratory developed) methods.

If one would like to compare data it would indeed be necessary to have sufficient detailed information on the methods. You could think of asking for the following information:

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 used procedure;
2. If a CEN / ISO method is used with modifications, the information of point 1. would be needed, as well as the information on the modifications;
3. If a national standard method is followed, it might be sufficient if the laboratory gives the number of the national standard method (and the year of publication), depending on the fact whether EFSA is able to obtain these methods from the national standardisation bodies. If this latter is a problem (also the language might be a problem) and if the method is also not available in international literature, then it might be necessary to ask for a more detailed description of the method (like used media, incubation temperatures and times, method of confirmation);
4. If an "*own*" method is used, it might be sufficient to ask for the reference in the literature. If this is not available, it might be necessary to ask for more details (see point 3.);
5. If neither an ISO or CEN method is used, is the method validated and / or compared to the relevant ISO / CEN method?

If molecular (PCR) methods are used

6. Name of the test and manufacturer of commercially available test.
7. Use of the PCR in combination with a conventional method. Which step of the conventional method is replaced by the PCR (*e.g.* confirmation step)?
8. Is the test validated? If so, by which organisation (AFNOR, AOAC, MICROVAL or other)?

If immunological (serological) methods are used

9. Name of the test and manufacturer of commercially available tests;
10. 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)?
11. Type of test;
12. Is the test validated? If so, by which organisation (AFNOR, AOAC, MICROVAL or other)?

Annex II. Definitions

1. General definitions

Antimicrobial - drug which, at low concentrations, exerts an action against microbial pathogens and exhibits selective toxicity towards them (from "*Opinion of the Scientific Steering Committee on Antimicrobial Resistance 28 May 1999*"). Antimicrobials typically include antibiotics but also antivirals and other drugs effective against microorganisms.

Antibiotic - substance produced by or derived from a microorganism, which destroys or inhibits the growth of other microorganisms (from "*Opinion of the Scientific Steering Committee on Antimicrobial Resistance 28 May 1999*").

Antimicrobial resistance - the ability of microorganisms of certain species to survive or even to grow in the presence of a given concentration of an antimicrobial agent, that is usually sufficient to inhibit or kill microorganisms of the same species (Dir. 2003/99/EC). Resistance against an antimicrobial is considered to be present if the Minimum Inhibitory Concentration (MIC) exceeds the breakpoint or the epidemiological cut-off value.

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 (Reg. (EC) No 2073/2005).

Notification system - a system, where the disease or infection has to be reported to the competent authority based on a legal obligation.

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: departement;
- Italy: provincia;
- Luxemburg: -
- 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: -
- Poland: powiat;
- Slovenia: območje;
- Slovakia: kraj.

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

Zoonosis - any disease and / or infection which is naturally transmissible directly or indirectly between animals and humans (Dir. 2003/99/EC).

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

2. 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 (Reg. (EC) No 853/2004[22]).

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

[22] OJ L 139, 30.4.2004, p. 55.

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 which is taken under statistical consideration to provide representative data (Dec. 98/179/EC[23]).

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, which 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 which has produced it (Reg. (EC) No 2073/2005).

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

Sample weight - the weight (in g or ml or cm^2) of the specimen used in the laboratory for analysis.

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 data, the sampling unit might be "*Single"* or "*Batch"*.

Single - means a foodstuff or a feedingstuff comprised of 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 which is sampled and intended to be analysed.

3. Definitions regarding the sampling context

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[24], the

[23] OJ L 65, 5.3.1998, p. 31.
[24] OJ L 145, 13.6.1977, p. 44.

eradication programmes are so devised that, on their completion, herds are classified as brucellosis / tuberculosis officially free.

HACCP (Hazard Analysis and Critical Control Point) - programme designed to effectively control processes by identifying Critical Control Points (CCP), establishing critical limits for each CCP, monitoring CCP, gathering data, record keeping, 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 (Dir. 2003/99/EC).

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 (Reg. (EC) No 882/2004[25]).

Official sampling - sampling performed under 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 with 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 surveys.

Selective sampling- planned strategy where 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.

[25] OJ L 165, 30.4.2004, p. 1.

Suspect sampling - unplanned selection of a sample, where 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 sampling – strategy where all units of the population are sampled.

Convenience sampling – is used in exploratory research where the researcher is interested in getting an inexpensive approximation of the truth. The sample is selected because they are convenient. 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 Reg. (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 taken when positive cases are detected. This type of programme does not necessarily have a defined target for diseases / contamination occurrence reduction.

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 findings of the survey are to be extrapolated. The units to examine are to be selected randomly (Rothman, 1986 and Noordhuizen et al., 2001).

4. Definitions of foodstuffs

Carcase - the body of an animal after slaughter and dressing (Reg. (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 action, in accordance with food law and the instructions given by the competent authority (Reg. (EC) No 2073/2005).

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

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

Dairy products - processed products resulting from the processing of raw milk or from the further processing of such processed products (Reg. (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 (Reg. (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 (Reg. (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 (Reg. (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 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 (Dir. 1999/21/EC[26]).

[26] OJ L 91, 7.4.1999, p. 29.

Food (or foodstuff) - any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans (Reg. (EC) No 178/2002[27]).

Food intended for infants - food specifically intended for infants (Dir. 2006/141/EC[28]).

Food intended for special medical purposes - dietary food for special medical purposes (Dir. 99/21/EC).

Food safety criterion - criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market (Reg. (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(Reg. (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 (Reg. (EC) No 853/2004).

Frog 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* (Reg. (EC) No 853/2004).

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

Meat - edible parts of the animals below mentioned, including blood (Reg. (EC) No 853/2004).

- '*Domestic ungulates*' - domestic bovine (including *Bubalus* and *Bison* species), porcine, ovine and caprine animals, and domestic solipeds.
- '*Poultry*' - farmed birds, including birds that are not considered as domestic but which are farmed as domestic animals, with the exception of ratites which are considered as '*Farmed game*'.
- '*Lagomorphs*' - rabbits, hares and rodents.

[27] OJ L 31, 1.2.2002, p. 1.
[28] OJ L 401, 30.12.2006, p. 1.

- '*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 applicable 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 (Reg. (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 (Reg. (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 (Reg. (EC) No 2073/2005).

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

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

Packing centre - establishment where eggs are graded by quality and weight (Reg. (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[29].

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

[29] OJ L 330, 5.12.1998, p. 32.

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 contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law (Reg. (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 (Reg. (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 (Reg. (EC) No 852/2004[30]).

Processing - any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes (Reg. (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 (Reg. (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 (Reg. (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 effective to eliminate or reduce to acceptable level microorganisms of concern (Reg. (EC) No 2073/2005).

Shelf-life - the period preceding the "*Use by*" or the minimum durability date (Dir. 2000/13/EC[31]).

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

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

[30] OJ L 139, 30.4.2004, p. 1
[31] OJ L 109, 6.5.2000, p. 29

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

5. Definitions of animals

Animal - any animal of the species referred to in EU Directives (Dir. 64/432/EEC, Dir. 91/68/EEC and Dir. 92/102/EEC[32]).

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 only move to slaughter (Dir. 64/432/EEC and Dir. 91/68/EEC).

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 (Dir. 64/432/EEC).

Breeding poultry - poultry 72 hours old or more, intended for the production of hatching eggs (Dir. 90/539/EEC[33]).

Steers - male bovine animal castrated before sexual maturity.

Calves - domestic animals of the bovine species not exceeding a live weight of 300 kg, which do not yet have their second teeth (Dec. 94/433/EC[34]).

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

Cows - female bovine animals which have already calved (Dec. 94/433/EC).

Cows, dairy - cows which 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 (Dec. 94/433/EC).

[32] OJ L 355, 5.12.1992, p. 32.
[33] OJ L 303, 31.10.1990, p. 6.
[34] OJ L 179, 13.7.1994, p. 27.

Day-old chicks - all poultry less than 72 hours old, not yet fed; however, Barbary ducks may be fed (Dir. 90/539/EEC).

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

Ewes, Milk – ewes which 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 which have already lambed at least once as well as those which 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 (Reg. (EC) No 2160/2003[35]).

Goats – domestic animals of the species *Capra*.

Hatching eggs - eggs for incubation, laid by poultry (Dir. 90/539/EEC).

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

Heifers for slaughter - heifers bred for meat production (Dec. 94/433/EC).

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

Herd - an animal or group of animals kept on a holding as an epidemiological unit (Reg. (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 (Dir. 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 (Dir. 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.

[35] OJ L 325, 12.12.2003, p. 1.

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 (Reg. (CE) 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 (Dir. 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 (Dir. 91/68/EEC).

Pigs – domestic animals of the species *Suis*.

Controlled housing conditions (in integrated production systems for pigs): a type of animal husbandry where swine are kept at all times under conditions controlled by the food business operator with regard to feeding and housing (Commission Regulation (EC) N 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 re-stocking supplies of game (Dir. 90/539/EEC).

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 (Dir. 90/539/EEC).

Period:

- **Rearing period -** the period wherein 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 one week old and ends when they are slaughtered (usually at 6 weeks).
- **Before slaughter -** the period just before sending animals to slaughter (typically 2, 3 weeks before).

Sheep – domestic animals of the species *Ovis*.

Spent hens - laying hens that do not produce eggs any more.

6. Definitions of feedingstuffs

Compound feedingstuffs - mixtures of feed materials, containing additives whether or not, which are intended for oral animal feeding as complete or complementary feedingstuffs (Directive 96/25/EC[36]).

Cereal grains, their products and by-products (Directive 96/25/EC)**:**

- Oats (and derived) - oats, oat flakes, oat middlings, oat hulls and 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-gelatinized 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 (Reg. (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 (Directive 96/25/EC).

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; cereals straw, treated**;** cereals straw (Directive 96/25/EC).

Land animal products - meat meal; meat and bone meal; bone meal; greaves; poultry meal; feather meal, hydrolysed; blood meal; animal fat (Directive 96/25/EC).

[36] OJ L 125, 23.5.1996, p. 35.

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 (Directive 96/25/EC).

Milk products - skimmed-milk powder; buttermilk powder; whey powder; whey protein powder; casein powder; lactose powder; whey powder, low in sugar (Directive 96/25/EC).

Oil seeds, oil fruits, their products and by-products (Directive 96/25/EC)**:**

- 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.
- 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 (Directive 96/25/EC).

Other plants, their products and by-products - (sugar) cane molasses; (sugar) cane vinasse; (cane) sugar; seaweed meal (Directive 96/25/EC).

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 (Directive 96/25/EC).

Annex III. List of general abbreviations

AFNOR	*Associacion Française de Normalisation*
AOAC	Association of Analytical Communities
BST	Brucellosis Skin Test
CEN	European Committee for Standardization
CFT	Complement Fixation Test
CFU	Colony forming unit
CSLI	Clinical and Laboratory Standards Institute
DIN	*Deutsches Institut fur Normung*
EBL	European Bat *Lyssavirus*
EC	European Community
ECDC	European Centre for Disease Prevention and Control
EEC	European Economic Community
EFSA	European Food Safety Authority
ELISA	Enzyme-Linked Immunosorbent Assay
EN	European Norm
EU	European Union
EU-RL	European Union Reference Laboratory
FAT	Fluorescent Antibody Test
HACCP	Hazard Analysis Critical Control Point
HPLC	High Performance Liquid Chromatography
ISO	International Organization for Standardization
MRSA	Methicillin-resistant *Staphylococcus aureus*
MICROVAL	European Validation and Certification Organisation
MRT	Milk Ring Test
MS	Member State of the European Union
NCCLS	National Committee for Clinical Laboratory Standards
NEN	Dutch Standardization Institute
NMKL	Nordic Committee on Food Analysis
OBF	Officially Brucellosis Free

OBmF	Officially *Brucella melitensis* Free
OIE	World Organization for Animal Health
OTF	Officially Tuberculosis Free
PCR	Polymerase Chain Reaction
RBT	Rose Bengal Test
SAT	Slow Agglutination Test
Spa	*Staphylococcus* protein A
VTEC	Verotoxigenic *Escherichia coli*
WHO	World Health Organization

Annex IV. Regional reporting scenarios

According to the level of details 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 is 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** region 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.