

Data dictionaries—guidelines for reporting data on zoonoses, antimicrobial resistance and food-borne outbreaks using the EFSA data models for the Data Collection Framework (DCF) to be used in 2016, for 2015 data

European Food Safety Authority

Abstract

This technical report of the European Food Safety Authority (EFSA) presents guidance to reporting European Union (EU) Member States (MSs) and non-Member States in data submission using extensible markup language (XML)/Microsoft Office Excel data transfer covering the reporting of isolate-based quantitative antimicrobial resistance data, as well as reporting of prevalence data on zoonoses and food-borne contaminants, food-borne outbreak data, animal population data, disease status data and text forms. For data collection purposes, EFSA has created the Data Collection Framework (DCF) application. The present report provides data dictionaries to guide the reporting of information deriving from 2015 under the framework of Directive 2003/99/EC, Regulation (EU) 1375/2015, Regulation (EU) 218/2014 and Decision 2013/652/EC. The objective is to explain in detail the individual data elements that are included in the EFSA data models to be used for the XML/Excel data transmission through the DCF. In particular, the data elements to be reported are explained, including information about the data type, a reference to the list of allowed terms and any additional business rule or requirement that may apply.

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Summary

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

For the reporting of the annual data, EFSA provides the Data Collection Framework (DCF) that allows data providers to submit data in extensible markup language (XML)/Microsoft Office Excel formats through a web service. Data models are provided to the reporting countries describing the format and the content requested for submitting data through the DCF.

To support reporting countries in data submission using XML/Excel data transfer, specific guidelines are given in this report covering the reporting of isolate-based quantitative antimicrobial resistance data, as well as reporting of prevalence data on zoonoses and food-borne contaminants, food-borne outbreak data, animal population data, disease status data and text forms. These data dictionaries are specifically aimed at guiding the reporting of information deriving from 2015 under the framework of Directive 2003/99/EC, Regulation (EU) 1375/2015, Regulation (EU) 218/2014 and Decision 2013/652/EC.

The objective is to explain in detail the individual data elements that are included in the EFSA data models to be used for the XML/Excel data transmission through the DCF. In particular the data elements to be reported are explained, including information about the data type, a reference to the list of allowed terms and any additional business rule or requirement that may apply.

The list of controlled terminologies (catalogues of allowed terms) to which some element values have to comply are provided in a separate Excel file published on EFSA's website together with these guidelines. For data elements referring to a catalogue, the name of the catalogue is provided (corresponding to the name of the provided Excel sheet containing the list of terms) as well as the name of the relevant domain. Domains are subsets of terms belonging to the catalogue that apply to a specific data element and are documented in the form of columns indicating if a term belongs (TRUE) or does not belong (FALSE) to the domain of a data element.

An overview of the EFSA data models' structures and the complete set of business rules applied for data validation for zoonoses, antimicrobial resistance, food-borne outbreak, animal population, disease status and text forms are given in Sections 2–8.

Further information on the scientific aspects of the data to be reported can be found in the Manual for reporting on zoonoses and zoonotic agents, within the framework of Directive 2003/99/EC, and on some other pathogenic microbiological agents for information deriving from the year 2015 (EFSA, 2016a); in the Manual for reporting on antimicrobial resistance within the framework of Directive 2003/99/EC and Decision 2013/652/EU for information deriving from the year 2015 (EFSA, 2016b); and in the Manual for reporting on food-borne outbreaks in accordance with Directive 2003/99/EC for information deriving from the year 2015 (EFSA, 2016c). Detailed guidelines for reporting on antimicrobial resistance data have been issued by EFSA for meticillin-resistant *Staphylococcus aureus* (MRSA) (EFSA, 2012).

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1. Introduction

1.1. Background and Terms of Reference as provided by EFSA¹

The Directive 2003/99/EC² lays down the European Union (EU) system for monitoring and reporting of information on zoonoses, which obligates the Member States (MSs) to collect data on zoonoses, zoonotic agents, antimicrobial resistance (AMR) and food-borne outbreaks (FBO). The European Food Safety Authority (EFSA) is assigned the tasks of examining the data collected and preparing the EU Summary Reports (EUSR) in collaboration with European Centre for Disease Prevention and Control (ECDC).

In 2013, based on the proposals issued by EFSA, the European Commission (EC) put forward and discussed with the MSs a new legislation on the harmonised monitoring of AMR in *Salmonella*, *Campylobacter* and indicator bacteria in food-producing animals and food derived thereof. The Commission implementing Decision 2013/652/EU³ of 12 November 2013 establishes a list of combinations of bacterial agents, food-producing animal populations and food products and sets up priorities for the monitoring of AMR from a public health perspective.

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

EFSA enables reporting in extensible markup language (XML)/Microsoft Office Excel format via the Data Collection Framework (DCF). New XML reporting schemas are created before the start of the reporting period in April each year and are supported by revised guidance documents.

The BIOCONTAM and DATA units are invited to:

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

This technical report specifically addresses the fifth term of reference above: to revise the guidelines (data dictionaries) for XML/Excel data reporting each year and publish them as an EFSA technical report.

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

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

³ Commission Implementing Decision 2013/652/EU of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria. OJ L 303, 14.11.2013, p. 26–39.

2. Antimicrobial resistance isolate-based data model 2015

2.1. Introduction

This data dictionary provides guidance for reporting on AMR in animals and food at the isolate level pursuant to Article 9 of Directive 2003/99/EC and to Annex, part B, of Commission implementing Decision 2013/652/EU. The objective is to explain in detail the individual data elements that are included in the EFSA data model to be used for the XML/Excel transmission of isolate-based data on AMR through EFSA's DCF.

Refer to Table 5 for information to be reported for sampling unit type, sampling stage, sampling type, sampling context, sampler and sampling strategy based on the requirements of Commission implementing Decision 2013/652/EU.

The EFSA data model for isolate-based AMR data is summarised in Table 6 and some business rules are presented in Table 7.

Although this data model also allows for reporting results of diffusion methods, Member States (MSs) should report quantitative minimum inhibitory concentration (MIC) data from dilution methods in accordance with the requirements of Commission implementing Decision 2013/652/EU.

Specific guidance for reporting mandatory data on *Salmonella* spp. and commensal *E. coli* producers of ESBLs/AmpC/carbapenemases obtained from the harmonised routine monitoring, and ESBL-/AmpC-/Carbapenemase-producing *E. coli* derived from specific monitoring, as well as voluntary data derived from the specific monitoring of carbapenemase-producers, were included.

2.1.1. Illustrative example of how to use the data model

An example of how to report antimicrobial susceptibility results to gentamicin and cefotaxime related to six isolates tested by the dilution method through the AMR isolate-based data model is shown in Table 1. It is intended to demonstrate which values have to be repeated over several rows. The example displays only a subset of data elements of the data model in an Excel file. Please, note that the terms still need to be coded before transmission to the DCF.

Data submitted to EFSA's DCF by using the isolate-based data model will be aggregated and migrated automatically to a quantitative AMR table in the Scientific Data Warehouse. Figure 1 shows how the first row of Table 1 could look in an XML file according to the AMR isolate-based data model.

Table 1: Example data on testing and reporting MIC values of 6 isolates tested for susceptibility to gentamicin and cefotaxime, presented as subset of a DCF—AMR isolate-based data model—Excel file (some mandatory columns are not displayed here and terms have to be coded before transmission to DCF)

| resultCode | zoonosis | matrix | totUnits Tested | totUnits Positive | totSamp UnitsTested | totSamp UnitsPositive | labIsol Code | labTot Isol | substance | cutoff Value | lowest | highest | MIC |
|------------|----------------------------------|----------------------------|-----------------|-------------------|---------------------|-----------------------|--------------|-------------|------------------------------|--------------|--------|---------|--------|
| isol1_GEN | <i>Salmonella</i> - S. Saintpaul | Turkeys - fattening flocks | 300 | 160 | 500 | 280 | isol1 | 42 | Aminoglycosides - Gentamicin | 2 | 0.5 | 32 | 2 |
| isol1_CTX | <i>Salmonella</i> - S. Saintpaul | Turkeys - fattening flocks | 300 | 160 | 500 | 280 | isol1 | 42 | Cephalosporins - Cefotaxime | 0.5 | 0.25 | 4 | <=0.25 |
| isol2_GEN | <i>Salmonella</i> - S. Saintpaul | Turkeys - fattening flocks | 300 | 160 | 500 | 280 | isol2 | 42 | Aminoglycosides - Gentamicin | 2 | 0.5 | 32 | 32 |
| isol2_CTX | <i>Salmonella</i> - S. Saintpaul | Turkeys - fattening flocks | 300 | 160 | 500 | 280 | isol2 | 42 | Cephalosporins - Cefotaxime | 0.5 | 0.25 | 4 | <=0.25 |
| isol3_GEN | <i>Salmonella</i> - S. Saintpaul | Turkeys - fattening flocks | 300 | 160 | 500 | 280 | isol3 | 42 | Aminoglycosides - Gentamicin | 2 | 0.5 | 32 | 32 |
| isol3_CTX | <i>Salmonella</i> - S. Saintpaul | Turkeys - fattening flocks | 300 | 160 | 500 | 280 | isol3 | 42 | Cephalosporins - Cefotaxime | 0.5 | 0.25 | 4 | 0.5 |
| isol4_GEN | <i>Salmonella</i> - S. Saintpaul | Turkeys - fattening flocks | 300 | 160 | 500 | 280 | isol4 | 42 | Aminoglycosides - Gentamicin | 2 | 0.5 | 32 | 32 |
| isol4_CTX | <i>Salmonella</i> - S. Saintpaul | Turkeys - fattening flocks | 300 | 160 | 500 | 280 | isol4 | 42 | Cephalosporins - Cefotaxime | 0.5 | 0.25 | 4 | 4 |
| isol5_GEN | <i>Salmonella</i> - S. Saintpaul | Turkeys - fattening flocks | 300 | 160 | 500 | 280 | isol5 | 42 | Aminoglycosides - Gentamicin | 2 | 0.5 | 32 | > 32 |
| isol5_CTX | <i>Salmonella</i> - S. Saintpaul | Turkeys - fattening flocks | 300 | 160 | 500 | 280 | isol5 | 42 | Cephalosporins - Cefotaxime | 0.5 | 0.25 | 4 | 4 |
| isol6_GEN | <i>Salmonella</i> - S. Saintpaul | Turkeys - fattening flocks | 300 | 160 | 500 | 280 | isol6 | 42 | Aminoglycosides - Gentamicin | 2 | 0.5 | 32 | > 32 |
| isol6_CTX | <i>Salmonella</i> - S. Saintpaul | Turkeys - fattening flocks | 300 | 160 | 500 | 280 | isol6 | 42 | Cephalosporins - Cefotaxime | 0.5 | 0.25 | 4 | > 4 |

```

<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<dataset>
  <result>
    <resultCode>isol1_GEN</resultCode>
    <repYear>2014</repYear>
    <repCountry>PN</repCountry>
    <lang>en</lang>
    <zoonosis>RF-00001234-MCG</zoonosis>
    <matrix>A041277A</matrix>
    <totUnitsTested>300</totUnitsTested>
    <totUnitsPositive>160</totUnitsPositive>
    <totSampUnitsTested>500</totSampUnitsTested>
    <totSampUnitsPositive>280</totSampUnitsPositive>
    <sampUnitType>G202A</sampUnitType>
    <sampStage>E101A</sampStage>
    <sampOrig>PN</sampOrig>
    <sampType>S005A</sampType>
    <sampContext>K021A</sampContext>
    <sampler>CX03A</sampler>
    <progCode>AMRP01A</progCode>
    <progSampStrategy>ST50A</progSampStrategy>
    <labCode>NRL-Salm</labCode>
    <labIsolCode>isol1</labIsolCode>
    <labTotIsol>42</labTotIsol>
    <sampY>2014</sampY>
    <sampM>1</sampM>
    <sampD>27</sampD>
    <anMethCode>F132A</anMethCode>
    <substance>RF-00000536-VET</substance>
    <cutoffValue>2</cutoffValue>
    <lowest>R016A</lowest>
    <highest>R052A</highest>
    <MIC>R020A</MIC>
  </result>
  [...]
</dataset>

```

Figure 1: Example data in XML according to the DCF's AMR isolate-based data model

2.1.2. How to report the minimum inhibitory concentration

Figure 2 shows how MIC values relate to the data reported in the isolate-based data model through DCF.

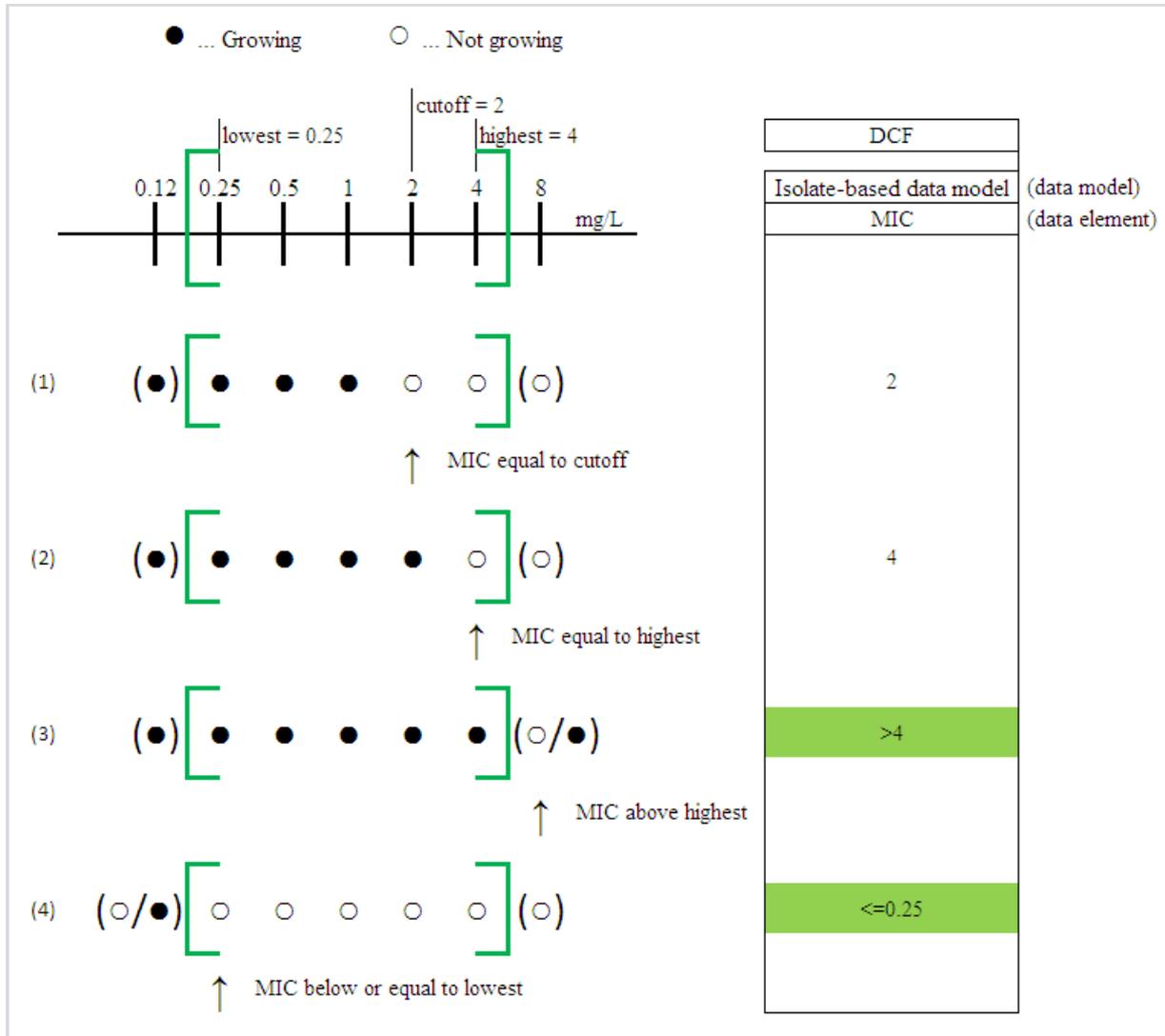


Figure 2: MIC in the isolate-based data model. The right-hand column displays which MIC values should be reported for the respective test results in the data element *MIC* (MIC values have to be coded before transmission to DCF)

2.2. General information and identification of the isolate/result

2.2.1. Result code (*resultCode AMR.01*)

This data element is **mandatory**. It is the **unique** identifier/code of the result, provided by the laboratory performing the antimicrobial susceptibility testing of the isolate, which should include the unique isolate code (*labIsolCode*). The **result code** must be **unique for the country**.

2.2.2. Reporting year (*repYear AMR.02*)

This data element is **mandatory**. It is a numerical data element consisting of four digits. It is the reporting year, which is the year to which reported data refers.

2.2.3. Reporting country (*repCountry AMR.03*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_COUNTRY, domain: D_ALL_repCountry). The list includes the 28 EU MSs, as well as Norway, Iceland and Switzerland.

2.2.4. Language (*lang AMR.04*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_LANG, domain: D_ALL_lang); however, **only the code 'en' for 'English' should be used**, as text in the free text data elements (data elements AMR.14 Sampling details and AMR.37 Comment) should be provided in English.

2.3. Information about type and source of samples and isolates

2.3.1. Zoonotic agent (*zoonosis AMR.05*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_PARAM_ZOO, domain: D_AMR_zoonosis). **The value in zoonosis must be reported at least at level 2 of the pick list (domain D_AMR_zoonosis)**. It enables reporting, when relevant, of the bacterial agents tested for AMR, specifying the genus, species and serovar/serotype/phagetype/*Staphylococcus spa*-type of the bacteria in question, particularly for *Salmonella* and meticillin-resistant *Staphylococcus aureus* (MRSA).

It is mandatory that AMR data are reported for *Salmonella* (at the serovar level) and indicator *Escherichia coli*.

For *Salmonella*, consistent reporting of AMR data at the serovar level (level 2 term) is mandatory as required by Decision 2013/652/EU, as it is scientifically relevant to analyse resistance and multi-resistance at this level, particularly for the serovars of public health significance, emerging serovars and serovars exhibiting particular combinations of resistance. If available and for further refinement, susceptibility data can be also reported at an even greater level of detail at the phagetype level, e.g. '*Salmonella* - *S. Typhimurium* - DT 137' (code 'RF-00002322-MCG').

Reporting of AMR data for *Campylobacter* spp. should be avoided because resistance patterns vary for different *Campylobacter* species. Data should therefore be reported separately for the two species: *C. jejuni* (code 'RF-00000061-MCG') and *C. coli* (code 'RF-00000054-MCG').

Note that AMR data on indicator bacteria should be reported using level 2 of the catalogue for zoonotic agents: *E. coli* should be reported as '*Escherichia coli*, non-pathogenic - *E. coli*, non-pathogenic, unspecified' (code 'RF-00003897-MCG'), indicator *Enterococcus faecium* should be reported as '*Enterococcus*, non-pathogenic - *E. faecium*' (code 'RF-00000114-MCG') and indicator *Enterococcus faecalis* should be reported as '*Enterococcus*, non-pathogenic - *E. faecalis*' (code 'RF-00000113-MCG').

Regarding MRSA, the catalogue for zoonotic agents has been extended to accommodate, when known, the reporting of MRSA characterisation of multi-locus sequence typing (MLST) and clonal complexes in addition to *spa*-types. Reporting of MLST and *spa*-types not yet covered by the

catalogue is encouraged by requesting the inclusion of corresponding terms in the catalogue to EFSA (e-mail to be sent to 'zoonose support').

2.3.2. Matrix (*matrix AMR.06*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_MATRIX). It represents the food/feed category or the animal population from which the isolate tested for AMR derives. In addition, more detailed breakdown information is included at levels 2–4, such as the type of animals (wild, farmed), production category (breeding, fattening animals), subcategory of food (minced meat, hard cheese) and type of food (frozen, ready-to-eat, etc.).

As regards the reporting of the food-producing animal population investigated, it is recommended that, where appropriate, the AMR data reported are stratified by animal age/production stage and/or production type. This is because levels of resistance may be quite distinct between these groups, reflecting the widely differing treatment regimes, management practices and hygienic conditions encountered.

In accordance with Commission implementing Decision 2013/652/EU, AMR data on the animal populations/food categories listed and marked in bold in Table 2 should be reported mandatorily for the year 2015.

If relevant information is available, AMR data may also be reported separately for isolates from breeding flocks of *Gallus gallus* for egg production lines and for meat production. AMR data in young and adult cattle may also be distinguished between the dairy and meat production sectors.

For example: '*Gallus gallus* (fowl) - laying hens' (code 'A031741A'); '*Gallus gallus* (fowl) - broilers' (code 'A007101A'); 'Cattle (bovine animals) - calves (under 1 year) - veal calves' (code 'A004721A'), 'Pigs - fattening pigs - unspecified - weaners to growers' (code 'A042366A').

Table 2: Recommended categories to be used for the reporting of the origin of the isolates

| Bacteria | Animal species/food categories |
|---|---|
| <i>Salmonella</i> | Laying hens, broilers, fattening turkeys Carcases of broilers, fattening turkeys, fattening pigs and bovines under one year of age |
| <i>Campylobacter</i> | Broilers, fattening turkeys, fattening pigs ^(a) |
| Indicator <i>E. coli</i> | Broilers, fattening turkeys, fattening pigs, bovines under one year of age ^(b) Fresh broiler meat, pig meat and bovine meat ^(b) |
| Indicator enterococci | Broilers, fattening pigs, fattening turkeys, fattening pigs, bovines under one year of age ^(c) |
| Meticillin-resistant <i>Staphylococcus aureus</i> (MRSA)^(d) | Broilers, breeders of <i>Gallus gallus</i> (meat sector), fattening turkeys, breeders of turkeys, fattening pigs, breeders of pigs, dairy cattle, fattening veal calves (under 1 year of age) ^(e) , beef animals, horses Fresh broiler meat, turkey meat, pig meat, bovine meat, fresh veal and raw milk and/or raw milk products |

Note: In 2014, 2016, 2018 and 2020, for laying hens and broilers and fresh meat thereof, and fattening turkeys. In **2015**, 2017 and 2019, for **pigs, bovines under one year of age, pig meat and bovine meat**.

(a): Where an MS decides to test *C. coli*.

(b): For the purpose of monitoring of extended-spectrum β -lactamase-, AmpC- or carbapenemase-producing *E. coli*.

(c): Where an MS decides to test *E. faecalis* and *E. faecium*.

(d): Where an MS decides to test MRSA.

(e): In certain MSs, the calf population to be monitored for MRSA may also include fattening veal calves older than one year.

2.4. Information about the sampling performed

2.4.1. Total units tested (*totUnitsTested AMR.07*)

This data element is **optional**, but it is strongly recommended to report the information for the samples taken based on Commission implementing Decision 2013/652/EU. This data element is

mandatory⁴ for data related to the specific monitoring of ESBL-/AmpC-/carbapenemase-producing *E. coli* (mandatory reporting in 2015), related to the specific monitoring of carbapenemase-producers (in the case of voluntary reporting), as well as for those related to the voluntary AMR monitoring in *Campylobacter jejuni/coli* in fattening pigs. It is an integer numerical data element. It is the total number of epidemiological units of interest (e.g. animal, flock, herd, slaughter batch⁵, single, batch) investigated in relation to a given matrix, for the presence of specific bacterial species, during the whole reporting year exercise of the AMR monitoring programme. These data may be used to assess the prevalence of resistant bacteria. **Please, note that the same number should be reported for all isolates coming from the same monitoring context.**

2.4.2. Total units positive (*totUnitsPositive AMR.49*)

This data element is **optional**, but it is strongly recommended to report the information for the samples taken based on Decision 2013/652/EU. This data element is **mandatory** for data related to the specific monitoring of ESBL-/AmpC-/Carbapenemase-producing *E. coli* (mandatory reporting in 2015), those related to the specific monitoring of carbapenemase-producers (in the case of voluntary reporting), as well as for those related to the voluntary AMR monitoring in *Campylobacter jejuni/coli* in fattening pigs. It is an integer numerical data element. It is the total number of epidemiological units of interest (e.g. animal, flock, herd, slaughter batch, single, batch) investigated in relation to a given matrix, and tested positive for a bacterial species, during the whole reporting year exercise of the AMR monitoring programme. These data may be used to assess the prevalence of resistant bacteria. **Please, note that the same number should be reported for all isolates coming from the same monitoring context.**

2.4.3. Total samples tested (*totSampUnitsTested AMR.44*)

This data element is **optional**, but it is **strongly recommended** to report the information for the samples taken based on Decision 2013/652/EU. It is an integer numerical data element. It is the total number of samples tested (i.e. individual swabs or single items in a batch) for the presence of the zoonotic agent from a given matrix and sampling context—whether positive or negative—in order to collect the bacterial isolates tested for antimicrobial susceptibility from a specific MS during the whole reporting year of the AMR monitoring programme. The matrix may be an animal (e.g. broilers, laying hens, fattening pigs, calves <1 year (level 2)) or a food category. These data are useful to assess the prevalence of resistant bacteria. Please, note that the same number should be reported for all isolates coming from the same sampling context (so that, for example, data deriving from clinical investigations are not mixed with data deriving from epidemiological monitoring of AMR). In the particular case where one sample (e.g. one caecal sample obtained from one carcase of fattening pigs) is taken from each epidemiological unit (e.g. slaughter batch of fattening pigs), 'Total samples tested' equates 'Total units tested'. This case corresponds to the approach of the legislation.

2.4.4. Total samples positive (*totSampUnitsPositive AMR.50*)

This data element is **optional**, but it is **strongly recommended** to report the information for the samples taken based on Decision 2013/652/EU. It is an integer numerical data element. It is the total number of samples tested positive (i.e. individual swabs or single items in a batch) for the zoonotic agent from a given matrix and sampling context, in order to collect the bacterial isolates tested for antimicrobial susceptibility from a specific MS during the whole reporting year of the AMR monitoring programme. The matrix may be an animal (e.g. broilers, laying hens, fattening pigs, calves < 1 year (level 2)) or a food category. Please, note that the same number should be reported for all isolates coming from the same sampling context (so that, for example, data deriving from clinical investigations are not mixed with data deriving from epidemiological monitoring of AMR). These data are useful to assess the prevalence of resistant bacteria, and each value should be less than or equal to the total number of samples tested. In the particular case where one sample (e.g. one caecal sample obtained from one carcase of fattening pigs) is taken from each epidemiological unit (e.g.

⁴ This condition is checked by specific business rules. Please, see Table7.

⁵ Slaughter batch of fattening pigs is intended within the meaning of the slaughterhouse but within the meaning of the farm, providing the slaughterhouse with a group of fattening pigs to be slaughtered a given day.

slaughter batch of fattening pigs), 'Total samples positive' equates 'Total units positive'. This case corresponds to the approach of the legislation.

2.4.5. Sampling unit type (*sampUnitType* AMR.45)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_UNIT, domain: D_AMR_sampUnitType). It defines the type of sampling unit taken in the sampling event, e.g. 'animal' (code 'G199A'), 'herd/flock' (code 'G202A'), 'slaughter batch' (code 'G200A'), 'single (food/feed)' (code 'G203A'), 'batch (food/feed)' (code 'G204A').

2.4.6. Sampling stage (*sampStage* AMR.08)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SMPNT, domain: D_PRV_sampStage). The sampling stage is the stage along the food chain at which the sample has been collected, e.g. 'Farm' (code 'E101A'), 'Slaughterhouse' (code 'E311A') or 'Retail' (code 'E520A'). Please, see Table 5 for more details about the sampling stage which could be reported for the isolates tested in accordance with Commission implementing Decision 2013/652/EU.

2.4.7. Sample origin (*sampOrig* AMR.46)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_COUNTRY). Sample origin is used to indicate the country of origin of the animal, food or feed sampled (ISO 3166-1-alpha-2 country code). If the exact country of origin of the sampled item is unknown, the following terms may be reported: 'European Union' (code 'EU'), 'Non-EU' (code 'XE'), 'Non-EEA' (code 'XC') or 'Unknown' (code 'XX'). For the data reported as required in Commission implementing Decision 2013/652/EU only domestic production should be considered for carcasses and caecal samples of fattening pigs and bovines under one year of age. The sampling origin for fresh meat tested for the specific monitoring of ESBL-/AmpC-/carbapenemase-producing *E. coli* can be different than the domestic production.

2.4.8. Sample type (*sampType* AMR.09)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SMPTYP). It describes the biological source of the sample and allows for characterisation of the sample category (i.e. animal, food, feed or environmental sample) and the sample type (e.g. faeces, caecal content, boot swabs, neck skin), e.g. 'animal sample - nasal swab' (code 'S015A'), 'food sample - carcass swab' (code 'S021A').

2.4.9. Sampling context (*sampContext* AMR.10)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SRCTYP, domain: D_ALL_sampContext). It identifies the **type of programme** in the framework of which **samples** have been collected. It is possible to distinguish between different types of sampling schemes, e.g. 'Monitoring - EFSA specifications' (code 'K025A'), 'Survey - national survey' (code 'K028A'), 'Control and eradication programmes' (code 'K021A'). In the particular case of clinical isolates, the item 'Clinical investigations' (code 'K020A') should be used. Reporting of the sampling context is mandatory to enable evaluation of the representativeness of the AMR monitoring programmes. Please, see Table 5 for more details about the sampling context which could be reported for the isolates tested according Decision 2013/652/EU.

2.4.10. Sampler (*sampler* AMR.11)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SMPLR). It indicates the type of body that performed the sampling, e.g. 'Industry sampling' (code 'CX01A'), 'Official sampling' (code 'CX02A'). Please, see Table 5 for more details about the sampler which could be reported for the isolates tested according Commission implementing Decision 2013/652/EU.

2.4.11. Programme code (*progCode AMR.12*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_AMRPROG). It identifies the basis of the programme in the framework of which the sample/isolate has been collected/analysed.

Monitoring of antimicrobial resistance in routine in accordance with Commission implementing Decision 2013/652/EU requisites:

- 'AMR MON' (code 'AMRP01A')
- 'AMR MON pnl2' (code 'AMRP02A') for *Salmonella* and *E. coli* tested against panel 2;
- 'ESBL MON' (code 'AMRP03A') for the specific monitoring of ESBL-/AmpC/-carbapenemase-producing *E. coli*;
- 'ESBL MON pnl2' (code 'AMRP08A') for the specific monitoring of ESBL-/AmpC/-carbapenemase-producing *E. coli* tested against panel 2;
- 'CARBA MON' (code 'AMRP05A') for the voluntary monitoring of carbapenemase-producing micro-organism in accordance with EURL-AR protocol. When reporting for other microorganisms (i.e. *Salmonella*), the code OTHER CARBA MON (code AMRP06A), should be chosen;
- 'CARBA MON pnl2' (code 'AMRP10A') for the voluntary monitoring of carbapenemase-producing micro-organism in accordance with EURL-AR protocol tested against panel 2. When reporting for other microorganisms (i.e. *Salmonella*) tested against panel 2, the code OTHER CARBA MON pnl2 (code AMRP11A), should be chosen;
- 'OTHER AMR MON' (code AMRP04A), 'OTHER ESBL MON' (code AMRP13A) and also 'OTHER CARBA MON' (code AMRP06A) should be used to report any other results. For example, AMR data deriving from clinical investigations or from isolates obtained from other matrices, sample types or gained with different isolation protocol than the ones mentioned in the Commission implementing Decision 2013/652/EU.
- 'OTHER AMR MON pnl2' (code AMRP09A), 'OTHER ESBL MON pnl2' (code AMRP14A) and also 'OTHER CARBA MON pnl2' (code AMRP11A) should be used to report any other results from isolates tested against panel 2. For example, AMR data deriving from clinical investigations or from isolates obtained from other matrices, sample types or gained with different isolation protocol than the ones mentioned in the Commission implementing Decision 2013/652/EU.

It refers to the specific Commission implementing Decision 2013/652/EU and, in particular, to the general provisions for reporting of data, referred to in point 1 of part B of the Annex of the Decision. Please, see the definitions of all the terms which are available in ZOO_CAT_AMRPROG. 'AMR MON' (code 'AMRP01A').

2.4.12. Sampling strategy (*progSampStrategy AMR.13*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SAMPSTR). It is the planned procedure for selecting samples from a population and for conducting the sampling in order to obtain the information needed, e.g. 'Objective sampling' (code 'ST10A'), 'Census' (code 'ST50A'). It should be consistent with information reported under 'sampling context'. Reporting of the sampling strategy is mandatory to enable evaluation of the representativeness of the AMR monitoring programmes. Please see Table 5 for more details about the sampling strategy which could be reported for the isolates tested according Decision 2013/652/EU.

2.4.13. Sampling details (*sampDetails AMR.14*)

This data element is **optional**. This is a free text of a maximum 2,000 alphanumeric characters. It can be used, when needed, to give more information on the sampling design, stage or context. It should be completed in English (see data element AMR.04 Language).

2.4.14. Area of sampling (*sampArea AMR.15*)

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a catalogue (ZOO_CAT_NUTS). It indicates the area, region or province in the country (in accordance with the Nomenclature of Territorial Units for Statistics (NUTS) standard) in which the animal/food/feed sample has been collected. The reporting of the area of sampling is recommended so that, for example, geographical spreading of some multi-resistant clones may be studied.

2.5. Information about the laboratory

2.5.1. Laboratory identification code (*labCode AMR.16*)

This data element is **optional but is recommended to be reported at the national level**. The codes in this data element identify the laboratory performing AMR testing for the 'isolate/antimicrobial' combination in question. A MS may have more than one laboratory performing the susceptibility tests; therefore, the code has to be unique in a given MS.

2.5.2. Laboratory isolate code (*labIsolCode AMR.17*)

This data element is **mandatory**. The codes in this data element should uniquely identify the isolate for which AMR testing was performed. Its type is alphanumeric consisting of a maximum 20 characters. It will be used by EFSA should an update be needed in the future data transmission or if additional clarifications are required. It must be unique for the country.

2.5.3. Total number of isolates in the laboratory (*labTotIsol AMR.18*)

This data element is **optional**. This is a numerical data element which should be left empty if unknown. It is the total number of isolates available in the laboratory testing for AMR for the specific bacterial species or serovar in relation to the given matrix. The reporting should be made at the bacterial species level for *C. jejuni*, *C. coli*, *E. coli*, *E. faecium* and *E. faecalis*. Regarding *Salmonella*, it is requested that reporting be at the serovar level. Regarding MRSA, it is recommended that reporting be at the *spa*-type/MLST/clonal complex level, if the isolates available have been characterised. Please note that you have to report the same number for all isolates coming from the same monitoring context.

2.6. Information about the sampling and testing for AMR

2.6.1. Sampling year/month/day (*sampY/sampM/sampD AMR.19/AMR.20/AMR.21*)

These data elements are **mandatory**. These are numerical data elements allowing a maximum of four digits for the data element year and a maximum of two digits for the data elements month and day. The sampling date refers to the collection date of the biological sample and must be a date before the Isolation year/month/day (see 2.6.2). Reporting of the sampling date is mandatory to enable evaluation of possible seasonal effects.

2.6.2. Isolation year/month/day (*isolY/isolM/isolD AMR.22/AMR.23/AMR.24*)

These data elements are **mandatory**. These are numerical data elements allowing a maximum of four digits for the data element year and a maximum of two digits for the data elements month and day and must be a date after Sampling year/month/day (see 2.6.1). It corresponds to the date when the isolation of the isolate in question from the biological sample was performed.

2.6.3. Susceptibility test year/month/day (*analysisY/analysisM/analysisD AMR.25/AMR.26/AMR.27*)

These data elements are **mandatory**. These are numerical data elements allowing a maximum of four digits for the data element year and a maximum of two digits for the data elements month and day and must be a date after Isolation year/month/day (see 2.6.2). It corresponds to the date when the AMR testing was performed.

2.7. Information about the method and the antimicrobials

2.7.1. Method (*anMethCode AMR.28*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_ANLYMD, domain: D_AMR_anMethCode). It indicates the test method used for AMR testing. Different types of diffusion or dilution methods are available for reporting, e.g. 'Microbiological tests - dilution' (code 'F128A'), 'Microbiological tests - dilution - micro-dilution method' (code 'F131A').

2.7.2. Antimicrobial substance (*substance AMR.29*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_PARAM_SUB). It indicates the antimicrobial substance against which the isolates were tested. Antimicrobial substances are listed within the catalogue according to antimicrobial families. For *Salmonella*, *Campylobacter*, indicator *E. coli* and indicator enterococci, it is recommended that results are reported at least for the set of antimicrobial substances listed in Table 3 (please note that in the catalogue you could also find other antimicrobial substances). Furthermore, the lists have been extended to include all substances recommended for susceptibility testing in Decision 2013/652/EU and in 'Technical specifications on the harmonised monitoring and reporting of antimicrobial resistance in methicillin-resistant *Staphylococcus aureus* in food-producing animals and food' (EFSA, 2012).

Please note that, for *Salmonella* and *E. coli*, the set of antimicrobial substances listed in Table 3 is complemented with the second panel of antimicrobial substances. All presumptive ESBL-, AmpC- or carbapenemase-producing *E. coli* isolates identified through the selective plating, as well as all *Salmonella* spp. and *E. coli* isolates randomly selected after testing with the first panel of antimicrobials in accordance with Table 3, are resistant to cefotaxime, ceftazidime or meropenem shall be further tested with a second panel of antimicrobial substances in accordance with Table 4.

Table 3: Recommended antimicrobials for susceptibility testing and their codes for DCF

| <i>Salmonella/Indicator E. coli</i> | <i>C. jejuni/ C. coli</i> | Indicator enterococci |
|-------------------------------------|--|--|
| Ampicillin RF-00000688-VET | Ciprofloxacin RF-00000695-VET | Ampicillin RF-00000688-VET |
| Azithromycin RF-00000541-VET | Erythromycin RF-00000589-VET | Chloramphenicol RF-00000525-VET |
| Cefotaxime RF-00000717-VET | Gentamicin RF-00000536-VET | Ciprofloxacin RF-00000695-VET |
| Ceftazidime RF-00000720-VET | Nalidixic acid RF-00000547-VET | Daptomycin RF-00000743-VET |
| Chloramphenicol RF-00000525-VET | Streptomycin ^(a) RF-0899-001-PPP | Erythromycin RF-00000589-VET |
| Ciprofloxacin RF-00000695-VET | Tetracycline RF-00000670-VET | Gentamicin RF-00000536-VET |
| Colistin RF-00000595-VET | | Linezolid RF-00000758-VET |
| Gentamicin RF-00000536-VET | | Quinupristin/dalfopristin RF-00000777-VET |
| Nalidixic acid RF-00000547-VET | | Streptomycin RF-0899-001-PPP |
| Meropenem RF-00000712-VET | | Teicoplanin RF-00000659-VET |
| Sulfamethoxazole RF-00000612-VET | | Tetracycline RF-00000670-VET |
| Tetracycline RF-00000670-VET | | Tigecycline RF-00000745-VET |
| Tigecycline RF-00000745-VET | | Vancomycin RF-00000569-VET |
| Trimethoprim RF-00000562-VET | | |

(a): On a voluntary basis.

Table 4: Recommended antimicrobials for susceptibility testing in the second panel and their codes for DCF

| <i>Salmonella</i> and indicator <i>E. coli</i> | DCF code |
|--|-----------------|
| Cefotaxime | RF-00000717-VET |
| Cefotaxime + clavulanic acid | RF-00000146-PAR |
| Ceftazidime | RF-00000720-VET |
| Ceftazidime + clavulanic acid | RF-00000147-PAR |
| Cefoxitin | RF-00000718-VET |
| Cefepime | RF-00000714-VET |
| Ertapenem | RF-00000143-PAR |
| Imipenem | RF-00000711-VET |
| Meropenem | RF-00000712-VET |
| Temocillin | RF-00002842-PAR |

The proposed lists of antimicrobials to be included in AMR monitoring in MRSA (EFSA, 2012) are the following:

- Recommended set: cefoxitin (RF-00000718-VET), chloramphenicol (RF-00000525-VET), ciprofloxacin (RF-00000695-VET), clindamycin (RF-00000545-VET), erythromycin (RF-00000589-VET), gentamicin (RF-00000547-VET), linezolid (RF-00000758-VET), mupirocin (RF-00000153-PAR), quinupristin/dalfopristin (RF-00000777-VET), sulfamethoxazole/trimethoprim (RF-00000794-VET), tetracycline (RF-00000670-VET), tiamulin (RF-00000582-VET), vancomycin (RF-00000569-VET).
- Optional set: ceftobiprole (RF-00000154-PAR), kanamycin (RF-00000527-VET), tigecycline (RF-00000745-VET), fusidic acid (RF-00000738-VET), daptomycin (RF-00000743-VET).

2.7.3. Cut-off value (*cutoffValue AMR.30*)

This data element is **mandatory**. This data element allows for numeric data values with decimal numbers greater than zero. The data element indicates the cut-off value for the dilution method that should be used, according to the reporting MS, for defining resistant isolates in the National Report.

EFSA will use harmonised epidemiological cut-off (ECOFF) values for the analysis of the data to be included in the EU Summary Report, based on the specifications from Decision 2013/652/EU and, where requested, from the EU Reference Laboratory on AMR/European Committee on Antimicrobial Susceptibility Testing (EUCAST). Nevertheless, an MS might use an *ad hoc* cut-off value for the interpretation of their national data or for the substances for which cut-off values are not defined.

Reporting duplicate AMR data using different ECOFFs should be avoided for the same isolates (e.g. harmonised ECOFF and *ad hoc* ECOFF).

2.8. Information about the dilution method

2.8.1. Lowest limit (*lowest AMR.31*)

This data element is **mandatory** for **dilution** method data. It contains codes linked to a catalogue (ZOO_CAT_FIXMEAS, domain: D_AMR_number). It is the lowest concentration of the concentration range used to test AMR in the laboratory. The lowest concentration should be between '0.002' (code 'R079A') and '4096' (code 'R071A') and the *Lowest limit* must be below the *Highest limit*.

2.8.2. Highest limit (*highest AMR.32*)

This data element is **mandatory** for **dilution** method data. It contains codes linked to a catalogue (ZOO_CAT_FIXMEAS, domain: D_AMR_number). It is the highest concentration of the concentration

range used to test AMR in the laboratory. The highest concentration should be between '0.002' (code 'R079A') and '4096' (code 'R071A') and the *Highest limit* must be above the *Lowest limit*.

2.8.3. Minimum inhibitory concentration value (mg/L) (*MIC AMR.33*)

This data element is **mandatory** for **dilution** method data. It represents the MIC value and contains codes linked to a catalogue (ZOO_CAT_FIXMEAS, domain: D_AMR_MIC). It is the MIC value (by default reported in mg/L) resulting from the susceptibility testing of the isolate in question. It is expected that the MIC value should lie between '<= 0.002' (code 'R080A') and '> 4096' (code 'R072A'). If no growth is observed at the lowest concentration tested, the MIC value should be reported as lower than or equal to the lowest concentration tested. If growth is still observed at the highest concentration tested, the MIC value should be reported as strictly greater than the highest concentration tested. The three data elements *Lowest limit*, *Highest limit* and *MIC value* are mandatory for dilution method data, as they are necessary to correctly interpret the MIC due to left censoring.

2.9. Information about the diffusion method

2.9.1. Disc concentration (microg) (*diskConc AMR.34*)

This data element is **mandatory** for **diffusion** method data. However, in the data model, it is marked as optional because, for dilution data, this data element must be left empty. The data element allows numeric data values with floating-point decimal numbers to be entered. It corresponds to the amount of the added antimicrobial in the test disc, which is reported by default in micrograms.

2.9.2. Disc diameter (mm) (*diskDiam AMR.35*)

This data element is **mandatory** for **diffusion** method data. However, in the data model, it is marked as optional because, for dilution data, this data element must be left empty. The data element allows numeric data values with floating-point decimal numbers to be entered. It corresponds to the diameter of the disc used in the testing, which is reported by default in millimetres.

2.9.3. IZD value (mm) (*IZD AMR.36*)

This data element is **mandatory** for **diffusion** data. However, in the data model, it is marked as optional because, for dilution data, this data element must be left empty. It contains codes linked to a catalogue (ZOO_CAT_FIXMEAS, domain: D_AMR_IZD). It represents the inhibition zone diameter values deriving from the AMR testing of the isolate, which is reported by default in millimetres.

2.10. Information about further isolate characterisation

2.10.1. ESBL genotype (*esbl AMR.38*)

This data element is **optional**, where *progCode* was 'AMR MON pnI2', 'ESBL MON pnI2', 'CARBA MON pnI2' etc, and contains codes linked to a catalogue (ZOO_CAT_ESBL). It allows MSs to report ESBL genotypes in isolates of *Salmonella* and *E. coli* through enzyme formulas (e.g. TEM-52, SHV-2, CTX-M-1). Please note that, if more than one gene in the same isolate is present, only a single code can be reported.

2.10.2. AmpC genotype (*ampC AMR.39*)

This data element is **optional**, where *progCode* was 'AMR MON pnI2', 'ESBL MON pnI2', 'CARBA MON pnI2' etc, and contains codes linked to a catalogue (ZOO_CAT_AMPC). It allows MSs to report AmpC genotypes in isolates of *Salmonella* and *E. coli* through enzyme formulas (e.g. CMY-2, AAC-1). Please note that, if more than one gene in the same isolate is present, only a single code can be reported.

2.10.3. Carbapenemase genotype (*carbapenem AMR.40*)

This data element is **optional**, where *progCode* was 'AMR MON pnI2', 'ESBL MON pnI2', 'CARBA MON pnI2' etc, and contains codes linked to a catalogue (ZOO_CAT_CARBPENEM). It allows MSs to report

carbapenemase genotypes in isolates of *Salmonella* and *E. coli* through enzyme formulas (e.g. KPC, OXA-48). Please note that, if more than one gene in the same isolate is present, only a single code can be reported.

2.10.4. Ceftazidime synergy test (*synTestCAZ AMR.41*)

This data element is **mandatory** when further testing with a second panel of antimicrobial substances was performed (where *progCode* was for example 'AMR MON pnl2', and 'ESBL MON pnl2' or 'CARBA MON pnl2') and contains codes linked to a catalogue (ZOO_CAT_POSNEG). However, in the data model, it is marked as optional because, in all of the other cases, this data element is to be left empty. It allows MSs to report the outcome of a synergy test performed to detect certain β -lactam resistant phenotypes.

2.10.5. Cefotaxime synergy test (*synTestCTX AMR.42*)

This data element is **mandatory** where further tested with a second panel of antimicrobial substances were performed (where *progCode* was for example 'AMR MON pnl2', 'ESBL MON pnl2' or 'CARBA MON pnl2') and contains codes linked to a catalogue (ZOO_CAT_POSNEG). However, in the data model, it is marked as optional because in all the other cases, this data element might be left empty. It allows MS to report the outcome of a synergy test performed to detect certain β -lactam resistance phenotypes.

2.10.6. Cefepime synergy test (*synTestFEP AMR.43*)

This data element is **optional** and contains codes linked to a catalogue (ZOO_CAT_POSNEG). It allows MSs to report the outcome of a synergy test performed to detect certain β -lactam resistance phenotypes.

2.10.7. Performed CC MRSA characterisation (*perCC AMR.47*)

This data element is **optional** and contains codes linked to a catalogue (ZOO_CAT_YESNO). It allows MSs to report whether the determination of the MRSA clonal complex results from a genetic test that has been performed ('Yes' code 'Y') or is inferred from other tests/online databases ('No' code 'N').

2.10.8. Performed MLST MRSA characterisation (*perMLST AMR.48*)

This data element is **optional** and contains codes linked to a catalogue (ZOO_CAT_YESNO). It allows MSs to report whether the determination of the MRSA MLST results from a genetic test that has been performed ('Yes' code 'Y') or is inferred from other tests/online databases ('No' code 'N').

2.11. Additional information

2.11.1. Comment (*resComm AMR.37*)

This free text data element is **optional**. This is a free text element of a maximum of 2,000 alphanumeric characters. This is an additional comment for the row (considered as a set of information). It should be completed in English (see data element AMR.04 Language). The variations on the protocols have to be reported under this data element.

Table 5: Requirements for isolate-based antimicrobial resistance data reporting based on Decision 2013/652/EU

| Bacteria | Origin of the isolates | Sampling unit type ^(a) | Sampling stage | Sample type | Sampling context | Sampler | Sampling strategy |
|---|---|-----------------------------------|------------------------|--|--|---|----------------------------|
| <i>Salmonella</i> spp. | Each population of laying hens, broilers and fattening turkeys sampled in the framework of the national control programmes, established in accordance with Article 5(1) of Regulation (EC) No 2160/2003 | Herd/flock (G202A) | Farm (E101A) | Environmental sample (please use level 2 of the sample type for, for example, environmental sample - boot swabs (S028A)) | Control and eradication programmes (K021A) | Official sampling (CX02A) or Official and industry sampling (CX03A) | Census (ST50A) |
| | Carcases of both broilers and fattening turkeys sampled for testing and verification of compliance, in accordance with point 2.1.5 of Chapter 2 of Annex I to Regulation (EC) No 2073/2005 | Slaughter batch (G200A) | Slaughterhouse (E311A) | Food sample - neck skin (S024A) | Monitoring (K022A) | HACCP and own checks (CX04A) | Objective sampling (ST10A) |
| | Carcases of fattening pigs sampled for testing and verification of compliance, in accordance with point 2.1.4 of Chapter 2 of Annex I to Regulation (EC) No 2073/2005 | Slaughter batch (G200A) | Slaughterhouse (E311A) | Food sample - carcass swabs (S021A) | Monitoring (K022A) | HACCP and own checks (CX04A) and/or Official sampling (CX02A) | Objective sampling (ST10A) |
| <i>C. jejuni</i> | Caecal samples gathered at slaughter from broilers and from fattening turkeys ^(b) | Slaughter batch (G200A) | Slaughterhouse (E311A) | Animal sample - caecum (S002A) | Monitoring (K022A) | Official sampling (CX02A) | Objective sampling (ST10A) |
| Indicator commensal <i>E. coli</i> | Caecal samples gathered at slaughter from broilers and from fattening turkeys ^(b) | Slaughter batch (G200A) | Slaughterhouse (E311A) | Animal sample - caecum (S002A) | Monitoring (K022A) | Official sampling (CX02A) | Objective sampling (ST10A) |
| | Caecal samples gathered at slaughter from fattening pigs and bovines under one year of age ^(b) | Slaughter batch (G200A) | Slaughterhouse (E311A) | Animal sample - caecum (S002A) | Monitoring (K022A) | Official sampling (CX02A) | Objective sampling (ST10A) |

| Bacteria | Origin of the isolates | Sampling unit type ^(a) | Sampling stage | Sample type | Sampling context | Sampler | Sampling strategy |
|---|---|-----------------------------------|------------------------|------------------------------|----------------------|---------------------------|----------------------------|
| Specific monitoring ESBL-/AmpC- /or carbapenemase-producing <i>E. coli</i> Specific monitoring of carbapenemase-producing micro-organism (voluntary) | Caecal samples gathered at slaughter from broilers and from fattening turkeys ^(b) | Slaughter batch (G200A) | Slaughterhouse (E311A) | Animal sample caecum (S002A) | - Monitoring (K022A) | Official sampling (CX02A) | Objective sampling (ST10A) |
| | Caecal samples gathered at slaughter from fattening pigs and bovines under one year of age ^(b) | Slaughter batch (G200A) | Slaughterhouse (E311A) | Animal sample caecum (S002A) | - Monitoring (K022A) | Official sampling (CX02A) | Objective sampling (ST10A) |
| | Samples of fresh meat of broilers, pig meat and bovine meat gathered at retail | Batch (G204A) | Retail (E520A) | Food sample - meat (S022A) | - Monitoring (K022A) | Official sampling (CX02A) | Objective sampling (ST10A) |
| <i>C. coli</i>^(c) | Caecal samples gathered at slaughter from broilers | Slaughter batch (G200A) | Slaughterhouse (E311A) | Animal sample caecum (S002A) | - Monitoring (K022A) | Official sampling (CX02A) | Objective sampling (ST10A) |
| | Caecal samples gathered at slaughter from fattening pigs | Slaughter batch (G200A) | Slaughterhouse (E311A) | Animal sample caecum (S002A) | - Monitoring (K022A) | Official sampling (CX02A) | Objective sampling (ST10A) |
| <i>E. faecalis</i> and <i>E. faecium</i>^(d) | Caecal samples gathered at slaughter from broilers and from fattening turkeys ^(b) | Slaughter batch (G200A) | Slaughterhouse (E311A) | Animal sample caecum (S002A) | - Monitoring (K022A) | Official sampling (CX02A) | Objective sampling (ST10A) |
| | Caecal samples gathered at slaughter from fattening pigs and bovines under one year of age ^(b) | Slaughter batch (G200A) | Slaughterhouse (E311A) | Animal sample caecum (S002A) | - Monitoring (K022A) | Official sampling (CX02A) | Objective sampling (ST10A) |

HACCP: Hazard Analysis and Critical Control Point.

(a): The Competent Authority may decide based on the sampling method and the analytical method.

(b): Where the production of the specific meat category in the MS is more than 10 000 tonnes slaughtered per year.

(c): Where an MS decides to test *C. coli* in accordance with Article 2(3)(a) of Decision 2013/652/EU.

(d): Where an MS decides to test *E. faecalis* and *E. faecium* in accordance with Article 2(3)(b) of Decision 2013/652/EU.

Table 6: EFSA data model for isolate-based antimicrobial resistance data reporting

| Element code | Element label | Element name (for XML/Excel transfer) | Type | Constraint | Catalogue | Domain |
|--------------|--|---------------------------------------|-----------------|------------|-------------------|--------------------|
| AMR.01 | Result code | resultCode | xs:string(100) | Mandatory | | |
| AMR.02 | Reporting year | repYear | xs:integer(4) | Mandatory | | |
| AMR.03 | Reporting country | repCountry | xs:string(2) | Mandatory | ZOO_CAT_COUNTRY | D_ALL_repCountry |
| AMR.04 | Language | lang | xs:string(2) | Mandatory | ZOO_CAT_LANG | D_ALL_lang |
| AMR.05 | Zoonotic agent | zoonosis | xs:string(15) | Mandatory | ZOO_CAT_PARAM_ZOO | D_AMR_zoonosis |
| AMR.06 | Matrix | matrix | xs:string(4000) | Mandatory | ZOO_CAT_MATRIX | |
| AMR.07 | Total units tested | totUnitTested | xs:integer(10) | Optional | | |
| AMR.49 | Total units positive | totUnitsPositive | xs:integer(10) | Optional | | |
| AMR.44 | Total samples tested | totSampUnitsTested | xs:integer(10) | Optional | | |
| AMR.50 | Total samples positive | totSampUnitsPositive | xs:integer(10) | Optional | | |
| AMR.45 | Sampling unit type | sampUnitType | xs:string(5) | Mandatory | ZOO_CAT_UNIT | D_AMR_sampUnitType |
| AMR.08 | Sampling stage | sampStage | xs:string(5) | Mandatory | ZOO_CAT_SMPNT | D_PRV_sampStage |
| AMR.46 | Sample origin | sampOrig | xs:string(2) | Mandatory | ZOO_CAT_COUNTRY | |
| AMR.09 | Sample type | sampType | xs:string(5) | Mandatory | ZOO_CAT_SMPTYP | |
| AMR.10 | Sampling context | sampContext | xs:string(5) | Mandatory | ZOO_CAT_SRCTYP | D_ALL_sampContext |
| AMR.11 | Sampler | sampler | xs:string(5) | Mandatory | ZOO_CAT_SMPLR | |
| AMR.12 | Programme code | progCode | xs:string(7) | Mandatory | ZOO_CAT_AMRPROG | |
| AMR.13 | Sampling strategy | progSampStrategy | xs:string(5) | Mandatory | ZOO_CAT_SAMPSTR | |
| AMR.14 | Sampling details | sampDetails | xs:string(2000) | Optional | | |
| AMR.15 | Area of sampling | sampArea | xs:string(5) | Optional | ZOO_CAT_NUTS | |
| AMR.16 | Laboratory identification code | labCode | xs:string(100) | Optional | | |
| AMR.17 | Laboratory isolate code | labIsolCode | xs:string(20) | Mandatory | | |
| AMR.18 | Total number of isolates in the laboratory | labTotIsol | xs:integer | Optional | | |
| AMR.19 | Sampling year | sampY | xs:integer(4) | Mandatory | | |
| AMR.20 | Sampling month | sampM | xs:integer(2) | Mandatory | | |
| AMR.21 | Sampling day | sampD | xs:integer(2) | Mandatory | | |
| AMR.22 | Isolation year | isolY | xs:integer(4) | Mandatory | | |
| AMR.23 | Isolation month | isolM | xs:integer(2) | Mandatory | | |
| AMR.24 | Isolation day | isolD | xs:integer(2) | Mandatory | | |
| AMR.25 | Susceptibility test year | analysisY | xs:integer(4) | Mandatory | | |
| AMR.26 | Susceptibility test month | analysisM | xs:integer(2) | Mandatory | | |
| AMR.27 | Susceptibility test day | analysisD | xs:integer(2) | Mandatory | | |

| Element code | Element label | Element name (for XML/Excel transfer) | Type | Constraint | Catalogue | Domain |
|--------------|--------------------------------------|---------------------------------------|-----------------|------------|--------------------|------------------|
| AMR.28 | Method | anMethCode | xs:string(5) | Mandatory | ZOO_CAT_ANLYMD | D_AMR_anMethCode |
| AMR.29 | Antimicrobial substance | substance | xs:string(15) | Mandatory | ZOO_CAT_PARAM_SUB | |
| AMR.30 | Cut-off value | cutoffValue | xs:double | Mandatory | | |
| AMR.31 | Lowest limit | lowest | xs:string(5) | Mandatory | ZOO_CAT_FIXMEAS | D_AMR_number |
| AMR.32 | Highest limit | highest | xs:string(5) | Mandatory | ZOO_CAT_FIXMEAS | D_AMR_number |
| AMR.33 | MIC value (mg/L) | MIC | xs:string(5) | Mandatory | ZOO_CAT_FIXMEAS | D_AMR_MIC |
| AMR.34 | Disc concentration (microg) | diskConc | xs:double | Optional | | |
| AMR.35 | Disc diameter (mm) | diskDiam | xs:double | Optional | | |
| AMR.36 | IZD value (mm) | IZD | xs:string(5) | Optional | ZOO_CAT_FIXMEAS | D_AMR_IZD |
| AMR.38 | ESBL genotype | esbl | xs:string(5) | Optional | ZOO_CAT_ESBL | |
| AMR.39 | AmpC genotype | ampC | xs:string(5) | Optional | ZOO_CAT_AMPC | |
| AMR.40 | Carbapenemase genotype | carbapenem | xs:string(5) | Optional | ZOO_CAT_CARBAPENEM | |
| AMR.41 | Ceftazidime synergy test | synTestCAZ | xs:string(3) | Optional | ZOO_CAT_POSNEG | |
| AMR.42 | Cefotaxime synergy test | synTestCTX | xs:string(3) | Optional | ZOO_CAT_POSNEG | |
| AMR.43 | Cefepime synergy test | synTestFEP | xs:string(3) | Optional | ZOO_CAT_POSNEG | |
| AMR.47 | Performed CC MRSA characterisation | perCC | xs:string(1) | Optional | ZOO_CAT_YESNO | |
| AMR.48 | Performed MLST MRSA characterisation | perMLST | xs:string(1) | Optional | ZOO_CAT_YESNO | |
| AMR.37 | Comment | resComm | xs:string(2000) | Optional | | |

Table 7: EFSA business rules for isolate-based antimicrobial resistance data reporting

| Element code | Element name | Error type | Error code | Rule |
|--------------|------------------|------------|------------|--|
| AMR.01 | resultCode | E | AMR03 | The result code must be unique |
| AMR.02 | repYear | E | AMR01 | The value in repYear must be the same as the data collection reporting year |
| AMR.04 | Lang | W | AMR08 | WARNING. The value in lang should be 'English' ('en') |
| AMR.06 | matrix | W | AMR32 | WARNING. For data interpretation purposes, it is advised not to use general categories. The value in matrix should not be: ' <i>Gallus gallus</i> (fowl)' ('A006921A'), or ' <i>Gallus gallus</i> (fowl) - unspecified' ('A031721A'), or 'Compound feedingstuffs, not specified' ('A001421A') |
| AMR.07 | totUnitsTested | E | AMR02 | If reported, the value in totUnitsTested must be greater than '0' |
| AMR.07 | totUnitsTested | E | AMR80 | If progCode is specific monitoring of ESBL-/AmpC/-Carbapenemase- producing <i>E. coli</i> (code 'AMRP03A'), or specific monitoring of ESBL-/AmpC/-Carbapenemase- producing <i>E. coli</i> tested against panel 2 (code 'AMRP08A'), or voluntary monitoring of Carbapenemase-producing microorganisms in accordance with EURL-AMR protocol (code 'AMRP05A'), or voluntary monitoring of Carbapenemase-producing microorganisms in accordance with EURL-AMR protocol tested against panel 2 (code 'AMRP10A') or specific monitoring of Carbapenemase-producing micro-organisms performed with different isolation protocols than the EURL-AMR ones or aiming other micro-organism e.g. <i>Salmonella</i> (code 'AMRP06A'), then a value in totUnitsTested must be reported |
| AMR.08 | sampStage | E | AMR28 | For data interpretation purposes, sampStage must be reported |
| AMR.09 | sampType | | AMR54 | For data interpretation purposes, sampType must be reported |
| AMR.10 | sampContext | E | AMR29 | For data interpretation purposes, a value in sampContext must be reported |
| AMR.11 | sampler | E | AMR30 | For data interpretation purposes, a value in sampler must be reported |
| AMR.12 | progCode | E | AMR56 | For data interpretation purposes, a value in progCode must be reported |
| AMR.13 | progSampStrategy | E | AMR31 | For data interpretation purposes, a value in progSampStrategy must be reported |
| AMR.17 | labIsolCode | E | AMR21 | For data interpretation purposes, a value in labIsolCode must be reported |
| AMR.17 | labIsolCode | E | AMR22 | The value in labIsolCode must be unique |
| AMR.18 | labTotIsol | E | AMR17 | If reported, the value in labTotIsol must be greater than or equal to '0' |
| AMR.19 | sampY | E | AMR04 | The value in sampY must be greater than or equal to data collection reporting year minus 1 and less than or equal to the data collection reporting year plus 1 |
| AMR20 | sampM | E | AMR44 | For data interpretation purposes, the value in sampM must be reported |
| AMR21 | sampD | E | AMR45 | For data interpretation purposes, the value in sampD must be reported |
| AMR20 | sampM | E | AMR66 | sampM must be between 1 and 12 |
| AMR21 | sampD | E | AMR67 | sampD must be between 1 and 31 |
| AMR.19 | sampY | E | AMR57 | The date of the sampling must be a valid date |
| AMR.20 | sampM | | | |
| AMR.21 | sampD | | | |
| AMR.19 | sampY | E | AMR74 | The date of the sampling must be the same for each isolate and progCode |
| AMR.20 | sampM | | | |
| AMR.21 | sampD | | | |

| Element code | Element name | Error type | Error code | Rule |
|----------------------------|-------------------------------------|------------|------------|---|
| AMR.19 AMR.20 AMR.21 | sampY sampM sampD | E | AMR72 | The date of the sampling, reported in sampD, sampM, and sampY, must be less than or equal to the date of the isolation, reported in isoID, isoIM, and isoLY |
| AMR.22 | isoLY | E | AMR05 | The value in isoLY must be greater than or equal to data collection reporting year minus 1 and less than or equal to the data collection reporting year plus 1 |
| AMR.22 | isoLY | E | AMR46 | For data interpretation purposes, the value in isoLY must be reported |
| AMR.23 | isoIM | E | AMR47 | For data interpretation purposes, the value in isoIM must be reported |
| AMR.24 | isoID | E | AMR48 | For data interpretation purposes, the value in isoID must be reported |
| AMR.23 | isoIM | E | AMR68 | isoIM must be between 1 and 12 |
| AMR.24 | isoID | E | AMR69 | isoID must be between 1 and 31 |
| AMR.22 AMR.23 AMR.24 | isoLY isoIM isoID | E | AMR58 | The date of the isolation must be a valid date |
| AMR.22 AMR.23 AMR.24 | isoLY isoIM isoID | E | AMR75 | The date of the isolation must be the same for each isolate and progCode |
| AMR.22 AMR.23 AMR.24 | isoLY isoIM isoID | E | AMR73 | The date of the isolation, reported in isoID, isoIM, and isoLY, must be less than or equal to the date of the susceptibility test, reported in analysisY, analysisM, and analysisD |
| AMR.25 | analysisY | E | AMR49 | For data interpretation purposes, the value in analysisY must be reported |
| AMR.26 | analysisM | E | AMR50 | For data interpretation purposes, the value in analysisM must be reported |
| AMR.27 | analysisD | E | AMR51 | For data interpretation purposes, the value in analysisD must be reported |
| AMR.26 | analysisM | E | AMR70 | analysisM must be between 1 and 12 |
| AMR.27 | analysisD | E | AMR71 | analysisD must be between 1 and 31 |
| AMR.25 | analysisY | E | AMR06 | The value in analysisY must be greater than or equal to data collection reporting year minus 1 and less than or equal to the data collection reporting year plus 1 |
| AMR.25 AMR.26 AMR.27 | analysisY analysisM analysisD | E | AMR59 | The date of the analysis must be a valid date |
| AMR.25 AMR.26 AMR.27 | analysisY analysisM analysisD | E | AMR76 | The date of the analysis must be the same for each isolate and progCode |
| AMR.28 | anMethCode | E | AMR24 | For data interpretation purposes, anMethCode must be reported |
| AMR.29 | substance | E | AMR25 | For data interpretation purposes, substance must be reported |
| AMR.29 | substance | E | AMR93 | If progCode is 'AMR MON' (AMRP01A), or 'ESBL MON' (AMRP03A), or 'CARBA MON' (AMRP05A) and zoonosis is <i>Salmonella</i> or indicator <i>E. coli</i> (RF-00003897-MCG) then results must be reported at least for the set of these antimicrobial substances: Ampicillin (RF-00000688-VET), Azithromycin (RF-00000541-VET), Cefotaxime (RF-00000717-VET), Ceftazidime (RF-00000720-VET), Chloramphenicol (RF-00000525-VET), |

| Element code | Element name | Error type | Error code | Rule |
|--------------|--------------|------------|------------|--|
| | | | | Ciprofloxacin (RF-00000695-VET), Colistin (RF-00000595-VET), Gentamicin (RF-00000536-VET), Nalidixic acid (RF-00000547-VET), Meropenem (RF-00000712-VET), Sulfamethoxazole (RF-00000612-VET), Tetracycline (RF-00000670-VET), Tigecycline (RF-00000745-VET), Trimethoprim (RF-00000562-VET) |
| AMR.29 | substance | E | AMR94 | If progCode is 'AMR MON' (AMRP01A), and zoonosis is <i>C. jejuni</i> (RF-00000061-MCG) or <i>C. coli</i> (RF-00000054-MCG), then results must be reported at least for the set of these antimicrobial substances: Ciprofloxacin (RF-00000695-VET), Erythromycin (RF-00000589-VET), Gentamicin (RF-00000536-VET), Nalidixic acid (RF-00000547-VET), Tetracycline (RF-00000670-VET) |
| AMR.29 | substance | E | AMR95 | If progCode is 'AMR MON' (AMRP01A) and zoonosis is <i>E. faecalis</i> (RF-00000113-MCG) or <i>E. faecium</i> (RF-00000114-MCG), then results must be reported at least for the set of these antimicrobial substances: Ampicillin (RF-00000688-VET), Chloramphenicol (RF-00000525-VET), Ciprofloxacin (RF-00000695-VET), Daptomycin (RF-00000743-VET), Erythromycin (RF-00000589-VET), Gentamicin (RF-00000536-VET), Linezolid (RF-00000758-VET), Quinupristin/dalfopristin (RF-00000777-VET), Streptomycin (RF-0899-001-PPP), Teicoplanin (RF-00000659-VET), Tetracycline (RF-00000670-VET), Tigecycline (RF-00000745-VET), Vancomycin (RF-00000569-VET) |
| AMR.29 | substance | E | AMR96 | If progCode is 'AMR MON pni2' (AMRP02A), or 'ESBL MON pni2' (AMRP08A), or 'CARBA MON pni2' (AMRP10A) and zoonosis is <i>Salmonella</i> or Indicator <i>E. coli</i> (RF-00003897-MCG), then results must be reported at least for the set of these antimicrobial substances: Cefotaxime (RF-00000717-VET), Cefotaxime + clavulanic acid (RF-00000146-PAR), Ceftazidime (RF-00000720-VET), Ceftazidime + clavulanic acid (RF-00000147-PAR), Ceftoxitin (RF-00000718-VET), Cefepime (RF-00000714-VET), Ertapenem (RF-00000143-PAR), Imipenem (RF-00000711-VET), Meropenem (RF-00000712-VET), Temocillin (RF-00002842-PAR) |
| AMR.30 | cutoffValue | E | AMR07 | The value in cutoffValue must be greater than '0' and less than or equal to '5 000' |
| AMR.30 | cutoffValue | E | AMR16 | The value in cutoffValue must be greater than or equal to the value in lowest and less than the value in highest |
| AMR.30 | cutoffValue | E | AMR37 | The value in cutoffValue must be the same for each combination of values in zoonosis at level 2 and substance |
| AMR.31 | lowest | E | AMR09 | If the value in anMethCode is in level 2 'dilution', then a value in lowest must be reported |
| AMR.32 | highest | E | AMR10 | If the value in anMethCode is in level 2 'dilution', then a value in highest must be reported |
| AMR.33 | MIC | E | AMR11 | If the value in anMethCode is in level 2 'dilution', then a value in MIC must be reported |
| AMR.33 | MIC | E | AMR18 | If the value in MIC contains a less-than-or-equal-to sign, then the value in MIC must be the same as the value in lowest |
| AMR.33 | MIC | E | AMR19 | If the value in MIC contains a greater-than sign, then the value in MIC must be the same as the value in highest |
| AMR.33 | MIC | E | AMR20 | If the value in MIC is numeric, then the value in MIC must be greater than the value in lowest and less than or equal to the value in highest |
| AMR.33 | MIC | E | AMR77 | For a given combination of zoonosis, substance and progCode only one MIC result should be reported |
| AMR.34 | diskConc | E | AMR12 | The value in diskConc must be greater than '0' |
| AMR.34 | diskConc | E | AMR13 | If the value in anMethCode is in level 2 'diffusion', then a value in diskConc must be reported |
| AMR.35 | diskDiam | E | AMR14 | If the value in anMethCode is in level 2 'diffusion', then a value in diskDiam must be reported |

| Element code | Element name | Error type | Error code | Rule |
|--------------|----------------------|------------|------------|--|
| AMR.36 | IZD | E | AMR15 | If the value in anMethCode is in level 2 'diffusion', then a value in IZD must be reported |
| AMR.44 | totSampUnitsTested | E | AMR40 | If reported, the value in totSampUnitsTested must be greater than '0' |
| AMR.46 | sampOrig | E | AMR33 | For data interpretation purposes, a value in sampOrig must be reported |
| AMR.45 | sampUnitType | E | AMR52 | For data interpretation purposes, a value in sampUnitType must be reported |
| AMR.47 | perCC | E | AMR35 | If the value in zoonosis is an MRSA clonal complex, then a value in perCC must be reported to indicate whether the result was inferred or tested |
| AMR.48 | perMLST | E | AMR36 | If the value in zoonosis is a MRSA MLST, then a value in perMLST must be reported to indicate whether the result was inferred or tested |
| AMR.49 | totUnitsPositive | E | AMR39 | If reported, the value in totUnitsPositive must be greater than or equal to '0' |
| AMR.49 | totUnitsPositive | E | AMR42 | The value in totUnitsPositive must be less than or equal to the value in totUnitsTested |
| AMR.50 | totSampUnitsPositive | E | AMR41 | If reported, the value in totSampUnitsPositive must be greater than or equal to '0' |
| AMR.50 | totSampUnitsPositive | E | AMR43 | The value in totSampUnitsPositive must be less than or equal to the value in totSampUnitsTested |

3. 2015 data model used for reporting specific monitoring of ESBL-/AmpC-/carbapenemase-producing bacteria, in the absence of isolate detected

3.1. Introduction

This data dictionary provides specific guidance for reporting data deriving from the specific monitoring of *E. coli* producers of ESBLs/AmpC/carbapenemases, as well as the specific monitoring of carbapenemase-producers (voluntary reporting), **in the absence of any isolates detected**. The objective is to explain in detail the data elements included in the EFSA data model to be used for the XML/Excel transmission through EFSA's DCF. The EFSA data model used for reporting specific monitoring of ESBL-/AmpC-/carbapenemase-producing bacteria, including the specific monitoring of carbapenemase-producing micro-organisms in the absence of isolate detected is summarised in Table 8 and the complete set of business rules applied for data validation are presented in Table 9.

This data model is therefore to be used when Total units positive (*totUnitsPositive ESBL.06*) equals zero '0'. This data model will be used mainly for reporting the results of the specific monitoring of carbapenemase producers, as the absence of carbapenemase producers may not be infrequent in food-producing animal populations and food derived thereof.

3.2. General information

3.2.1. Reporting year (*repYear ESBL.01*)

This data element is **mandatory**. It is a numerical data element consisting of four digits. It is the reporting year, which is the year to which reported data refers.

3.2.2. Reporting country (*repCountry ESBL.02*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_COUNTRY, domain: D_ALL_repCountry). The list includes the 28 EU MSs, as well as Norway, Iceland and Switzerland.

3.3. Information about type and source of samples

3.3.1. Zoonotic agent (*zoonosis ESBL.03*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_PARAM_ZOO, domain: D_AMR_zoonosis). **The value in zoonosis must be reported at least at level 2 of the pick list.**

3.3.2. Matrix (*matrix ESBL.04*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_MATRIX). It represents the food/feed category or the animal species from which the isolate tested for AMR derives. In addition, more detailed breakdown information is included at levels 2–4, such as the type of animals (wild, farmed), productions category (breeding, fattening animals), subcategory of food (minced meat, hard cheese) and type of food (frozen, ready-to-eat, etc.).

As regards the reporting of the food-producing animal population investigated, it is recommended that, where appropriate, the AMR data reported are stratified by animal age/production stage and/or production type. This is because levels of resistance may be quite distinct between these groups, reflecting the widely differing treatment regimes, management practices and hygienic conditions encountered.

Based on the requirements from Commission implementing Decision 2013/652/EU, it is mandatory that AMR data are reported for the animal populations/food categories listed in Table 2.

AMR data in young and adult cattle may also be distinguished between the dairy and meat production sectors.

For example: '*Gallus gallus* (fowl) - laying hens' (code 'A031741A'); '*Gallus gallus* (fowl) - broilers' (code 'A007101A'); 'Cattle (bovine animals) - calves (under 1 year) - veal calves' (code 'A004721A'), 'Pigs - fattening pigs - unspecified - weaners to growers' (code 'A042366A').

3.4. Information about the sampling performed

3.4.1. Total units tested (*totUnitsTested ESBL.05*)

This data element is **mandatory** for the specific monitoring ESBL-/AmpC-/Carbapenemase-producing *E. coli* and for the specific monitoring of carbapenemase-producing microorganisms. It is an **integer** numerical data element. It is the total number of epidemiological units of interest (e.g. animal, flock, herd, slaughter batch, single, batch) investigated in relation to a given matrix, for the presence of specific bacterial species, during the whole reporting year exercise of the AMR monitoring programme.

3.4.2. Total units positive (*totUnitsPositive ESBL.06*)

This data element is **mandatory** for the specific monitoring ESBL-/AmpC-/Carbapenemase-producing *E. coli* and for the specific monitoring of carbapenemase-producing microorganisms. It is an **integer** numerical data element. It is the total number of epidemiological units of interest (e.g. animal, flock, herd, slaughter batch, single, batch) investigated in relation to a given matrix, and tested positive for a bacterial species, during the whole reporting year exercise of the AMR monitoring programme.

3.4.3. Sampling unit type (*sampUnitType ESBL.07*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_UNIT, domain: D_AMR_sampUnitType). It defines the type of sampling unit taken in the sampling event, e.g. 'animal' (code 'G199A'), 'herd/flock' (code 'G202A'), 'slaughter batch' (code 'G200A'), 'single (food/feed)' (code 'G203A'), 'batch (food/feed)' (code 'G204A').

3.4.4. Sampling stage (*sampStage ESBL.08*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SMPNT, domain: D_PRV_sampStage). The sampling stage is the stage along the food chain at which the sample has been collected, e.g. 'Farm' (code 'E101A'), 'Slaughterhouse' (code 'E311A') or 'Retail' (code 'E520A'). Please see Table 5 for more details about the sampling stage which could be reported for the isolates tested according Decision 2013/652/EU.

3.4.5. Sample origin (*sampOrig ESBL.09*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_COUNTRY). Sample origin is used to indicate the country of origin of the animal, food or feed sampled (ISO 3166-1-alpha-2 country code). If the exact country of origin of the sampled item is unknown, the following terms may be reported: 'European Union' (code 'EU'), 'Non-EU' (code 'XE'), 'Non-EEA' (code 'XC') or 'Unknown' (code 'XX').

3.4.6. Sample type (*sampType ESBL.10*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SMPTYP). It describes the biological source of the sample and allows for characterisation of the sample category (i.e. animal, food, feed or environmental sample) and the sample type (e.g. faeces, caecal content, boot swabs, neck skin), e.g. 'animal sample - nasal swab' (code 'S015A'), 'food sample - carcass swab' (code 'S021A').

3.4.7. Sampling context (*sampContext ESBL.11*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SRCTYP, domain: D_ALL_sampContext). It identifies the type of programme in the framework of which **samples** have been collected. It is possible to distinguish between different types of sampling

schemes, e.g. 'Monitoring - EFSA specifications' (code 'K025A'), 'Survey - national survey' (code 'K028A'), 'Control and eradication programmes' (code 'K021A'). In the particular case of clinical isolates the item 'Clinical investigations' (code 'K020A') should be used. Reporting of the sampling context is mandatory to enable evaluation of the representativeness of the AMR monitoring programmes. Please, see Table 5 for more details about the sampling context which could be reported for the isolates tested according Commission implementing Decision 2013/652/EU.

3.4.8. Sampler (*sampler ESBL.12*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SMPLR). It indicates the type of body that performed the sampling, e.g. 'Industry sampling' (code 'CX01A'), 'Official sampling' (code 'CX02A'). Please, see Table 5 for more details about the sampler which could be reported for the isolates tested according Commission implementing Decision 2013/652/EU.

3.4.9. Programme code (*progCode ESBL.13*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_AMRPROG). It identifies the basis of the programme in the framework of which the sample/isolate has been collected/analysed.

Examples of codes of programmes performed in accordance with the requisites of Commission implementing Decision 2013/652/EU are:

- 'ESBL MON' (code 'AMRP03A') to be used for the specific monitoring of ESBL-/AmpC/-carbapenemase-producing *E. coli*;
- 'CARBA MON' (code 'AMRP05A') to be used for the voluntary specific monitoring of carbapenemase-producing micro-organism in accordance with the EURL-AR protocole;
- 'OTHER ESBL MON' (code AMRP13A) and 'OTHER CARBA MON' (code AMRP06A) to be used for the specific monitoring of ESBL-/AmpC/-carbapenemase-producing *E. coli* and for the voluntary monitoring of carbapenemase-producing micro-organism, respectively, to report results from isolates obtained from other matrices, sample types or gained with different isolation protocol than the ones mentioned in the Commission implementing Decision 2013/652/EU.

3.4.10. Sampling strategy (*progSampStrategy ESBL.14*)

This data element is mandatory. It contains codes linked to a catalogue (ZOO_CAT_SAMPSTR). It is the planned procedure for selecting samples from a population and for conducting the sampling in order to obtain the information needed, e.g. 'Objective sampling' (code 'ST10A'), 'Census' (code 'ST50A'). It should be consistent with information reported under 'sampling context'. Reporting of the sampling strategy is mandatory to enable evaluation of the representativeness of the AMR monitoring programmes. Please see Table 5 for more details about the sampling strategy which could be reported for the isolates tested according Commission implementing Decision 2013/652/EU.

3.4.11. Sampling details (*sampDetails ESBL.15*)

This data element is optional. This is a free text of a maximum 2,000 alphanumeric characters. It can be used, when needed, to give more information on the sampling design, stage or context. It should be completed in English (see data element AMR.04 Language).

3.1. Additional information

3.1.1. Comment (*resComm ESBL.16*)

This free text data element is **optional**. This is a free text element of a maximum of 2,000 alphanumeric characters. This is an additional comment for the row (considered as a set of information). It should be completed in English (see data element AMR.04 Language).

Table 8: EFSA data model for specific monitoring of ESBLs/AmpC/carbapenemases data reporting

| Element code | Element label | Element name (for XML/Excel transfer) | Type | Constraint | Catalogue | Domain |
|--------------|----------------------|---------------------------------------|-----------------|------------|-------------------|--------------------|
| ESBL.01 | Reporting year | repYear | xs:integer(4) | Mandatory | | |
| ESBL.02 | Reporting country | repCountry | xs:string(2) | Mandatory | ZOO_CAT_COUNTRY | D_ALL_repCountry |
| ESBL.03 | Zoonotic agent | zoonosis | xs:string(15) | Mandatory | ZOO_CAT_PARAM_ZOO | D_AMR_zoonosis |
| ESBL.04 | Matrix | matrix | xs:string(4000) | Mandatory | ZOO_CAT_MATRIX | |
| ESBL.05 | Total units tested | totUnitTested | xs:integer(10) | Mandatory | | |
| ESBL.06 | Total units positive | totUnitsPositive | xs:integer(10) | Mandatory | | |
| ESBL.07 | Sampling unit type | sampUnitType | xs:string(5) | Mandatory | ZOO_CAT_UNIT | D_AMR_sampUnitType |
| ESBL.08 | Sampling stage | sampStage | xs:string(5) | Mandatory | ZOO_CAT_SMPNT | D_PRV_sampStage |
| ESBL.09 | Sample origin | sampOrig | xs:string(2) | Mandatory | ZOO_CAT_COUNTRY | |
| ESBL.10 | Sample type | sampType | xs:string(5) | Mandatory | ZOO_CAT_SMPTYP | |
| ESBL.11 | Sampling context | sampContext | xs:string(5) | Mandatory | ZOO_CAT_SRCTYP | D_ALL_sampContext |
| ESBL.12 | Sampler | sampler | xs:string(5) | Mandatory | ZOO_CAT_SMPLR | |
| ESBL.13 | Programme code | progCode | xs:string(7) | Mandatory | ZOO_CAT_AMRPROG | |
| ESBL.14 | Sampling strategy | progSampStrategy | xs:string(5) | Mandatory | ZOO_CAT_SAMPSTR | |
| ESBL.15 | Sampling details | sampDetails | xs:string(2000) | Optional | | |
| ESBL.16 | Comment | resComm | xs:string(2000) | Optional | | |

Table 9: EFSA business rules for specific monitoring of ESBLs/AmpC/carbapenemases data reporting

| Element code | Element name | Error type | Error code | Rule |
|--------------|------------------|------------|------------|---|
| ESBL.01 | repYear | E | ESBL01 | The value in repYear must be the same as the data collection reporting year |
| ESBL.04 | matrix | W | ESBL02 | WARNING. For data interpretation purposes, it is advised not to use general categories. The value in matrix should not be: ' <i>Gallus gallus</i> (fowl)' ('A006921A'), or ' <i>Gallus gallus</i> (fowl) - unspecified' ('A031721A'), or 'Compound feedingstuffs, not specified' ('A001421A') |
| ESBL.05 | totUnitsTested | E | ESBL03 | The value in totUnitsTested must be greater than '0' |
| ESBL.05 | totUnitsTested | E | ESBL04 | A value in totUnitsTested must be reported |
| ESBL.06 | totUnitsPositive | E | ESBL05 | The value in totUnitsPositive must be less than or equal to the value in totUnitsTested |
| ESBL.16 | totUnitsPositive | E | ESBL05 | If reported, the value in totUnitsPositive must be '0' |
| ESBL.07 | sampUnitType | E | ESBL06 | For data interpretation purposes, a value in sampUnitType must be reported |
| ESBL.08 | sampStage | E | ESBL07 | For data interpretation purposes, sampStage must be reported |
| ESBL.09 | sampOrig | E | ESBL08 | For data interpretation purposes, a value in sampOrig must be reported |
| ESBL.10 | sampType | E | ESBL09 | For data interpretation purposes, sampType must be reported |
| ESBL.11 | sampContext | E | ESBL10 | For data interpretation purposes, a value in sampContext must be reported |
| ESBL.12 | sampler | E | ESBL11 | For data interpretation purposes, a value in sampler must be reported |
| ESBL.13 | progCode | E | ESBL12 | For data interpretation purposes, a value in progCode must be reported |
| ESBL.14 | progSampStrategy | E | ESBL13 | For data interpretation purposes, a value in progSampStrategy must be reported |

4. Animal population data model 2015

4.1. Introduction

This data dictionary provides guidance for reporting on aggregated animal population data under the framework of Directive 2003/99/EC. The EFSA data model for animal population tables is summarised in Table 10 and the complete set of business rules applied for data validation are presented in Table 11.

4.2. General information and identification of the data

4.2.1. Reporting year (*repYear POP.01*)

This data element is **mandatory**. It is a numerical data element consisting of four digits. It is the reporting year, which is the year to which the reported data refers.

4.2.2. Reporting country (*repCountry POP.02*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_COUNTRY, domain: D_ALL_repCountry). The list includes the 28 EU MSs, as well as Norway, Switzerland and Iceland.

4.2.3. Language (*lang POP.03*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_LANG, domain: D_ALL_lang); however, only **the code 'en' for 'English' should be used**; text in the free text data element (data element POP.08 Comment) should be provided in English.

4.3. Information about type and source of data

4.3.1. Matrix (*matrix POP.04*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_MATRIX, domain: D_POP_matrix). It is the animal species reported on. Detailed breakdown information can be included, such as the type of animals (e.g. wild, farmed, pet) or the production category (e.g. breeding, fattening animals). For example 'Gallus gallus (fowl) - laying hens' (code 'A031741A'), 'Cattle (bovine animals) - calves (under 1 year) - veal calves' (code 'A004721A').

The total population can be reported for the level 1 category. **In case that more detailed categories are available the level 1 should be used only to report the population not reported at more detailed categories.**

4.3.2. Source year (*sourceYear POP.05*)

This data element is **optional**. It is a numerical data element consisting of four digits. It is the source year of the data, if different from the current reporting year. If the source year and the reporting year are the same, this data element must be left empty.

4.3.3. Unit (*unit POP.06*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_UNIT, domain: D_POP_unit). It is the unit of measurement for the selected **matrix** (POP.04). For example 'slaughtered animal (heads)' (code 'G201A'), 'holding' (code 'G198A').

4.3.4. Population (*population POP.07*)

This data element is **mandatory**. This is a numerical data element. It is the population for the selected **matrix** in data element POP.04 expressed in the **unit** specified in data element POP.06 (in order to say e.g. '100 slaughtered animal (heads) of sheep').

4.4. Additional information

4.4.1. Comment (*resComm POP.08*)

This data element is **optional**. This is a free text element of a maximum of 2,000 alphanumeric characters. This is an additional comment for the row (= a set of information). It should be completed in English (see data element *POP.03* Language).

Table 10: EFSA data model for animal population data reporting

| Element code | Element label | Element name (for XML/Excel transfer) | Type | Constraint | Catalogue | Domain |
|--------------|-------------------|---------------------------------------|-----------------|------------|-----------------|------------------|
| POP.01 | Reporting year | repYear | xs:integer(4) | Mandatory | | |
| POP.02 | Reporting country | repCountry | xs:string(2) | Mandatory | ZOO_CAT_COUNTRY | D_ALL_repCountry |
| POP.03 | Language | lang | xs:string(2) | Mandatory | ZOO_CAT_LANG | D_ALL_lang |
| POP.04 | Matrix | matrix | xs:string(4000) | Mandatory | ZOO_CAT_MATRIX | D_POP_matrix |
| POP.05 | Source year | sourceYear | xs:integer(4) | Optional | | |
| POP.06 | Unit | unit | xs:string(5) | Mandatory | ZOO_CAT_UNIT | D_POP_unit |
| POP.07 | Population | population | xs:integer(10) | Mandatory | | |
| POP.08 | Comment | resComm | xs:string(2000) | Optional | | |

Table 11: EFSA business rules for animal population data reporting

| Element code | Element name | Error type | Error code | Rule |
|--------------|--------------|------------|------------|---|
| POP.01 | repYear | E | POP01 | The value in repYear must be the same as the data collection reporting year |
| POP.03 | Lang | W | POP02 | WARNING. The value in lang should be 'English' ('en') |
| POP.05 | sourceYear | E | POP03 | The value in sourceYear must be less than the value in repYear |
| POP.05 | sourceYear | E | POP05 | The value in sourceYear must be numeric |
| POP.07 | population | E | POP04 | The value in population must be numeric |
| POP.07 | population | E | POP07 | The number of herds/flocks of the same matrix must be less or equal to the number of animals |
| POP.07 | population | E | POP08 | The number of holdings of the same matrix must be less or equal to the number of herds/flocks |
| POP.07 | population | E | POP09 | The number of holdings must be less than the number of animals of the same matrix |

5. Disease status data model 2015

5.1. Introduction

This data dictionary provides guidance for reporting on aggregated disease status data under the framework of Directive 2003/99/EC. The objective is to explain in detail the individual data elements that are included in the EFSA data model to be used for the XML/Excel transmission of aggregated data on disease status data through the DCF. The EFSA data model for disease status tables is summarised in Table 25 and the complete set of business rules applied for data validation are presented in Table 26. Refer to Table 27 for the disease tables to be reported for each country based on the requirements of Decision 2013/722/EU.⁶

5.2. General information and identification of the sample

5.2.1. Reporting year (*repYear DST.01*)

This data element is **mandatory**. It is a numerical data element consisting of four digits. It is the reporting year, which is the year to which the reported data refers.

5.2.2. Reporting country (*repCountry DST.02*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_COUNTRY, domain: D_ALL_repCountry). The list includes the 28 EU MSs, as well as Norway, Switzerland and Iceland.

5.2.3. Region (*sampArea DST.03*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_NUTS). It indicates the area, region or province within the country (in accordance with the NUTS standard) where the animal sample has been collected. Reporting the total for the country is mandatory. To report the total for the country, the ZOO_CAT_NUTS code corresponding to the whole country should be reported in this data element.

5.2.4. Language (*lang DST.04*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_LANG, domain: D_ALL_lang); however, **only the code 'en' for 'English' should be used**, as text in the free text data element (data element DST.10 Comment) should be provided in English.

5.3. Information about type and source of data

5.3.1. Zoonotic agent (*zoonosis DST.05*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_PARAM_ZOO, domain: D_DST_zoonosis). It allows reporting on '*Mycobacterium bovis*' (code 'RF-00003002-MCG') or '*Brucella*' (code 'RF-00000028-MCG').

5.3.2. Matrix (*matrix DST.06*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_MATRIX, domain: D_DST_matrix). It represents the specification of the animal species reported on:

- 'Deer - farmed' (code 'A006881A');
- 'Cattle (bovine animals)' (code 'A006581A');
- 'Sheep and goats' (code 'A002841A').

⁶ 2013/722/EU: Commission Implementing Decision of 29 November 2013 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2014 and the following years. OJ L 328, 7.12.2013, p. 101–117.

5.3.3. Disease status unit (*unitDS DST.07*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_UNITDS). It indicates one of the data elements of the official EU reporting tables whose numeric value (e.g. population) is reported in the data element 'Number of units' (*numUnits DST.08*, see next paragraph). Refer to Tables 10 to 22 to get the list of disease status units to be reported for each table (mandatory and optional).

5.3.4. Number of units (*numUnits DST.08*)

This data element is **mandatory**. It is a numerical data element. It is the value (e.g. population) of the unit reported in the data element 'Disease status unit' (*unitDS DST.07*).

When reporting 'Interval between routine tuberculin tests' (code 'DU26A') in the data element 'Disease status unit' (*unitDS DST.07*), the number of months between routine tuberculin tests should be reported, while any additional information concerning the interval should be reported in the 'Comment' data element (*resComm DST.10*).

5.3.5. Table name (*tableName DST.09*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_DSTABLE). It indicates the official EU reporting tables to which the data refer. For example:

- Bovine brucellosis in countries and regions that do not receive Community co-financing for eradication programme (code 'ZT04A');
- Ovine or Caprine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' (code 'ZT08A');
- Bovine tuberculosis in countries and regions that do not receive Community co-financing for eradication programme' (code 'ZT12A').

Refer to Tables 12 to 24 for the list of Disease status units to be reported for each table (mandatory and optional).

5.4. Additional information

5.4.1. Comment (*resComm DST.10*)

This data element is **optional**. This is a free text element of a maximum of 2,000 alphanumeric characters. This is an additional row for the comments. When reporting 'Interval between routine tuberculin tests' (code 'DU26A') in the data element 'Disease status unit' (*unitDS DST.07*), any additional information concerning the interval should be reported in this data element. It should be completed in English (see data element *DST.04* Language).

Table 12: Bovine brucellosis - data on herds - Community co-financed eradication programmes ('ZT02A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|--|--|
| Mandatory | DU02A | Number of herds under the program | Total number of herds under the programme |
| Mandatory | DU03A | Number of herds under the program tested/checked | Number of herds checked |
| Mandatory | DU05A | Number of new positive herds | Number of new positive herds |
| Mandatory | DU04A | Number of positive herds | Number of positive herds |
| Mandatory | DU01A | Total number of herds | Total number of herds |
| Optional | DU06A | Number of depopulated herds | Number of herds depopulated |

Table 13: Ovine or Caprine brucellosis - data on herds - Community co-financed eradication programmes ('ZT06A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|--|--|
| Mandatory | DU02A | Number of herds under the program | Total number of herds under the programme |
| Mandatory | DU03A | Number of herds under the program tested/checked | Number of herds checked |
| Mandatory | DU05A | Number of new positive herds | Number of new positive herds |
| Mandatory | DU04A | Number of positive herds | Number of positive herds |
| Mandatory | DU01A | Total number of herds | Total number of herds |
| Optional | DU06A | Number of depopulated herds | Number of herds depopulated |

Table 14: Bovine tuberculosis - data on herds - Community co-financed eradication programmes ('ZT10A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|--|--|
| Mandatory | DU02A | Number of herds under the program | Total number of herds under the programme |
| Mandatory | DU03A | Number of herds under the program tested/checked | Number of herds checked |
| Mandatory | DU05A | Number of new positive herds | Number of new positive herds |
| Mandatory | DU04A | Number of positive herds | Number of positive herds |
| Mandatory | DU01A | Total number of herds | Total number of herds |
| Optional | DU06A | Number of depopulated herds | Number of herds depopulated |

Table 15: Bovine brucellosis - data on animals - Community co-financed eradication programmes ('ZT01A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|--|--|
| Mandatory | DU09A | Number of animals tested | Number of animals tested |
| Mandatory | DU10A | Number of animals tested individually | Number of animals tested individually |
| Mandatory | DU08A | Number of animals to be tested under the program | Number of animals to be tested under the programme |
| Mandatory | DU11A | Number of positive animals | Number of positive animals |

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|--|---|
| Mandatory | DU07A | Total number of animals | Total number of animals |
| Optional | DU12A | Number of positive animals slaughtered | Slaughtering - Number of animals with positive result slaughtered or culled |
| Optional | DU13A | Total number of animals slaughtered | Slaughtering - Total number of animals slaughtered |

Table 16: Ovine or Caprine brucellosis - data on animals - Community co-financed eradication programmes ('ZT05A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|--|---|
| Mandatory | DU09A | Number of animals tested | Number of animals tested |
| Mandatory | DU10A | Number of animals tested individually | Number of animals tested individually |
| Mandatory | DU08A | Number of animals to be tested under the program | Number of animals to be tested under the programme |
| Mandatory | DU11A | Number of positive animals | Number of positive animals |
| Mandatory | DU07A | Total number of animals | Total number of animals |
| Optional | DU12A | Number of positive animals slaughtered | Slaughtering - Number of animals with positive result slaughtered or culled |
| Optional | DU13A | Total number of animals slaughtered | Slaughtering - Total number of animals slaughtered |

Table 17: Bovine tuberculosis - data on animals - Community co-financed eradication programmes ('ZT09A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|--|---|
| Mandatory | DU09A | Number of animals tested | Number of animals tested |
| Mandatory | DU10A | Number of animals tested individually | Number of animals tested individually |
| Mandatory | DU08A | Number of animals to be tested under the program | Number of animals to be tested under the programme |
| Mandatory | DU11A | Number of positive animals | Number of positive animals |
| Mandatory | DU07A | Total number of animals | Total number of animals |
| Optional | DU12A | Number of positive animals slaughtered | Slaughtering - Number of animals with positive result slaughtered or culled |
| Optional | DU13A | Total number of animals slaughtered | Slaughtering - Total number of animals slaughtered |

Table 18: Bovine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes ('ZT03A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|---|---|
| Mandatory | DU25A | Number of animals with status officially free, at the end of the period | Status of herds and animals under the programme - Officially free - Animals |
| Mandatory | DU24A | Number of herds with status officially free, at the end of the period | Status of herds and animals under the programme - Officially free - Herds |
| Mandatory | DU53A | Total number of animals under the program, at the end of the period | Status of herds and animals under the programme - Total number of herds and animals under the programme - Animals |
| Mandatory | DU52A | Total number of herds under the program, at the end of the period | Status of herds and animals under the programme - Total number of herds and animals under the programme - Herds |

| | | | |
|----------|-------|---|---|
| Optional | DU21A | Number of animals with status free or officially free suspended, at the end of the period | Status of herds and animals under the programme - Free or officially free suspended - Animals |
| Optional | DU23A | Number of animals with status free, at the end of the period | Status of herds and animals under the programme - Free - Animals |
| Optional | DU19A | Number of animals with status not free or not officially free and last check negative, at the end of the period | Status of herds and animals under the programme - Not free or not officially free - Last check negative - Animals |
| Optional | DU17A | Number of animals with status not free or not officially free and last check positive, at the end of the period | Status of herds and animals under the programme - Not free or not officially free - Last check positive - Animals |
| Optional | DU15A | Number of animals with unknown status, at the end of the period | Status of herds and animals under the programme - Unknown - Animals |
| Optional | DU20A | Number of herds with status free or officially free suspended, at the end of the period | Status of herds and animals under the programme - Free or officially free suspended - Herds |
| Optional | DU22A | Number of herds with status free, at the end of the period | Status of herds and animals under the programme - Free - Herds |
| Optional | DU18A | Number of herds with status not free or not officially free and last check negative, at the end of the period | Status of herds and animals under the programme - Not free or not officially free - Last check negative - Herds |
| Optional | DU16A | Number of herds with status not free or not officially free and last check positive, at the end of the period | Status of herds and animals under the programme - Not free or not officially free - Last check positive - Herds |
| Optional | DU14A | Number of herds with unknown status, at the end of the period | Status of herds and animals under the programme - Unknown - Herds |

Table 19: Ovine or Caprine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes ('ZT07A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|-------------------|-------------|---|---|
| Mandatory | DU25A | Number of animals with status officially free, at the end of the period | Status of herds and animals under the programme - Officially free - Animals |
| Mandatory | DU24A | Number of herds with status officially free, at the end of the period | Status of herds and animals under the programme - Officially free - Herds |
| Mandatory | DU53A | Total number of animals under the program, at the end of the period | Status of herds and animals under the programme - Total number of herds and animals under the programme - Animals |
| Mandatory | DU52A | Total number of herds under the program, at the end of the period | Status of herds and animals under the programme - Total number of herds and animals under the programme - Herds |
| Optional | DU21A | Number of animals with status free or officially free suspended, at the end of the period | Status of herds and animals under the programme - Free or officially free suspended - Animals |
| Optional | DU23A | Number of animals with status free, at the end of the period | Status of herds and animals under the programme - Free - Animals |
| Optional | DU19A | Number of animals with status not free or not officially free and last check negative, at the end of the period | Status of herds and animals under the programme - Not free or not officially free - Last check negative - Animals |
| Optional | DU17A | Number of animals with status not free or not officially free and last check positive, at the end of the period | Status of herds and animals under the programme - Not free or not officially free - Last check positive - Animals |
| Optional | DU15A | Number of animals with unknown status, at the end of the period | Status of herds and animals under the programme - Unknown - Animals |
| Optional | DU20A | Number of herds with status free or officially free suspended, at | Status of herds and animals under the programme - Free or officially free |

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|---|---|
| | | the end of the period | suspended - Herds |
| Optional | DU22A | Number of herds with status free, at the end of the period | Status of herds and animals under the programme - Free - Herds |
| Optional | DU18A | Number of herds with status not free or not officially free and last check negative, at the end of the period | Status of herds and animals under the programme - Not free or not officially free - Last check negative - Herds |
| Optional | DU16A | Number of herds with status not free or not officially free and last check positive, at the end of the period | Status of herds and animals under the programme - Not free or not officially free - Last check positive - Herds |
| Optional | DU14A | Number of herds with unknown status, at the end of the period | Status of herds and animals under the programme - Unknown - Herds |

Table 20: Bovine tuberculosis - data on status of herds at the end of the period - Community co-financed eradication programmes ('ZT11A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|---|---|
| Mandatory | DU25A | Number of animals with status officially free, at the end of the period | Status of herds and animals under the programme - Officially free - Animals |
| Mandatory | DU24A | Number of herds with status officially free, at the end of the period | Status of herds and animals under the programme - Officially free - Herds |
| Mandatory | DU53A | Total number of animals under the program, at the end of the period | Status of herds and animals under the programme - Total number of herds and animals under the programme - Animals |
| Mandatory | DU52A | Total number of herds under the program, at the end of the period | Status of herds and animals under the programme - Total number of herds and animals under the programme - Herds |
| Optional | DU21A | Number of animals with status free or officially free suspended, at the end of the period | Status of herds and animals under the programme - Free or officially free suspended - Animals |
| Optional | DU23A | Number of animals with status free, at the end of the period | Status of herds and animals under the programme - Free - Animals |
| Optional | DU19A | Number of animals with status not free or not officially free and last check negative, at the end of the period | Status of herds and animals under the programme - Not free or not officially free - Last check negative - Animals |
| Optional | DU17A | Number of animals with status not free or not officially free and last check positive, at the end of the period | Status of herds and animals under the programme - Not free or not officially free - Last check positive - Animals |
| Optional | DU15A | Number of animals with unknown status, at the end of the period | Status of herds and animals under the programme - Unknown - Animals |
| Optional | DU20A | Number of herds with status free or officially free suspended, at the end of the period | Status of herds and animals under the programme - Free or officially free suspended - Herds |
| Optional | DU22A | Number of herds with status free, at the end of the period | Status of herds and animals under the programme - Free - Herds |
| Optional | DU18A | Number of herds with status not free or not officially free and last check negative, at the end of the period | Status of herds and animals under the programme - Not free or not officially free - Last check negative - Herds |
| Optional | DU16A | Number of herds with status not free or not officially free and last check positive, at the end of the period | Status of herds and animals under the programme - Not free or not officially free - Last check positive - Herds |
| Optional | DU14A | Number of herds with unknown status, at the end of the period | Status of herds and animals under the programme - Unknown - Herds |

Table 21: Bovine brucellosis in countries and regions that do not receive Community co-financing for eradication programme ('ZT04A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|---|---|
| Mandatory | DU54A | Number of herds with status officially free | Officially free herds - Number of herds |
| Mandatory | DU56A | Number of infected herds | Infected herds - Number of herds |
| Mandatory | DU01A | Total number of herds | Total number of existing bovine - Herds |
| Optional | DU39A | Number of abortions due to <i>Brucella abortus</i> | Investigations of suspect cases - Information about abortions - Number of abortions due to <i>Brucella abortus</i> |
| Optional | DU35A | Number of animals or pools tested under surveillance by bulk milk | Surveillance - Examination of bulk milk samples - Number of animals or pools tested |
| Optional | DU45A | Number of animals positive in microbiological testing under investigations of suspect cases | Investigations of suspect cases - Epidemiological investigation - Number of animals positive microbiologically |
| Optional | DU43A | Number of animals positive to BST under investigations of suspect cases | Investigations of suspect cases - Epidemiological investigation - Number of positive animals - BST |
| Optional | DU40A | Number of animals serologically tested under investigations of suspect cases | Investigations of suspect cases - Epidemiological investigation - Number of animals tested with serological blood tests |
| Optional | DU44A | Number of animals tested by microbiology under investigations of suspect cases | Investigations of suspect cases - Epidemiological investigation - Number of animals examined microbiologically |
| Optional | DU32A | Number of animals tested under surveillance | Surveillance - Serological tests - Number of animals tested |
| Optional | DU31A | Number of herds tested under surveillance | Surveillance - Serological tests - Number of herds tested |
| Optional | DU34A | Number of herds tested under surveillance by bulk milk | Surveillance - Examination of bulk milk samples - Number of bovine herds tested |
| Optional | DU33A | Number of infected herds tested under surveillance | Surveillance - Serological tests - Number of infected herds |
| Optional | DU36A | Number of infected herds tested under surveillance by bulk milk | Surveillance - Examination of bulk milk samples - Number of infected herds |
| Optional | DU38A | Number of isolations of <i>Brucella</i> infections | Investigations of suspect cases - Information about abortions - Number of isolations of <i>Brucella</i> infection |
| Optional | DU37A | Number of notified abortions whatever cause | Investigations of suspect cases - Information about abortions - Number of notified abortions whatever cause |
| Optional | DU42A | Number of seropositive animals under investigations of suspect cases | Investigations of suspect cases - Epidemiological investigation - Number of positive animals - Serologically |
| Optional | DU41A | Number of suspended herds under investigations of suspect cases | Investigations of suspect cases - Epidemiological investigation - Number of suspended herds |
| Optional | DU07A | Total number of animals | Total number of existing bovine - Animals |

Table 22: Ovine or Caprine brucellosis in countries and regions that do not receive Community co-financing for eradication programme ('ZT08A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|---|---|
| Mandatory | DU54A | Number of herds with status officially free | Officially free herds - Number of herds |
| Mandatory | DU56A | Number of infected herds | Infected herds - Number of herds |
| Mandatory | DU01A | Total number of herds | Total number of existing ovine/caprine - Herds |
| Optional | DU45A | Number of animals positive in microbiological testing under investigations of suspect cases | Investigations of suspect cases - Number of animals positive microbiologically |
| Optional | DU40A | Number of animals serologically tested under investigations of suspect cases | Investigations of suspect cases - Number of animals tested with serological blood tests |
| Optional | DU44A | Number of animals tested by microbiology under investigations of suspect cases | Investigations of suspect cases - Number of animals examined microbiologically |
| Optional | DU32A | Number of animals tested under surveillance | Surveillance - Number of animals tested |
| Optional | DU31A | Number of herds tested under surveillance | Surveillance - Number of herds tested |
| Optional | DU33A | Number of infected herds tested under surveillance | Surveillance - Number of infected herds |
| Optional | DU42A | Number of seropositive animals under investigations of suspect cases | Investigations of suspect cases - Number of animals positive serologically |
| Optional | DU41A | Number of suspended herds under investigations of suspect cases | Investigations of suspect cases - Number of suspended herds |
| Optional | DU07A | Total number of animals | Total number of existing ovine / caprine - Animals |

Table 23: Bovine tuberculosis in countries and regions that do not receive Community co-financing for eradication programme ('ZT12A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|--|--|
| Mandatory | DU54A | Number of herds with status officially free | Officially free herds - Number of herds |
| Mandatory | DU56A | Number of infected herds | Infected herds - Number of herds |
| Mandatory | DU01A | Total number of herds | Total number of existing bovine - Herds |
| Optional | DU26A | Interval between routine tuberculin tests | Routine tuberculin testing - Interval between routine tuberculin tests |
| Optional | DU30A | Number of animals detected positive in bacteriological examination | Number of animals detected positive in bacteriological examination |
| Optional | DU27A | Number of animals tested with tuberculin routine testing | Routine tuberculin testing - Number of animals tested |
| Optional | DU29A | Number of animals with suspicious lesions of tuberculosis examined and submitted to histopathological and bacteriological examinations | Number of animals with suspicious lesions of tuberculosis examined and submitted to histopathological and bacteriological examinations |
| Optional | DU28A | Number of tuberculin tests carried out before the introduction into the herds | Number of tuberculin tests carried out before the introduction into the herds (Annex A(I)(2)(c) third indent of Directive 64/432/EEC) |
| Optional | DU07A | Total number of animals | Total number of existing bovine - Animals |

Table 24: Tuberculosis in farmed deer ('ZT13A')

| Constraint | Code | Disease status unit | Column heading in Zoonoses Web Application |
|------------|-------|--|--|
| Mandatory | DU56A | Number of infected herds | Infected herds - Number of herds |
| Mandatory | DU01A | Total number of herds | Total number of existing farmed deer - Herds |
| Optional | DU26A | Interval between routine tuberculin tests | Routine tuberculin testing - Interval between routine tuberculin tests |
| Optional | DU30A | Number of animals detected positive in bacteriological examination | Number of animals detected positive in bacteriological examination |
| Optional | DU27A | Number of animals tested with tuberculin routine testing | Routine tuberculin testing - Number of animals tested |
| Optional | DU29A | Number of animals with suspicious lesions of tuberculosis examined and submitted to histopathological and bacteriological examinations | Number of animals with suspicious lesions of tuberculosis examined and submitted to histopathological and bacteriological examinations |
| Optional | DU57A | Number of herds with status free | Free herds - Number of herds |
| Optional | DU28A | Number of tuberculin tests carried out before the introduction into the herds | Number of tuberculin tests carried out before the introduction into the herds |
| Optional | DU07A | Total number of animals | Total number of existing farmed deer - Animals |

Table 25: EFSA data model for disease status data reporting

| Element code | Element label | Element name (for XML/Excel transfer) | Type | Constraint | Catalogue | Domain |
|--------------|---------------------|---------------------------------------|-----------------|------------|-------------------|------------------|
| DST.01 | Reporting year | repYear | xs:integer(4) | Mandatory | | |
| DST.02 | Reporting country | repCountry | xs:string(2) | Mandatory | ZOO_CAT_COUNTRY | D_ALL_repCountry |
| DST.03 | Region | sampArea | xs:string(5) | Mandatory | ZOO_CAT_NUTS | |
| DST.04 | Language | lang | xs:string(2) | Mandatory | ZOO_CAT_LANG | D_ALL_lang |
| DST.05 | Zoonotic agent | zoonosis | xs:string(15) | Mandatory | ZOO_CAT_PARAM_ZOO | D_DST_zoonosis |
| DST.06 | Matrix | matrix | xs:string(4000) | Mandatory | ZOO_CAT_MATRIX | D_DST_matrix |
| DST.07 | Disease status unit | unitDS | xs:string(5) | Mandatory | ZOO_CAT_UNITDS | |
| DST.08 | Number of units | numUnits | xs:integer(10) | Mandatory | | |
| DST.09 | Table name | tableName | xs:string(5) | Mandatory | ZOO_CAT_DSTABLE | |
| DST.10 | Comment | resComm | xs:string(2000) | Optional | | |

Table 26: EFSA business rules for disease status data reporting

| Element code | Element name | Error type | Error code | Rule |
|--------------|--------------|------------|------------|---|
| DST.01 | repYear | E | DST01 | The value in repYear must be the same as the data collection reporting year |
| DST.04 | lang | W | DST02 | WARNING. The value in lang should be 'English' ('en') |
| DST.05 | zoonosis | E | DST31 | If the value in tableName is 'Bovine tuberculosis - data on animals - Community co-financed eradication programmes' ('ZT09A'), or 'Bovine tuberculosis - data on herds - Community co-financed eradication programmes' ('ZT10A'), or 'Bovine tuberculosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT11A'), or 'Bovine tuberculosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT12A'), or 'Tuberculosis in farmed deer' ('ZT13A'), then the value in zoonosis must be ' <i>Mycobacterium bovis</i> ' ('RF-00003002-MCG') |
| DST.05 | zoonosis | E | DST32 | If the value in tableName is 'Bovine brucellosis - data on animals - Community co-financed eradication programmes' ('ZT01A'), or 'Bovine brucellosis - data on herds - Community co-financed eradication programmes' ('ZT02A'), or 'Bovine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT03A'), or 'Bovine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT04A'), or 'Ovine or Caprine brucellosis - data on animals - Community co-financed eradication programmes' ('ZT05A'), or 'Ovine or Caprine brucellosis - data on herds - Community co-financed eradication programmes' ('ZT06A'), or 'Ovine or Caprine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT07A'), or 'Ovine or Caprine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT08A'), then the value in zoonosis must be ' <i>Brucella</i> ' ('RF-00000028-MCG') |
| DST.06 | matrix | E | DST33 | If the value in tableName is 'Ovine or Caprine brucellosis - data on animals - Community co-financed eradication programmes' ('ZT05A'), or 'Ovine or Caprine brucellosis - data on herds - Community co-financed eradication programmes' ('ZT06A'), or 'Ovine or Caprine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT07A'), or 'Ovine or Caprine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT08A'), then the value in matrix must be 'Sheep and goats' ('A002841A') |
| DST.06 | matrix | E | DST34 | If the value in tableName is 'Tuberculosis in farmed deer' ('ZT13A'), then the value in matrix must be 'Deer - farmed' ('A006881A') |
| DST.06 | matrix | E | DST35 | If the value in tableName is 'Bovine brucellosis - data on animals - Community co-financed eradication |

| Element code | Element name | Error type | Error code | Rule |
|--------------|--------------|------------|------------|---|
| | | | | programmes' ('ZT01A'), or 'Bovine brucellosis - data on herds - Community co-financed eradication programmes' ('ZT02A'), or 'Bovine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT03A'), or 'Bovine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT04A'), or 'Bovine tuberculosis - data on animals - Community co-financed eradication programmes' ('ZT09A'), or 'Bovine tuberculosis - data on herds - Community co-financed eradication programmes' ('ZT10A'), or 'Bovine tuberculosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT11A'), or 'Bovine tuberculosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT12A'), then the value in matrix must be 'Cattle (bovine animals)' ('A006581A'); |
| DST.07 | unitDS | E | DST18 | If the value in tableName is 'Bovine tuberculosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT12A'), then the value in unitDS must be 'Number of herds with status officially free' ('DU54A'), or 'Number of infected herds' ('DU56A'), or 'Total number of herds' ('DU01A'), or 'Interval between routine tuberculin tests' ('DU26A'), or 'Number of animals detected positive in bacteriological examination' ('DU30A'), or 'Number of animals tested with tuberculin routine testing' ('DU27A'), or 'Number of animals with suspicious lesions of tuberculosis examined and submitted to histopathological and bacteriological examinations' ('DU29A'), or 'Number of tuberculin tests carried out before the introduction into the herds' ('DU28A'), or 'Total number of animals' ('DU07A') |
| DST.07 | unitDS | E | DST19 | If the value in tableName is 'Bovine tuberculosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT11A'), then the value in unitDS must be 'Number of animals with status officially free, at the end of the period' ('DU25A'), or 'Number of herds with status officially free, at the end of the period' ('DU24A'), or 'Total number of animals under the program, at the end of the period' ('DU53A'), or 'Total number of herds under the program, at the end of the period' ('DU52A'), or 'Number of animals with status free or officially free suspended, at the end of the period' ('DU21A'), or 'Number of animals with status free, at the end of the period' ('DU23A'), or 'Number of animals with status not free or not officially free and last check negative, at the end of the period' ('DU19A'), or 'Number of animals with status not free or not officially free and last check positive, at the end of the period' ('DU17A'), or 'Number of animals with unknown status, at the end of the period' ('DU15A'), or 'Number of herds with status free or officially free suspended, at the end of the period' ('DU20A'), or |

| Element code | Element name | Error type | Error code | Rule |
|--------------|--------------|------------|------------|---|
| | | | | 'Number of herds with status free, at the end of the period' ('DU22A'), or 'Number of herds with status not free or not officially free and last check negative, at the end of the period' ('DU18A'), or 'Number of herds with status not free or not officially free and last check positive, at the end of the period' ('DU16A'), or 'Number of herds with unknown status, at the end of the period' ('DU14A') |
| DST.07 | unitDS | E | DST20 | If the value in tableName is 'Bovine tuberculosis - data on animals - Community co-financed eradication programmes' ('ZT09A'), then the value in unitDS must be 'Number of animals tested' ('DU09A'), or 'Number of animals tested individually' ('DU10A'), or 'Number of animals to be tested under the program' ('DU08A'), or 'Number of positive animals' ('DU11A'), or 'Total number of animals' ('DU07A'), or 'Number of positive animals slaughtered' ('DU12A'), or 'Total number of animals slaughtered' ('DU13A') |
| DST.07 | unitDS | E | DST21 | If the value in tableName is 'Bovine tuberculosis - data on herds - Community co-financed eradication programmes' ('ZT10A'), then the value in unitDS must be 'Number of herds under the program' ('DU02A'), or 'Number of herds under the program tested/checked' ('DU03A'), or 'Number of new positive herds' ('DU05A'), or 'Number of positive herds' ('DU04A'), or 'Total number of herds' ('DU01A'), or 'Number of depopulated herds' ('DU06A') |
| DST.07 | unitDS | E | DST22 | If the value in tableName is 'Ovine or Caprine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT08A'), then the value in unitDS must be 'Number of herds with status officially free' ('DU54A'), or 'Number of infected herds' ('DU56A'), or 'Total number of herds' ('DU01A'), or 'Number of animals positive in microbiological testing under investigations of suspect cases' ('DU45A'), or 'Number of animals serologically tested under investigations of suspect cases' ('DU40A'), or 'Number of animals tested by microbiology under investigations of suspect cases' ('DU44A'), or 'Number of animals tested under surveillance' ('DU32A'), 'Number of herds tested under surveillance' ('DU31A'), or 'Number of infected herds tested under surveillance' ('DU33A'), or 'Number of seropositive animals under investigations of suspect cases' ('DU42A'), or 'Number of suspended herds under investigations of suspect cases' ('DU41A'), or 'Total number of animals' ('DU07A') |

| Element code | Element name | Error type | Error code | Rule |
|--------------|--------------|------------|------------|--|
| DST.07 | unitDS | E | DST23 | <p>If the value in tableName is 'Ovine or Caprine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT07A'), then the value in unitDS must be</p> <p>'Number of animals with status officially free, at the end of the period' ('DU25A'), or 'Number of herds with status officially free, at the end of the period' ('DU24A'), or 'Total number of animals under the program, at the end of the period' ('DU53A'), or 'Total number of herds under the program, at the end of the period' ('DU52A'), or 'Number of animals with status free or officially free suspended, at the end of the period' ('DU21A'), or 'Number of animals with status free, at the end of the period' ('DU23A'), or 'Number of animals with status not free or not officially free and last check negative, at the end of the period' ('DU19A'), or 'Number of animals with status not free or not officially free and last check positive, at the end of the period' ('DU17A'), or 'Number of animals with unknown status, at the end of the period' ('DU15A'), or 'Number of herds with status free or officially free suspended, at the end of the period' ('DU20A'), or 'Number of herds with status free, at the end of the period' ('DU22A'), or 'Number of herds with status not free or not officially free and last check negative, at the end of the period' ('DU18A'), or 'Number of herds with status not free or not officially free and last check positive, at the end of the period' ('DU16A'), or 'Number of herds with unknown status, at the end of the period' ('DU14A')</p> |
| DST.07 | unitDS | E | DST24 | <p>If the value in tableName is 'Ovine or Caprine brucellosis - data on animals - Community co-financed eradication programmes' ('ZT05A'), then the value in unitDS must be</p> <p>'Number of animals tested' ('DU09A'), or 'Number of animals tested individually' ('DU10A'), or 'Number of animals to be tested under the program' ('DU08A'), or 'Number of positive animals' ('DU11A'), or 'Total number of animals' ('DU07A'), or 'Number of positive animals slaughtered' ('DU12A'), or 'Total number of animals slaughtered' ('DU13A')</p> |
| DST.07 | unitDS | E | DST25 | <p>If the value in tableName is 'Ovine or Caprine brucellosis - data on herds - Community co-financed eradication programmes' ('ZT06A'), then the value in unitDS must be</p> <p>'Number of herds under the program' ('DU02A'), or 'Number of herds under the program tested/checked' ('DU03A'), or 'Number of new positive herds' ('DU05A'), or 'Number of positive herds' ('DU04A'), or 'Total number of herds' ('DU01A'), or</p> |

| Element code | Element name | Error type | Error code | Rule |
|--------------|--------------|------------|------------|--|
| DST.07 | unitDS | E | DST26 | <p>'Number of depopulated herds' ('DU06A')</p> <p>If the value in tableName is 'Bovine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT04A'), then the value in unitDS must be</p> <p>'Number of herds with status officially free' ('DU54A'), or</p> <p>'Number of infected herds' ('DU56A'), or</p> <p>'Total number of herds' ('DU01A'), or</p> <p>'Number of abortions due to <i>Brucella abortus</i>' ('DU39A'), or</p> <p>'Number of animals or pools tested under surveillance by bulk milk' ('DU35A'), or</p> <p>'Number of animals positive in microbiological testing under investigations of suspect cases' ('DU45A'), or</p> <p>'Number of animals positive to BST under investigations of suspect cases' ('DU43A'), or</p> <p>'Number of animals serologically tested under investigations of suspect cases' ('DU40A'), or</p> <p>'Number of animals tested by microbiology under investigations of suspect cases' ('DU44A'), or</p> <p>'Number of animals tested under surveillance' ('DU32A'), or</p> <p>'Number of herds tested under surveillance' ('DU31A'), or</p> <p>'Number of herds tested under surveillance by bulk milk' ('DU34A'), or</p> <p>'Number of infected herds tested under surveillance' ('DU33A'), or</p> <p>'Number of infected herds tested under surveillance by bulk milk' ('DU36A'), or</p> <p>'Number of isolations of <i>Brucella</i> infections' ('DU38A'), or</p> <p>'Number of notified abortions whatever cause' ('DU37A'), or</p> <p>'Number of seropositive animals under investigations of suspect cases' ('DU42A'), or</p> <p>'Number of suspended herds under investigations of suspect cases' ('DU41A'), or</p> <p>'Total number of animals' ('DU07A')</p> |
| DST.07 | unitDS | E | DST27 | <p>If the value in tableName is 'Bovine brucellosis - data on status of herds at the end of the period - Community co-financed eradication' ('ZT03A'), then the value in unitDS must be</p> <p>'Number of animals with status officially free, at the end of the period' ('DU25A'), or</p> <p>'Number of herds with status officially free, at the end of the period' ('DU24A'), or</p> <p>'Total number of animals under the program, at the end of the period' ('DU53A'), or</p> <p>'Total number of herds under the program, at the end of the period' ('DU52A'), or</p> <p>'Number of animals with status free or officially free suspended, at the end of the period' ('DU21A'), or</p> <p>'Number of animals with status free, at the end of the period' ('DU23A'), or</p> <p>'Number of animals with status not free or not officially free and last check negative, at the end of the period' ('DU19A'), or</p> <p>'Number of animals with status not free or not officially free and last check positive, at the end of the period' ('DU17A'), or</p> <p>'Number of animals with unknown status, at the end of the period' ('DU15A'), or</p> <p>'Number of herds with status free or officially free suspended, at the end of the period' ('DU20A'), or</p> <p>'Number of herds with status free, at the end of the period' ('DU22A'), or</p> |

| Element code | Element name | Error type | Error code | Rule |
|--------------|--------------|------------|------------|--|
| | | | | 'Number of herds with status not free or not officially free and last check negative, at the end of the period' ('DU18A'), or 'Number of herds with status not free or not officially free and last check positive, at the end of the period' ('DU16A'), or 'Number of herds with unknown status, at the end of the period' ('DU14A') |
| DST.07 | unitDS | E | DST28 | If the value in tableName is 'Bovine brucellosis - data on animals - Community co-financed eradication programmes' ('ZT01A'), then the value in unitDS must be 'Number of animals tested' ('DU09A'), or 'Number of animals tested individually' ('DU10A'), or 'Number of animals to be tested under the program' ('DU08A'), or 'Number of positive animals' ('DU11A'), or 'Total number of animals' ('DU07A'), or 'Number of positive animals slaughtered' ('DU12A'), or 'Total number of animals slaughtered' ('DU13A') |
| DST.07 | unitDS | E | DST29 | If the value in tableName is 'Bovine brucellosis - data on herds - Community co-financed eradication programmes' ('ZT02A'), then the value in unitDS must be 'Number of herds under the program' ('DU02A'), or 'Number of herds under the program tested/checked' ('DU03A'), or 'Number of new positive herds' ('DU05A'), or 'Number of positive herds' ('DU04A'), or 'Total number of herds' ('DU01A'), or 'Number of depopulated herds' ('DU06A') |
| DST.07 | unitDS | E | DST30 | If the value in tableName is 'Tuberculosis in farmed deer' ('ZT13A'), then the value in unitDS must be 'Number of infected herds' ('DU56A'), or 'Total number of herds' ('DU01A'), or 'Interval between routine tuberculin tests' ('DU26A'), or 'Number of animals detected positive in bacteriological examination' ('DU30A'), or 'Number of animals tested with tuberculin routine testing' ('DU27A'), or 'Number of animals with suspicious lesions of tuberculosis examined and submitted to histopathological and bacteriological examinations' ('DU29A'), or 'Number of herds with status free' ('DU57A'), or 'Number of tuberculin tests carried out before the introduction into the herds' ('DU28A'), or 'Total number of animals' ('DU07A') |
| DST.08 | numUnits | E | DST03 | If unitsDS is not 'Routine tuberculin testing - Interval between routine tuberculin tests', then the value in numUnits must be numeric |

| Element code | Element name | Error type | Error code | Rule |
|--------------|--------------|------------|------------|--|
| DST.08 | numUnits | E | DST06 | For each combination of values in matrix and zoonosis, the value in numUnits reported as the 'Total number of herds' ('DU01A') must be greater than or equal to the value in numUnits reported as the 'Number of herds under the program' ('DU02A') |
| DST.08 | numUnits | E | DST07 | For each combination of values in matrix and zoonosis, the value in numUnits reported as the 'Number of herds under the program' ('DU02A') must be greater than or equal to the value in numUnits reported as the 'Number of herds under the program tested/checked' ('DU03A') |
| DST.08 | numUnits | E | DST08 | For each combination of values in matrix and zoonosis, the value in numUnits reported as the 'Number of herds under the program tested/checked' ('DU03A') must be greater than or equal to the value in numUnits reported as the 'Number of positive herds' ('DU04A') |
| DST.08 | numUnits | E | DST09 | For each combination of values in matrix and zoonosis, the value in numUnits reported as the 'Number of positive herds' ('DU04A') must be greater than or equal to the value in numUnits reported as the 'Number of new positive herds' ('DU05A') |
| DST.08 | numUnits | E | DST10 | For each combination of values in matrix and zoonosis, the value in numUnits reported as the 'Number of herds under the program' ('DU02A') must be greater than or equal to the value in numUnits reported as the 'Number of depopulated herds' ('DU06A') |
| DST.08 | numUnits | E | DST11 | For each combination of values in matrix and zoonosis, the value in numUnits reported as the 'Total number of animals' ('DU07A') must be greater than or equal to the value in numUnits reported as the 'Number of animals to be tested under the program' ('DU08A') |
| DST.08 | numUnits | E | DST12 | For each combination of values in matrix and zoonosis, the value in numUnits reported as the 'Number of animals to be tested under the program' ('DU08A') must be greater than or equal to the value in numUnits reported as the 'Number of animals tested' ('DU09A') |
| DST.08 | numUnits | E | DST13 | For each combination of values in matrix and zoonosis, the value in numUnits reported as the 'Number of animals tested' ('DU09A') must be greater than or equal to the value in numUnits reported as the 'Number of positive animals' ('DU11A') |
| DST.08 | numUnits | E | DST14 | For each combination of values in matrix and zoonosis, the value in numUnits reported as the 'Total number of animals under the programme, at the end of the period' ('DU53A') must be equal to the sum of the value in numUnits reported as the 'Number of animals with unknown status, at the end of the period' ('DU15A'), plus the value in numUnits reported as the 'Number of herds with status not free or not officially free and last check positive, at the end of the period' ('DU16A'), plus the value in numUnits reported as the 'Number of animals with status not free or not officially free and last check positive, at the end of the period' ('DU17A'), plus the value in numUnits reported as the 'Number of herds with status not free or not officially free and last check negative, at the end of the period' ('DU18A'), plus the value in numUnits reported as the 'Number of animals with status not free or not officially free and last check negative, at the end of the period' ('DU19A'), plus the value in numUnits reported as the 'Number of herds with status free or officially free suspended, at the end of |

| Element code | Element name | Error type | Error code | Rule |
|--------------|--------------|------------|------------|---|
| | | | | <p>the period' ('DU20A'), plus the value in numUnits reported as the 'Number of animals with status free or officially free suspended, at the end of the period' ('DU21A'), plus the value in numUnits reported as the 'Number of herds with status free, at the end of the period' ('DU22A'), plus the value in numUnits reported as the 'Number of animals with status free, at the end of the period' ('DU23A'), plus the value in numUnits reported as the 'Number of herds with status officially free, at the end of the period' ('DU24A'), plus the value in numUnits reported as the 'Number of animals with status officially free, at the end of the period' ('DU25A')</p> $(DU53A = DU15A + DU16A + DU17A + DU18A + DU19A + DU20A + DU21A + DU22A + DU23A + DU24A + DU25A)$ |
| DST.08 | numUnits | E | DST15 | <p>For each combination of values in matrix and zoonosis, the value in numUnits reported as the 'Total number of herds under the program, at the end of the period' ('DU52A') must be equal to the sum of the value in numUnits reported as the 'Number of herds with unknown status, at the end of the period' ('DU14A'), plus the value in numUnits reported as the 'Number of herds with status not free or not officially free and last check positive, at the end of the period' ('DU16A'), plus the value in numUnits reported as the 'Number of herds with status not free or not officially free and last check negative, at the end of the period' ('DU18A'), plus the value in numUnits reported as the 'Number of herds with status free or officially free suspended, at the end of the period' ('DU20A'), plus the value in numUnits reported as the 'Number of herds with status free, at the end of the period' ('DU22A'), plus the value in numUnits reported as the 'Number of herds with status officially free, at the end of the period' ('DU24A')</p> $(DU52A = DU14A + DU16A + DU18A + DU20A + DU22A + DU24A)$ |
| DST.08 | numUnits | E | DST36 | <p>If the value in tableName is 'Bovine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' (ZT04A), then the value in numUnits corresponding to the 'Disease status unit' (unitDS) with the value 'Number of abortions due to Brucella abortus' (DU39A) must be less than or equal to the value in numUnits corresponding to the 'Disease status unit' (unitDS) with the value 'Number of isolations of Brucella infections' (DU38A);</p> |
| Context | Context | E | DST04 | <p>The combination of values in sampArea, zoonosis, matrix, unitDS and tableName must be unique (the numbers in numUnits must be aggregated accordingly)</p> |
| General rule | General rule | E | DST05 | <p>MSs have to fill in the relevant tables depending on their official disease status and according to whether they receive Community co-financing or not for their control and eradication programmes</p> |

Table 27: Disease status data reporting based on Decision 2013/722/EU

| Table name | Table code | Countries required to report data ^(a) |
|--|------------|--|
| Bovine tuberculosis | | |
| Bovine tuberculosis - data on herds - Community co-financed eradication programmes | ZT10A | AT, ES, HR, IE, IT, PT, UK |
| Bovine tuberculosis - data on animals - Community co-financed eradication programmes | ZT09A | AT, ES, HR, IE, IT, PT, UK |
| Bovine tuberculosis - data on status of herds at the end of the period - Community co-financed eradication programmes | ZT11A | AT, ES, HR, IE, IT, PT, UK |
| Bovine tuberculosis in countries and regions that do not receive Community co-financing for eradication programme | ZT12A | BE, BG, CY, CZ, DK, EE, FI, FR, DE, GR, HU, IT, LV, LT, LU, MT, NL, PL, RO, SK, SI, SE |
| Bovine brucellosis | | |
| Bovine brucellosis - data on herds - Community co-financed eradication programmes | ZT02A | ES, HR, IT, PT, UK |
| Bovine brucellosis - data on animals - Community co-financed eradication programmes | ZT01A | ES, HR, IT, PT, UK |
| Bovine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes | ZT03A | ES, HR, IT, PT, UK |
| Bovine brucellosis in countries and regions that do not receive Community co-financing for eradication programme | ZT04A | AT, BE, BG, CY, CZ, DK, EE, FI, FR, DE, GR, HU, IE, IT, LV, LT, LU, MT, NL, PL, RO, SK, SI, SE |
| Ovine or Caprine brucellosis | | |
| Ovine or Caprine brucellosis - data on herds - Community co-financed eradication programmes | ZT06A | GR, ES, HR, IT, PT |
| Ovine or Caprine brucellosis - data on animals - Community co-financed eradication programmes | ZT05A | GR, ES, HR, IT, PT |
| Ovine or Caprine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes | ZT07A | GR, ES, HR, IT, PT |
| Ovine or Caprine brucellosis in countries and regions that do not receive Community co-financing for eradication programme | ZT08A | AT, BE, BG, CZ, CY, DK, EE, FI, FR, DE, HU, IE, IT, LV, LT, LU, MT, NL, PL, RO, SK, SI, SE, UK |

(a): Where an MS has regions/provinces with officially different free status, then co-financed and non-co-financed tables can be reported.

6. Food-borne outbreaks data model 2015

6.1. Introduction

This data dictionary provides guidance for reporting on food-borne outbreak (FBO) data under the framework of Directive 2003/99/EC and in accordance with the update of the technical specifications for harmonised reporting of FBOs through the EU reporting system in accordance with Directive 2003/99/EC (EFSA, 2014a). The EFSA data model for FBO tables is summarised in Table 29 and the business rules applied for data validation are presented in Table 30.

6.2. General constraints

6.2.1. Context and uniqueness of information for food-borne outbreak reporting

The data elements Number of outbreaks, Number of human cases, Number of hospitalised, and Number of deaths must be aggregated so that the information reported for the following set of data elements (context) is unique (Table 28).

Table 28: Data elements defining the 'context' for FBOs

| Element Label | Element name | |
|-------------------------------|-------------------------|-------------------------|
| | Strong-evidence FBO | Weak-evidence FBO |
| Reporting year | repYear | repYear |
| Reporting country | repCountry | repCountry |
| Outbreak strength | fboStrengthStrong = 'Y' | fboStrengthStrong = 'N' |
| Causative agent | fboAgent | fboAgent |
| FBO national code | fboCode | fboCode |
| Mixed outbreaks | fboOtherAgents | fboOtherAgents |
| Extent of outbreak | fboType | fboType |
| Food vehicle | fboVehicle | fboVehicle |
| More food vehicle information | fboVehicleInfo | fboVehicleInfo |
| Nature of evidence | fboEvidence | fboEvidence |
| Place of exposure | fboSetting | fboSetting |
| Place of origin of problem | fboPlaceOrigin | fboPlaceOrigin |
| Origin of food vehicle | fboVehicleOrigin | fboVehicleOrigin |
| Contributory factors | fboFactor | fboFactor |

6.3. General information and identification of the isolate

6.3.1. Reporting year (*repYear FBO.01*)

This data element is **mandatory**. It is a numerical data element consisting of four digits. It is the reporting year, which is the year to which reported data refer.

6.3.2. Reporting country (*repCountry FBO.02*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_COUNTRY, domain: D_ALL_repCountry). The list includes the 28 EU MSs, as well as Norway, Switzerland and Iceland.

6.3.3. Language (*lang FBO.03*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_LANG, domain: D_ALL_lang); however, **only the code 'en' for 'English' should be used**, as text in the free text data elements (data elements *FBO.11* More food vehicle information and *FBO.21* Comment) should be provided in English.

6.4. Information about type of food-borne outbreak

6.4.1. Outbreak strength (*fboStrengthStrong FBO.04*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_YESNO) with the only allowed values 'Yes' or 'No'.

'Yes' (code 'Y') indicates reporting on a strong-evidence FBO (= FBO where evidence implicating a particular food vehicle is strong).

'No' (code 'N') indicates reporting on a weak-evidence FBO (= FBO where evidence implicating a particular food vehicle is weak or where no particular food vehicle was identified).

6.4.2. Causative agent group (*fboAgentGroup FBO.05*)

This data element is deprecated, as the collection of weak and strong evidence FBOs has been uniformised. This data element should therefore be left empty.

6.4.3. Causative agent (*fboAgent FBO.06*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_PARAM_ZOO, domain: D_FBO_fboCausativeAgent) and it indicates the causative agent. The causative agent is the agent considered the cause of the FBO(s) and typically the one detected in the persons affected and/or in the implicated food vehicle or in the food chain. The catalogue has four levels which will enable the reporting of different agent species, serovars and serotypes. It is recommended that the causative agent be reported using the most detailed description available.

6.5. Information about the outbreak

6.5.1. FBO national code (*fboCodeFBO.07*)

This data element is **optional**. It is used to include a national code for the FBO as a reference to a national database, if such a code exists. If two independent outbreaks happen to have the same context, this data element must be reported for their distinction.

6.5.2. Mixed outbreaks (*fboOtherAgents FBO.08*)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_PARAM_ZOO, domain: D_FBO_fboCausativeAgent). It is used in addition to the data element Causative agent (*fboAgent FBO.06*) to report other causative agents if more than one have been identified within the same outbreak. In order to report more than one 'other agent', use a comma-separated list of codes (without spacing) up to a maximum of 15 codes. For example, 'RF-00000054-MCG,RF-00000061-MCG'.

6.5.3. Extent of outbreak (*fboType FBO.09*)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_OUTBRK). The catalogue includes the terms 'General' (code 'TB01A') and 'Household' (code 'TB02A') in order to distinguish between these types of outbreaks. If this information is not available, the value 'Unknown' (code 'TB03A') can be reported.

6.5.4. Food vehicle (*fboVehicle FBO.10*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_FOODVH). This list covers the food vehicle categories, e.g. 'Eggs and egg products' (code 'B09647B').

6.5.5. More food vehicle information (*fboVehicleInfo FBO.11*)

This data element is **optional**. It is a free text data element for a maximum of 2,000 alphanumeric characters and can be used to give more detailed information on the food vehicle (for example 'salad of raw carrots'). It should be completed in English (see data element *FBO.03* Language).

6.5.6. Nature of evidence (*fboEvidence FBO.12*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_EVDNC). It is used to indicate the nature of the evidence supporting the FBO. For FBOs where more than one type of evidence was observed, all relevant evidence types should be reported as a comma-separated list of codes (without spacing). The value 'Unknown' (code 'TB03A') can be reported for only weak-evidence FBOs.

6.5.7. Place of exposure (*fboSetting FBO.13*)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_SMPNT, domain: D_FBO_fboSetting). The setting is the place of exposure to the implicated food which can be the location where the food was consumed or where the final stages of preparation of the suspect food took place, e.g. 'Take-away or fast-food outlet' (code 'E930A').

6.5.8. Place of origin of problem (*fboPlaceOrigin FBO.14*)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_SMPNT, domain: D_FBO_fboPlaceOrigin). The place of origin of the problem is the place, other than the setting, where the mishandling of the food took place and/or where the contamination occurred. More than one value (up to all values in the catalogue) can be chosen from the catalogue and reported as a comma-separated list of codes (without spacing).

6.5.9. Origin of food vehicle (*fboVehicleOrigin FBO.15*)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_COUNTRY, domain: D_FBO_fboVehicleOrigin). It indicates the country from which the food vehicle originated.

6.5.10. Contributory factors (*fboFactor FBO.16*)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_CONFACT). Contributory factors may include deficiencies in food handling or the use of contaminated material. More than one value (up to all values from the catalogue) can be reported as a comma-separated list of codes (without spacing).

6.5.11. Number of outbreaks (*numOutbreaks FBO.17*)

This data element is **mandatory**. It is a numerical integer data element. It is the number of outbreaks sharing the same set of context data elements (see Section 6.2.1).

6.5.12. Number of human cases (*numHumanCases FBO.18*)

This data element is **mandatory**. It is a numerical integer data element. It indicates the number of human cases involved in the FBO(s) as defined by the investigators. If this number is unknown, '-1' can be reported.

6.5.13. Number of hospitalised (*numHospitalised FBO.19*)

This data element is **mandatory**. It is a numerical integer data element. It indicates the number of hospitalised human cases defined as admission to hospital with illness due to the causative agent including at least one over-night stay. If this number is unknown, '-1' can be reported.

6.5.14. Number of deaths (*numDeaths FBO.20*)

This data element is **mandatory**. It is a numerical integer data element. It indicates the number of humans who died as a result of the FBO(s). Only deaths attributable to the causative agent that has been identified as responsible for the outbreak(s) should be reported. If this number is unknown, '-1' can be reported.

6.6. Additional information

6.6.1. Comment (*resComm FBO.21*)

This data element is **optional**. It is a free text element of a maximum of 2,000 alphanumeric characters. This is an additional comment for the row and should be completed in English (see data element *FBO.03* Language).

Table 29: EFSA data model for food-borne outbreak data reporting

| Element code | Element label | Element name (for XML/Excel transfer) | Type | Constraint | Catalogue | Domain |
|--------------|-------------------------------|---------------------------------------|-----------------|------------|-------------------|-------------------------|
| FBO.01 | Reporting year | repYear | xs:integer(4) | Mandatory | | |
| FBO.02 | Reporting country | repCountry | xs:string(2) | Mandatory | ZOO_CAT_COUNTRY | D_ALL_repCountry |
| FBO.03 | Language | lang | xs:string(2) | Mandatory | ZOO_CAT_LANG | D_ALL_lang |
| FBO.04 | Outbreak strength | fboStrengthStrong | xs:string(1) | Mandatory | ZOO_CAT_YESNO | |
| FBO.05 | Causative agent group | fboAgentGroup | | | | |
| FBO.06 | Causative agent | fboAgent | xs:string(15) | Mandatory | ZOO_CAT_PARAM_ZOO | D_FBO_fboCausativeAgent |
| FBO.07 | FBO national code | fboCode | xs:string(100) | Optional | | |
| FBO.08 | Mixed outbreaks | fboOtherAgents | xs:string(250) | Optional | ZOO_CAT_PARAM_ZOO | D_FBO_fboCausativeAgent |
| FBO.09 | Extent of outbreak | fboType | xs:string(5) | Optional | ZOO_CAT_OUTBRK | |
| FBO.10 | Food vehicle | fboVehicle | xs:string(7) | Mandatory | ZOO_CAT_FOODVH | |
| FBO.11 | More food vehicle information | fboVehicleInfo | xs:string(2000) | Optional | | |
| FBO.12 | Nature of evidence | fboEvidence | xs:string(250) | Mandatory | ZOO_CAT_EVDNC | |
| FBO.13 | Place of exposure | fboSetting | xs:string(5) | Optional | ZOO_CAT_SMPNT | D_FBO_fboSetting |
| FBO.14 | Place of origin of problem | fboPlaceOrigin | xs:string(250) | Optional | ZOO_CAT_SMPNT | D_FBO_fboPlaceOrigin |
| FBO.15 | Origin of food vehicle | fboVehicleOrigin | xs:string(2) | Optional | ZOO_CAT_COUNTRY | D_FBO_fboVehicleOrigin |
| FBO.16 | Contributory factors | fboFactor | xs:string(250) | Optional | ZOO_CAT_CONFACT | |
| FBO.17 | Number of outbreaks | numOutbreaks | xs:integer(10) | Mandatory | | |
| FBO.18 | Number of human cases | numHumanCases | xs:integer(10) | Mandatory | | |
| FBO.19 | Number of hospitalised | numHospitalised | xs:integer(10) | Mandatory | | |
| FBO.20 | Number of deaths | numDeaths | xs:integer(10) | Mandatory | | |
| FBO.21 | Comment | resComm | xs:string(2000) | Optional | | |

Table 30: EFSA business rules for food-borne outbreak data reporting

| Element code | Element name | Error type | Error code | Rule |
|--|---|------------|------------|---|
| FBO.01 | repYear | E | FBO01 | The value in repYear must be the same as the data collection reporting year |
| FBO.03 | lang | W | FBO02 | WARNING. The value in lang should be 'English' ('en') |
| FBO.06 | fboAgent | E | FBO03 | A value in fboAgent must be reported |
| FBO.10 | fboVehicle | E | FBO05 | A value in fboVehicle must be reported |
| FBO.12 | fboEvidence | E | FBO06 | A value in fboEvidence must be reported |
| FBO.12 | fboEvidence | E | FBO13 | If fboStrengthStrong is 'Yes' ('Y'), then the value can not be 'Unknown'('EV07A') |
| FBO.17 | numOutbreaks | E | FBO07 | The value in numOutbreaks must be greater than '0' |
| FBO.17 & FBO.18 & FBO.19 & FBO.20 | numOutbreaks & numHumanCases & numHospitalised & numDeaths | E | FBO27 | The combination of values in repYear, repCountry, fboAgent, fboCode, fboOtherAgents, fboType, fboVehicle, fboVehicleInfo, fboEvidence, fboSetting, fboPlaceOrigin, fboVehicleOrigin, and fboFactor must be unique (the numbers in numOutbreaks, numHumanCases, numHospitalised, and numDeaths must be aggregated accordingly) |
| FBO.18 | numHumanCases | E | FBO08 | The value in numHumanCases must be equal to '-1' or greater or equal than '2' |
| FBO.19 | numHospitalised | E | FBO09 | The value in numHospitalised must be greater than or equal to '-1' |
| FBO.19 | numHospitalised | E | FBO11 | The value in numHospitalised must be less than or equal to the value in numHumanCases |
| FBO.20 | numDeaths | E | FBO10 | The value in numDeaths must be greater than or equal to '-1' |
| FBO.20 | numDeaths | E | FBO12 | The value in numDeaths must be less than or equal to the value in numHumanCases |

7. Prevalence data model 2015

7.1. Introduction

This data dictionary provides guidance for reporting on aggregated prevalence data on zoonoses and food-borne pathogens in food, animals and feed under the framework of Directive 2003/99/EC. The objective is to explain in detail the individual data elements that are included in the EFSA data model to be used for the XML transmission of aggregated prevalence data through the DCF. The EFSA data model for prevalence tables is summarised in Table 35 and the business rules applied for data validation are presented in Table 36. Refer to Table 37 to Table 40 for examples on how to report prevalence data using the provided data model described in these guidelines.

7.2. General constraints

7.2.1. Context for aggregated data elements

For prevalence data, the set of data elements shown in Table 31 defines the so-called 'context', that is the set of information that represents an aggregated sample. Aggregated data elements refer to this set of information and need to be the same for each record sharing the same 'context' (Table 32).

Table 31: List of data elements defining the 'context'

| Element label | Element name |
|---------------------------|---------------------|
| Reporting year | repYear |
| Reporting country | repCountry |
| Zoonotic agent at Level 1 | zoonosis at Level 1 |
| Matrix | matrix |
| Sampling stage | sampStage |
| Sample origin | sampOrig |
| Sample type | sampType |
| Sampling context | sampContext |
| Sampler | sampler |
| Sampling strategy | progSampStrategy |
| Sampling details | sampDetails |
| Area of sampling | sampArea |
| Sampling unit | sampUnit |
| Sample weight | sampWeight |
| Sample weight unit | sampWeightUnit |
| Source of information | sourceInfo |
| Target verification | target |
| Vaccination status | vaccination |
| Analytical method | anMethCode |

Table 32: Aggregate data elements that must have the same value for each record sharing the same 'context'

| Element label | Element name |
|--|------------------|
| Number of flocks under control programme | contrFlocks |
| Number of clinically affected herds | affectHerds |
| Total units tested | totUnitsTested |
| Total units positive | totUnitsPositive |

For example, when reporting results for *Salmonella* (e.g. results for different serovars), the Total units tested and Total units positive represent the total units tested and positive for *Salmonella*, while the Units Positive data element (unitsPositive) will be used to express the number of units positive to the specific serovar (Table 37). It is possible that the same sample will test positive for more than one zoonotic agent species (zoonosis level 2); in this case, the positivity must be counted only once, when

reporting the Total units positive (Table 37 example on *Gallus gallus* (fowl) - breeding flocks test results).

Duplicated records are not allowed for the same 'context'; this means that all sampling results (listed in Table 32) need to be aggregated by the set of data elements listed in Table 31 with the following exceptions presented in Table 33.

There is an exception to this definition of the context applied to *Listeria monocytogenes*, *Escherichia coli*, pathogenic - Verotoxigenic *E. coli* (VTEC); and *Staphylococcus* - *S. aureus*, meticillin resistant (MRSA) that affects the meaning of the following aggregated data elements:

- Total units tested (totUnitsTested)
- Total units positive (totUnitsPositive)

For *Listeria monocytogenes*, *Escherichia coli*, pathogenic - Verotoxigenic *E. coli* (VTEC) and *Staphylococcus* - *S. aureus*, meticillin resistant (MRSA) the context is defined using level 2 of the zoonotic agent and all aggregated data elements refer to this level. This means that the Total units tested and the Total units positive represent the number of units tested and positive, respectively, for *Listeria monocytogenes*; for *Escherichia coli*, pathogenic - Verotoxigenic *E. coli* (VTEC) and for *Staphylococcus* - *S. aureus*, meticillin resistant (MRSA) (Table 38).

In addition, for *Listeria monocytogenes*, the analytical method (*anMethCode*), the quantity (*quantity*) and the sample weight (*sampWeight*) are not part of the context. Thus, the Total units tested (*totUnitsTested*) represents the number of all units tested for *Listeria monocytogenes* with the same context, regardless of whether the units were tested with a detection method or an enumeration or with both methods. The Total units positive (*totUnitsPositive*) represents the number of all units tested for *Listeria monocytogenes* with the same context that was considered positive. The Units tested (*unitsTested*) expresses the number of units tested by the specified method (either detection or enumeration method). Accordingly, the Units positive (*unitsPositive*) expresses the number of units tested as positive for *Listeria monocytogenes* by the specified analytical method (Table 38).

Table 33: List of data elements defining the 'context' for specific pathogens and affecting the meaning of the aggregated data elements Total units tested (totUnitsTested) and Total units positive (totUnitsPositive)

| Element label Most zoonotic agents (Table 31) | Element label <i>Listeria monocytogenes</i> | Element label VTEC - MRSA | Element label Histamine |
|---|--|-------------------------------------|-------------------------------------|
| Reporting year | Reporting year | Reporting year | Reporting year |
| Reporting country | Reporting country | Reporting country | Reporting country |
| Zoonotic agent at Level 1 | Zoonotic agent at Level 2 | Zoonotic agent at Level 2 | Zoonotic agent at Level 1 |
| Matrix | Matrix | Matrix | Matrix |
| Sampling stage | Sampling stage | Sampling stage | Sampling stage |
| Sample origin | Sample origin | Sample origin | Sample origin |
| Sample type | Sample type | Sample type | Sample type |
| Sampling context | Sampling context | Sampling context | Sampling context |
| Sampler | Sampler | Sampler | Sampler |
| Sampling strategy | Sampling strategy | Sampling strategy | Sampling strategy |
| Sampling details | Sampling details | Sampling details | Sampling details |
| Area of sampling | Area of sampling | Area of sampling | Area of sampling |
| Sampling unit | Sampling unit | Sampling unit | Sampling unit |
| Sample weight | | Sample weight | Sample weight |
| Sample weight unit | Sample weight unit | Sample weight unit | Sample weight unit |
| Source of information | Source of information | Source of information | Source of information |
| Target verification | | | |
| Vaccination status | | | |
| Analytical method | | Analytical method | Analytical method |

7.2.2. Reporting units positive at different levels of detail (zoonosis level 2 and above)

As mentioned previously, the *unitsPositive* data element is used to report the number of units positive for the serovar reported in the current row. Only the *unitsPositive* of the most detailed typing level needs to be reported. The same positive units should not be reported also at the parent level (i.e. no double reporting).

The units positive for *S. Enteritidis* for *Gallus gallus* (fowl) - laying hens - adult in Table 37 will be calculated by summing the units positive for the zoonosis level 2 *Salmonella* - *S. Enteritidis* (1 unit) and the zoonosis level 3 *Salmonella* - *S. Enteritidis* - PT 12 (2 units), thus the result will be equal to 3 units.

7.2.3. Reporting data at various levels of the *matrix* and *sampArea* data elements

Sample aggregated results reported for a detailed matrix (e.g. *Gallus gallus* (fowl) - laying hens - adult) should not be reported again in the figures at the parent level of the matrix (e.g. *Gallus gallus*), as this will result in so-called 'double reporting'.

However, if reporting regional data (records for which a region is specified in the data element Area of sampling (*sampArea*)), an additional row should be reported with the total for the country, and all the other data elements of the context should have the same value as for the regional data. To report data at the country level, the *sampArea* data element shall be left empty.

7.2.4. Comparison with the Zoonoses Web Application

The three figures below (Figures 3 to 5) show how the data elements in the Prevalence data model are linked to the tables in the Zoonoses Web Application. Special attention should be given to identifying which values (represented as upper case letters) must be repeated in all rows sharing the same context in the DCF. For simplification, in the following examples, the context is indicated by only the *matrix* data element (although it includes other data elements such as Sampling stage, Sampling context, Sampler, etc., as described in Section 7.2.1).

| Samonella | | | | | DCF | | | | | | | |
|-----------|--------------------|---|-----------------------|-----------------------|-----------------------|--------|----------------|------------------|------------|-------------|----------|---------------|
| ZooWebApp | | | | | | | | | | | | |
| Matrix | Total units tested | Total units positive for <i>Salmonella</i> spp. | <i>S. Enteritidis</i> | <i>S. Typhimurium</i> | zoonosis | matrix | totUnitsTested | totUnitsPositive | anMethCode | unitsTested | quantity | unitsPositive |
| M | A | B | C | D | <i>S. Enteritidis</i> | M | A | B | | | | C |
| | | | | | <i>S. Typhimurium</i> | M | A | B | | | | D |

Figure 3: Comparison between the web-based reporting tables and the data model for prevalence data on *Salmonella*

Listeria monocytogenes

| ZooWebApp | | | | | | | DCF | | | | | | | | |
|-----------|--------------------|--|------------------------------------|---|--------------------------------------|--|------------------------------------|------------------|--------|----------------|------------------|-------------|-------------|----------|---------------|
| Matrix | Total units tested | Total units positive for <i>L. monocytogenes</i> | Units tested with detection method | <i>L. monocytogenes</i> presence in x g | Units tested with enumeration method | <i>L. monocytogenes</i> >detection limit but <=100 cfu/g | <i>L. monocytogenes</i> >100 cfu/g | zoonosis | matrix | totUnitsTested | totUnitsPositive | anMethCode | unitsTested | quantity | unitsPositive |
| M | A | B | C | D | E | F | G | L. monocytogenes | M | A | B | detection | C | | D |
| | | | | | | | | L. monocytogenes | M | A | B | enumeration | E | <= 100 | F |
| | | | | | | | | L. monocytogenes | M | A | B | enumeration | E | > 100 | G |

Figure 4: Comparison between the web-based reporting tables and the data model for prevalence data on *Listeria* in food

| ZooWebApp | | | | | | | DCF | | | | | | | |
|-----------|--------------------|-------------------------------|-------------|----------------------|----------------------|-------------|-----------|--------|----------------|------------------|------------|-------------|----------------|---------------|
| Matrix | Total units tested | Total units in non-conformity | <=100 mg/kg | > 100 to <=200 mg/kg | > 200 to <=400 mg/kg | > 400 mg/kg | zoonosis | matrix | totUnitsTested | totUnitsPositive | anMethCode | unitsTested | quantity | unitsPositive |
| M1 | A | B | C | D | E | n.a. | Histamine | | A | B | HPLC | | <=100 | C |
| | | | | | | | Histamine | | A | B | HPLC | | > 100 to <=200 | D |
| | | | | | | | Histamine | | A | B | HPLC | | > 200 | E |
| M2 | F | G | n.a. | H | I | J | Histamine | | F | G | HPLC | | <=200 | H |
| | | | | | | | Histamine | | F | G | HPLC | | > 200 to <=400 | I |
| | | | | | | | Histamine | | F | G | HPLC | | > 400 | J |

M1: Fish - Fishery products from fish species associated with a high amount of histidine - not enzyme matured
M2: Fish - Fishery products which have undergone enzyme maturation treatment in brine
na: not applicable

Figure 5: Comparison between the web-based reporting tables and the data model for prevalence data on histamine in food

7.2.5. Reporting VTEC and MRSA using facets

VTEC

The list of Verotoxigenic *Escherichia coli* (VTEC) has been revised and reorganized.

The new classification is based on O antigens and taking into account the more frequent detected ones (O26 O103 O111 O145 O157):

- RF-0000132-MCG - Verotoxigenic *E. coli* (VTEC)
- RF-0000202-MCG - VTEC O157
- RF-0000193-MCG - VTEC non-O157
- RF-0000139-MCG - VTEC O26
- RF-0000175-MCG - VTEC O103
- RF-0000182-MCG - VTEC O111
- RF-0000155-MCG - VTEC O145

RF-00003228-PAR - VTEC other than (O157 O26 O103 O111 O145)

RF-00000191-MCG - VTEC O1

RF-00000145-MCG - VTEC O2

RF-00003229-PAR - VTEC O3

...all others O antigens...

Three facets have been defined based on H antigen (antH), verotoxin pheno-genotyping (vt) and adhesion genes(ag).

The facet antH: should be used for reporting the H antigen.

Possible values are:

| code | antigenH |
|-------|----------|
| P000H | H- |
| P001H | H1 |
| P002H | H2 |
| P003H | H3 |
| P004H | H4 |
| P005H | H5 |
| P006H | H6 |
| P007H | H7 |
| P008H | H8 |
| P009H | H9 |
| P010H | H10 |
| P011H | H11 |
| P012H | H12 |
| P014H | H14 |
| P015H | H15 |
| P016H | H16 |
| P017H | H17 |
| P018H | H18 |
| P019H | H19 |
| P020H | H20 |
| P021H | H21 |
| P023H | H23 |
| P024H | H24 |
| P025H | H25 |
| P026H | H26 |
| P027H | H27 |
| P028H | H28 |
| P029H | H29 |

| P030H | H30 |
|-------|----------|
| code | antigenH |
| P031H | H31 |
| P032H | H32 |
| P033H | H33 |
| P034H | H34 |
| P035H | H35 |
| P036H | H36 |
| P037H | H37 |
| P038H | H38 |
| P039H | H39 |
| P040H | H40 |
| P041H | H41 |
| P042H | H42 |
| P043H | H43 |
| P044H | H44 |
| P045H | H45 |
| P046H | H46 |
| P047H | H47 |
| P048H | H48 |
| P049H | H49 |
| P051H | H51 |
| P052H | H52 |
| P053H | H53 |
| P054H | H54 |
| P055H | H55 |
| P056H | H56 |
| PX01H | Unknown |
| PX02H | HNT |
| PX03H | Hrough |

For example: VTEC O157:H16 can be provided as RF-00000202-MCG#antH=P016H, where RF-00000202-MCG stands for 'VTEC O157' antH=P016H stands for 'H16'

The facet vt: should be used for reporting verotoxin pheno-genotyping.

Possible values are:

| code | verotoxin pheno-genotyping |
|-------|--|
| P001V | Verotoxin production not applicable |
| P002V | Verotoxin production, toxin type unknown |
| P003V | Verotoxin production, VT1 |

| code | verotoxin pheno-genotyping |
|-------|---|
| P004V | VT1, gene identified, subtype unspecified |
| P005V | VT1a |
| P007V | VT1c |
| P008V | VT1d |
| P009V | Verotoxin production, VT2 |
| P010V | VT2, gene identified, subtype unspecified |
| P011V | VT2a |
| P012V | VT2b |
| P014V | VT2c |
| P015V | VT2e |
| P016V | VT2f |

For example 'VTEC O157:H16 vt1 positive vt2 negative' can be provided as:

- RF-00000202-MCG#antH=P016H\$vt=P003V if the toxin has been detected through a phenotyping method or
- RF-00000202-MCG#antH=P016H\$vt=P004V if the toxin has been detected through a genotyping method

It is possible also to report subtypes of the genes if they have been detected:

RF-00000202-MCG#antH=P007H\$vt=P005V\$vt=P011V\$vt=P012V translates into 'VTEC O157:H7 vt1a vt2b vt2c'

If the method to assess the production of the verotoxin is unknown, the value P002V shall be used: RF-00000202-MCG#antH=P006H\$vt=P002V translates into 'VTEC O157:H6 Verotoxin production, toxin type unknown'

The facet ag: should be used for reporting adhesion genes.

Possible values:

| code | adhesion genes |
|-------|---|
| P001A | Adhesion genes investigation not applicable |
| P002A | Adhesion genes investigation not reported |
| P003A | Adhesion genes not investigated |
| P004A | eae positive |
| P005A | Entero-aggregative adhesion genes positive |
| P006A | aatA positive |
| P007A | aggR positive |
| P008A | aaiC positive |
| P009A | eae negative |
| P010A | Entero-aggregative adhesion genes negative |

In case the data provider does not know if the adhesion genes have been investigated, the value 'P002A' shall be used:

RF-00000202-MCG#antH=P007H\$vt=P005V\$vt=P011V\$vt=P012V\$ag=P002A translates into 'VTEC O157:H7 vt1a vt2b vt2c adhesion genes not reported'.

In case the data provider knows that the adhesion genes have not been investigated, the value 'P003A' shall be used:

RF-00000202-MCG#antH=P007H\$vt=P005V\$vt=P011V\$vt=P012V\$ag=P003A translates into 'VTEC O157:H7 vt1a vt2b vt2c adhesion genes not investigated'.

MRSA

Thousands combinations of spa-types (STs), multi locus sequence types (MLSTs) and Clonal Complex (CC) are possible and also for the MRSA terms the use of facets have been introduced:

t: spa-type

ST: multi locus sequence (MLST)

CC: clonal complex

For example: MRSA, spa-type t007 CC30 ST39 can be reported as

RF-00003853-MCG#t=7\$CC=30\$ST=39, where RF-00003853-MCG is the code of the base term *Staphylococcus aureus*, methicillin resistant (MRSA)

7.3. General information and identification of the sample

7.3.1. Reporting year (*repYear PRV.01*)

This data element is **mandatory**. It is a numerical data element consisting of four digits. It is the reporting year, which is the year to which reported data refer.

7.3.2. Reporting country (*repCountry PRV.02*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_COUNTRY, domain: D_ALL_repCountry). The list includes the 28 EU MSs, as well as Norway, Switzerland and Iceland.

7.3.3. Language (*lang PRV.03*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_LANG, domain: D_ALL_lang); however, **only the code 'en' for 'English' should be used**, as text in the free text data elements (data elements PRV.12 Sampling details, PRV.17 Source of information and PRV.27 Comment) should be provided in English.

7.3.4. Zoonotic agent (*zoonosis PRV.04*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_PARAM_ZOO, domain: D_PRV_zoonosis). It allows for the reporting on, for example, the following zoonoses, zoonotic agents and food-borne pathogens:

- *Brucella*
- *Campylobacter*
- *Echinococcus*
- *Listeria*
- *Salmonella*
- *Trichinella*
- *Mycobacteria*
- Verotoxigenic *Escherichia coli*
- *Yersinia*
- *Toxoplasma*
- *Coxiella*
- Rabies
- West Nile virus
- *Staphylococcus - S. aureus*, methicillin-resistant (MRSA)

- Histamine
- *Cronobacter*

However, the catalogue contains a number of other zoonotic or food-borne agents enabling reporting on them as well.

This catalogue allows reporting at different speciation levels (agent species, serovars/serotypes, phagetypes and virulence factors).

When there is no positive finding, the reporting can be made at zoonosis level 1.

When reporting positive findings for a zoonotic agent (e.g. *Salmonella*), level 2 or higher of the catalogue needs to be reported (e.g. *Salmonella* - *S. Enteritidis*). If the level 2 was not determined then the generic unspecified level 2 term should be used (e.g. *Salmonella* - *Salmonella* spp., unspecified).

An exception to this applies to those zoonoses where further speciation levels are not available (e.g. Histamine, Rotavirus, Astrovirus, etc.). In this case, positive findings will also be reported at zoonosis level 1.

Please refer to Section 7.2 for a description on how to report different levels of speciation for the same zoonotic agent.

The reporting of the zoonotic agent has been amended for VTEC. The following options are now available to report information on the zootic agent:

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

Algorithm for reporting VTEC serogroup detection at the Zoonosis L3 level

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

As a consequence of the above changes for VTEC:

- Please note that the intended double reporting is no longer required/allowed for VTEC. The results for VTEC should be reported only once.

- The VTEC, NT (Non Typeable) value are not accepted. This information strongly depends on the panel of serotyping reagents available in the laboratories. As a result, the information provided by the MSs with this value is not homogeneous and cannot be analysed, because its merging would be meaningless.

Reporting countries are strongly encouraged to submit information on the presence of virulence genes in the VTEC strains using the Zoonosis level 3 term.

7.3.5. Matrix (*matrix PRV.05*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_MATRIX, domain: D_PRV_matrix). It represents specific detail on the food, animal species or feed category reported on. In addition, more detailed breakdown information is included at levels 2–4, such as the type of animals (wild, farmed, pet), production category (breeding, fattening animals), subcategory of food (minced meat, hard cheese) and type of food (frozen, ready-to-eat, etc.). It is recommended that relevant animal, food or feed subcategories (corresponding to level 2, 3 and 4 terms) are selected, as far as the available information makes this possible and as enabled by the detailed catalogue. For example: '*Gallus gallus* (fowl) - laying hens' (code 'A031741A'); 'Cattle (bovine animals) - calves (under 1 year) - veal calves' (code 'A004721A'), 'Milk, goats' - raw milk (code 'A001821A').

Please note that, for *Listeria monocytogenes* in food, information should be reported at least at level 3 of the matrices. For information provided at level 3 of the matrices tested for **Listeria it is important to clarify if a matrix can be considered 'ready-to-eat' or not**. This information will be used to build the *Listeria* tables, where only ready-to-eat food categories are included.

Please see the specific requirements for data reporting on *Trichinella* and on *Salmonella* in pig carcasses from the 'Manual for reporting on zoonoses, zoonotic agents in the framework of Directive 2003/99/EC and on some other pathogenic microbiological agents for information derived from the year 2014' (EFSA, 2015a) (based on Regulation (EU) No 1375/2015⁷ and Regulation (EU) No 218/2014⁸).

7.4. Information about the sampling

7.4.1. Sampling stage (*sampStage PRV.06*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SMPNT, domain: D_PRV_sampStage). The sampling stage is the stage along the food chain where the sample has been collected, e.g. 'Farm' (code 'E101A'), 'Slaughterhouse' (code 'E311A'), 'Retail' (code 'E520A') or 'Unknown' (code 'E980A').

7.4.2. Sample origin (*sampOrig PRV.07*)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_COUNTRY, domain: D_PRV_sampOrig). Sample origin is used to indicate the country of origin of the animal, food or feed sampled (ISO 3166-1-alpha-2 country code).

7.4.3. Sample type (*sampType PRV.08*)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_SMPTYP). It describes the type of sample (specimen) taken for the analyses, e.g. 'animal sample - nasal swab' (code 'S015A'), 'food sample - carcass swabs' (code 'S021A').

7.4.4. Sampling context (*sampContext PRV.09*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SRCTYP, domain: D_ALL_sampContext). It identifies the type of programme in the framework of which samples have been collected. It is possible to distinguish between different types of sampling schemes used,

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

⁸ Commission Regulation (EU) No 218/2014 of 7 March 2014 amending Annexes to Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council and Commission Regulation (EC) No 2074/2005. OJ L 69, 8.3.2014, p. 95–98.

e.g. 'Surveillance' (code 'K026A'), 'Monitoring - EFSA specifications' (code 'K025A'), 'Survey - national survey' (code 'K028A'). In the case of clinical examinations of animals, the item 'Clinical investigations' (code 'K020A') has to be used. Reporting of the sampling context is recommended to enable the correct interpretation of the data reported. If not known, the term 'unspecified' (code 'K029A') is available. Refer to Table 34 for more details about the sampling context which could be reported for the samples tested according Regulation (EU) No 218/2014.

7.4.5. Sampler (*sampler PRV.10*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SMPLR). It indicates the type of body that performed the sampling, e.g. 'Industry sampling' (code 'CX01A'), 'Official sampling' (code 'CX02A') or 'not applicable' (code 'CX99A'). Refer to Table 34 for more details about the sampler which could be reported for the samples tested according Regulation (EU) No 218/2014.

Table 34: Requirements for samples tested according Regulation (EU) No 218/2014

| Zoonoses | Matrix | Specification | Sampling context | Sampler |
|------------------------|--------------------------------------|--|--|--|
| Salmonella spp. | Meat from pig – carcass ('A004161A') | Official sampling using the same method and sampling area as food business operators. At least 49 ^(a) random samples shall be taken in each slaughterhouse each year. This number of samples may be reduced in small slaughterhouses based on a risk evaluation. | Control and eradication programmes (K021A) | Official, based on Regulation 218/2014 (CX06A) |
| | | Information on the total number and the number of <i>Salmonella</i> -positive samples taken by food business operators in accordance with Article 5(5) of Regulation (EC) No 2073/2005, within the frame of point 2.1.4 of Annex I thereof. | Control and eradication programmes (K021A) | HACCP and own checks (CX04A) |
| | | Information on the total number and the number of <i>Salmonella</i> -positive samples taken within the frame of national control programmes in MSs or regions of MSs for which special guarantees have been approved in accordance with Article 8 of Regulation (EC) No 853/2004 as regards pork production. | Control and eradication programmes (K021A) | Official sampling (CX02A) |

(a): If all negative, 95 % statistical certainty is provided that the prevalence is below 6 %.

7.4.6. Sampling strategy (*progSampStrategy PRV.11*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_SAMPSTR). It is the sampling strategy performed in the programme or project identified by Programme code, e.g. 'Objective sampling' (code 'ST10A'), 'Census' (code 'ST50A'). Reporting of the sampling strategy is necessary to enable evaluation of the representativeness of the data. If not known, the term 'unspecified' (code 'STXXA') is available.

7.4.7. Sampling details (*sampDetails PRV.12*)

This data element is **optional**. This is a free text element of a maximum of 2,000 alphanumeric characters. It can be used, when needed, to give more information on the sampling stage or context. It should be completed in English (see data element *PRV.03* Language).

7.4.8. Area of sampling (*sampArea PRV.13*)

This data element is **strongly recommended** when reporting data on rabies, *Echinococcus* and West Nile virus.

It contains codes linked to a catalogue (ZOO_CAT_NUTS). It indicates the area, region or province of the sampling in which the animal/food/feed sample has been collected according to the NUTS coding system.

When reporting regional data, it is mandatory to report, in addition (i.e. intended double reporting), **the total for the country** either by reporting the code corresponding to the whole country (i.e. the country code consisting of only two letters) or by leaving this data element empty.

7.4.9. Sampling unit (*sampUnit PRV.14*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_UNIT, domain: D_PRV_sampUnit). The sampling unit refers to the unit considered positive, upon a positive result. For food and feed, the terms 'single (food/feed)' (code 'G203A') and 'batch (food/feed)' (code 'G204A') are used. For animals, the sampling unit may be 'animal' (code 'G199A'), 'herd/flock' (code 'G202A'), 'holding' (code 'G198A') or 'slaughter batch' (code 'G200A').

7.4.10. Source of information (*sourceInfo PRV.17*)

This data element is **optional**. This is a free text element of a maximum of 2,000 alphanumeric characters. It is the source of the provided data, whether it is an institute, laboratory or other organisation. It should be completed in English (see data element *PRV.03* Language).

7.5. Information about the herd/flock

7.5.1. Target verification (*target PRV.18*)

This data element is **mandatory** when reporting data on *Salmonella* in the following animals:

- `Gallus gallus` (fowl) - breeding flocks for broiler production line - adult' ('A041001A');
- `Gallus gallus` (fowl) - breeding flocks for egg production line - adult' ('A041019A');
- `Gallus gallus` (fowl) - breeding flocks, unspecified - adult' ('A041021A');
- `Gallus gallus` (fowl) - broilers - before slaughter' ('A000041A');
- `Gallus gallus` (fowl) - elite breeding flocks for broiler production line - adult' ('A041004A');
- `Gallus gallus` (fowl) - elite breeding flocks for egg production line - adult' ('A041022A');
- `Gallus gallus` (fowl) - elite breeding flocks, unspecified - adult' ('A041024A');
- `Gallus gallus` (fowl) - grandparent breeding flocks for broiler production line - adult' ('A041005A');
- `Gallus gallus` (fowl) - grandparent breeding flocks for egg production line - adult' ('A041025A');
- `Gallus gallus` (fowl) - grandparent breeding flocks, unspecified - adult' ('A041027A');
- `Gallus gallus` (fowl) - laying hens - adult' ('A041031A');
- `Gallus gallus` (fowl) - parent breeding flocks for broiler production line - adult' ('A041006A');
- `Gallus gallus` (fowl) - parent breeding flocks for egg production line - adult' ('A041028A');
- `Gallus gallus` (fowl) - parent breeding flocks, unspecified - adult' ('A041030A');
- `Turkeys` - breeding flocks, unspecified - adult' ('A041033A');
- `Turkeys` - elite breeding flocks - adult' ('A041034A');
- `Turkeys` - grandparent breeding flocks - adult' ('A041035A');
- `Turkeys` - parent breeding flocks - adult' ('A041036A');
- `Turkeys` - fattening flocks - before slaughter' ('A041278A').

For all data other than for *Salmonella* in the matrix categories cited above, the target verification data element should not be reported.

It contains codes linked to a catalogue with values 'Yes' (code 'Y'), 'No' (code 'N') and 'Unknown' (code 'U') (ZOO_CAT_YESNO, domain D_PRV_target). Target verification is used to indicate which

information is to be used for the purpose of verifying if the EU *Salmonella* reduction targets set by Commission Regulation (EC) No 200/2010⁹ for breeding flocks, Commission Regulation (EC) No 517/2011¹⁰ for laying hen flocks of *Gallus gallus*, Commission Regulation (EC) No 200/2012¹¹ for broiler flocks of *Gallus gallus* and Commission Regulation (EC) No 1190/2012¹² for turkey flocks have been met.

7.5.2. Number of flocks under control programme (*contrFlocks PRV.19*)

This data element is **mandatory when** the data element **Target verification (*target PRV.18*) is reported** and should be left empty in all other cases. This is a numerical data element. It is the number of flocks under the *Salmonella* control programme. For other zoonoses or animal species for which the target verification is not mandatory, the number of flocks under the control programme data element should not be reported.

7.5.3. Number of clinically affected herds (*affectHerds PRV.20*)

This data element is **mandatory when** reporting on ***Coxiella (Q fever) in animals*** and should be left empty when reporting on other zoonoses. This is a numerical data element. It is used to indicate the number of clinically affected herds fulfilling the definitions given in the report on 'Development of harmonised schemes for the monitoring and reporting of Q-fever in animals in the European Union' (Sidi-Boumedine et al., 2010). For zoonoses other than Q fever, the data element number of clinically affected herds should not be reported.

7.5.4. Vaccination status (*vaccination PRV.29*)

This data element is **mandatory when** reporting on **West Nile Virus in animals** and should be left empty when reporting on other zoonoses. It contains codes linked to a catalogue with values 'Yes' (code 'Y'), 'No' (code 'N') and 'Unknown' (code 'U') (ZOO_CAT_YESNO, domain D_PRV_vacc). It is used to indicate the vaccination status of animals tested.

7.6. Information about the result

7.6.1. Total units tested (*totUnitsTested PRV.21*)

This data element is **mandatory**. This is a numerical data element. It is the total number of units tested of the specified context for the selected zoonotic agent at level 1 (e.g. *Salmonella*, *Campylobacter*). For *Listeria monocytogenes*, *Escherichia coli*, pathogenic - Verotoxigenic *E. coli* (VTEC); and *Staphylococcus - S. aureus*, meticillin resistant (MRSA) only does this number refer to the zoonotic agent at level 2. See Section 7.2, General constraints, for a detailed description of how to report aggregated data elements (see Tables 37 to 40 for examples).

Based on the requirements laid down in Commission Regulation (EU) No 218/2014, MSs are requested to report the total number and the number of *Salmonella*-positive samples, differentiating between samples taken under the points listed in Table 34, when applied, in order to verify the correct implementation by food business operators of the process hygiene criterion for *Salmonella* on pig carcasses (Table 34).

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

¹⁰ Commission Regulation (EU) No 517/2011 of 25 May 2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of certain *Salmonella* serotypes in laying hens of *Gallus gallus* and amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) No 200/2010. OJ L 138, 26.5.2011, p. 45–51.

¹¹ Commission Regulation (EU) No 200/2012 of 8 March 2012 concerning a Union target for the reduction of *Salmonella* Enteritidis and *Salmonella* Typhimurium in flocks of broilers, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council Text and repealing Regulation (EC) No 646/2007. OJ L 71, 9.3.2012, p. 31–36.

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

7.6.2. Total units positive (*totUnitsPositive PRV.22*)

This data element is **mandatory**. This is a numerical data element. It is the total number of units found positive for the zoonotic agent at level 1 (e.g. *Salmonella*, *Campylobacter*) of the specified context out of the total units tested. For *Listeria monocytogenes*, *Escherichia coli*, pathogenic - Verotoxigenic *E. coli* (VTEC); and *Staphylococcus - S. aureus*, meticillin resistant (MRSA) only does this number refer to the zoonotic agent at level 2. This means, in the case of *Listeria*, that it is the total number of units found positive to *Listeria monocytogenes* based on the results of qualitative and/or quantitative analysis. Where both qualitative and quantitative analyses are used, a unit is considered to be positive if it was shown to be positive in either a qualitative and/or a quantitative test (either positive < 100 cfu/g or positive ≥ 100 cfu/g). In such cases it should be reported as a positive unit only once. It is important to note that, when reporting the total positive units detected using quantitative methods, both units positive < 100 cfu/g and ≥ 100 cfu/g are to be considered. See Section 7.2, General constraints, for a detailed description on how to report aggregated data elements (see Tables 37 to 40 for examples).

7.6.3. Quantity (*quantity PRV.24*)

This data element is **mandatory when** reporting on **enumeration method results of *Listeria* in food** (in colony-forming units (cfu)/g) and **histamine** (in mg/kg). It contains codes linked to a catalogue (ZOO_CAT_FIXMEAS, domain: D_PVR_Quantity). It indicates the quantity measured by the test.

In the table on *Listeria* in food, the code 'R073A' (corresponding to the term '<=100') is used to report results where *Listeria monocytogenes* was found in numbers over the quantification limit but less than or equal to 100 cfu/g. On the other hand, the code 'R077A' (corresponding to the term '> 100') is used to report results where *Listeria monocytogenes* was found in numbers greater than 100 cfu/g.

In the table on histamine in food, the codes 'R073A' to 'R076A' and 'R106A' and 'R107A' are used to report the numbers of units where histamine was found in quantities in the following ranges:

- less than or equal to 100 mg/kg ('<=100' code 'R073A');
- more than 100 mg/kg but below or equal to 200 mg/kg ('> 100 to <=200' code 'R075A');
- less than or equal to 200 mg/kg ('<=200' code 'R106A');
- more than 200 mg/kg ('> 200' code 'R107A');
- more than 200 mg/kg but below or equal to 400 mg/kg ('> 200 to <=400' code 'R076A');
- more than 400 mg/kg ('> 400' code 'R074A').

7.6.4. Number of units tested (*unitsTested PRV.25*)

This data element is **mandatory when** reporting data on ***Listeria* in food**. It should be left empty in all other cases, as reporting multiple analytical results for the same sample in cases other than *Listeria* in food is not permitted.

This is a numerical data element. It indicates the numbers of units tested for *Listeria* by the detection method or by the enumeration method. See Section 7.2 and Table 38 for further information and examples on how to report this data element for *Listeria* in food.

7.6.5. Number of units positive (*unitsPositive PRV.26*)

This data element is **mandatory when** reporting **positive results and for all results referring to *Listeria* or histamine**. This is a numerical data element. It indicates the number of units tested positive for the agent species, serovar (e.g. *Salmonella* Typhimurium, *Salmonella* Infantis, *Campylobacter jejuni*) or phagetype (e.g. *Salmonella* Enteritidis - PT 1) reported in the data element *zoonosis* (PRV.04).

In the case of *Listeria* in food, this data element must be used to report the number of units found to be positive for *Listeria monocytogenes* by the detection method and found to be '<=100' or '> 100' cfu/g by the enumeration method.

In the case of histamine, this data element must be used to report the number of units found in the six categories '<=100', '> 100 to <=200', '<=200', '>200', '> 200 to <=400', and '> 400' mg/kg.

See Section 7.2.1 and Tables 37 to 40 for further information and examples on how to report on this data element.

7.7. Information about the test method

7.7.1. Method (*anMethCode PRV.23*)

This data element is **mandatory when** reporting data on ***Listeria* in food**, data on **VTEC** and data on **histamine**, and it is highly **recommended when** reporting ***Toxoplasma*, Q fever, West Nile virus and *Mycobacterium***. It contains codes linked to a catalogue (ZOO_CAT_ANLYMD, domain: D_PRV_anMethCode). It indicates the diagnostic or analytical methods used in the laboratory to test the specimens. Whenever possible, a reference to the standard methods used is made (such as national, ISO or EN standard methods), or to the methods prescribed by the legislation. Recommendations on the analytical methods to be reported for VTEC are summarised below.

Analytical methods to report on VTEC in food:

- ISO 16654:2001 or NMKL 164:2005 or DIN 10167 (code 'F593A') or any alternative method validated against these methods, according to the ISO 16140. **These methods are specific for VTEC O157.**
- ISO/TS 13136:2012 (including the EU-RL adaptation for O104:H4) (code 'F173A') or any alternative method validated against this method, according to the ISO 16140. **These methods aim at detecting any VTEC, regardless of the serotype.**
- In house real time PCR methods based on ISO/TS 13136:2012 (code 'F594A'). **These methods aim at detecting any VTEC, regardless of the serotype.**
- Other methods based on PCR detection of vtx genes (code 'F595A'). **These methods aim at detecting any VTEC, regardless of the serotype.**
- DIN 10118:2004 (code 'F596A') or any alternative method validated against this method, according to the ISO 16140. **These methods aim at detecting any VTEC, regardless of the serotype.**
- Other methods based on the immunochemical detection of VT (code 'F597A'). **These are ELISA-based methods able to detect any VTEC by detection of VT toxin.**
- Unspecified (code 'F598A'). In this case, basic details on the method – when available - should be specified in the 'comment' data element.

Analytical methods to report on VTEC in animals:

- OIE recommended method for the detection of *E. coli* O157 in animal faeces (code 'F602A') or any other cultural methods based on ISO 16654/2001 adapted to animal samples are to be reported under the term 'OIE method for testing *E. coli* O157 in animal faecal samples'(code 'F602A').
- PCR methods based on ISO/TS 13136:2012, adapted to animal samples are to be reported under the term 'In house real time PCR methods based on ISO/TS 13136:2012'(code 'F594A').
- Other methods based on PCR detection of vtx genes (code 'F595A').
- Methods based on the immunochemical detection of VT (code 'F597A').
- Unspecified (code 'F598A').

See Table 40 for a description and examples on how to report VTEC results for testing food and animal samples using different analytical methods.

Results from different methods for the same samples can only be reported for *Listeria* in food where the code 'F145A' (corresponding to the term 'Detection method—presence in x g') is used to indicate the results from detection method (qualitative) analyses. The code 'F141A' (corresponding to the term 'Enumeration/Quantitative method') is used to indicate the results from enumeration method (quantitative) analyses. In all other cases, if the same specimen was tested using more than one method, only the aggregated result should be reported under the total number of units tested, total number of units positive and units positive, with the analytical method left blank or reported as 'Classification not possible' ('F001A'). See Sections 7.2.1 and 7.2.4 and Table 38 for a description and examples on how to report enumeration and detection method results for *Listeria* in food.

7.7.2. Sample weight (*sampWeight PRV.15*)

This data element is **mandatory when** sampling unit (*sampUnit PRV.14*) is equal to 'single (food/feed)' or 'batch (food/feed)', i.e. for **food and feed** samples.

This is a numerical data element (decimal numbers possible). It is the weight (in numbers) of the specimen used in the laboratory for analysis according to the analytical method used (e.g. 25) (weight of the test portion).

7.7.3. Sample weight unit (*sampWeightUnit PRV.16*)

This data element is **mandatory when sample weight** (*sampWeight PRV.15*) **is provided**. It contains codes linked to a catalogue (ZOO_CAT_UNIT, domain: D_PRV_sampWeightUnit). It is the unit of the indicated sample weight: 'Gram' (code 'G148A'), 'Kilogram' (code 'G167A'), 'Millilitre' (code 'G156A'), 'Square centimetre' (code 'G090A').

7.8. Additional information

7.8.1. Comment (*resComm PRV.27*)

This data element is **optional**. This is a free text element of a maximum of 2,000 alphanumeric characters that allows reporting additional information about the results that cannot be reported under other data elements. It should be completed in English (see data element *PRV.03* Language).

Table 35: EFSA data model for prevalence data reporting

| Element code | Element label | Element name (for XML/Excel transfer) | Constraint | Type | Catalogue | Domain |
|--------------|--|---------------------------------------|------------|-----------------|-------------------|----------------------|
| PRV.01 | Reporting year | repYear | Mandatory | xs:integer(4) | | |
| PRV.02 | Reporting country | repCountry | Mandatory | xs:string(2) | ZOO_CAT_COUNTRY | D_ALL_repCountry |
| PRV.03 | Language | lang | Mandatory | xs:string(2) | ZOO_CAT_LANG | D_ALL_lang |
| PRV.04 | Zoonotic agent | zoonosis | Mandatory | xs:string(15) | ZOO_CAT_PARAM_ZOO | D_PRV_zoonosis |
| PRV.05 | Matrix | matrix | Mandatory | xs:string(4000) | ZOO_CAT_MATRIX | D_PRV_matrix |
| PRV.06 | Sampling stage | sampStage | Mandatory | xs:string(5) | ZOO_CAT_SMPNT | D_PRV_sampStage |
| PRV.07 | Sample origin | sampOrig | Optional | xs:string(2) | ZOO_CAT_COUNTRY | D_PRV_sampOrig |
| PRV.08 | Sample type | sampType | Optional | xs:string(5) | ZOO_CAT_SMPTYP | |
| PRV.09 | Sampling context | sampContext | Mandatory | xs:string(5) | ZOO_CAT_SRCTYP | D_ALL_sampContext |
| PRV.10 | Sampler | sampler | Mandatory | xs:string(5) | ZOO_CAT_SMPLR | |
| PRV.11 | Sampling strategy | progSampStrategy | Mandatory | xs:string(5) | ZOO_CAT_SAMPSTR | |
| PRV.12 | Sampling details | sampDetails | Optional | xs:string(2000) | | |
| PRV.13 | Area of sampling | sampArea | Optional | xs:string(5) | ZOO_CAT_NUTS | |
| PRV.14 | Sampling unit | sampUnit | Mandatory | xs:string(5) | ZOO_CAT_UNIT | D_PRV_sampUnit |
| PRV.15 | Sample weight | sampWeight | Optional | xs:double | | |
| PRV.16 | Sample weight unit | sampWeightUnit | Optional | xs:string(5) | ZOO_CAT_UNIT | D_PRV_sampWeightUnit |
| PRV.17 | Source of information | sourceInfo | Optional | xs:string(2000) | | |
| PRV.18 | Target verification | target | Optional | xs:string(1) | ZOO_CAT_YESNO | |
| PRV.19 | Number of flocks under control programme | contrFlocks | Optional | xs:integer(10) | | |
| PRV.20 | Number of clinically affected herds | affectHerds | Optional | xs:integer(10) | | |
| PRV.29 | Vaccination status | vaccination | Optional | xs:string(1) | ZOO_CAT_YESNO | |
| PRV.21 | Total units tested | totUnitsTested | Mandatory | xs:integer(10) | | |
| PRV.22 | Total units positive | totUnitsPositive | Mandatory | xs:integer(10) | | |
| PRV.23 | Analytical method | anMethCode | Optional | xs:string(5) | ZOO_CAT_ANLYMD | D_PRV_anMethCode |
| PRV.24 | Quantity | quantity | Optional | xs:string(5) | ZOO_CAT_FIXMEAS | D_PRV_Quantity |
| PRV.25 | Number of units tested | unitsTested | Optional | xs:integer(8) | | |
| PRV.26 | Number of units positive | unitsPositive | Optional | xs:integer(8) | | |
| PRV.27 | Comment | resComm | Optional | xs:string(2000) | | |

Table 36: EFSA business rules for prevalence data reporting

| Element code | Element name | Error type | Error code | Rule |
|--------------|--------------|------------|------------|--|
| Entire row | Entire row | E | PRV46 | The 'Number of flocks under control programme' (contrFlocks), 'Number of clinically affected herds' (affectHerds), 'Total units tested' (totUnitsTested) and 'Total units positive' (totUnitsPositive) must be constant (the same) for all records with the same context. |
| Entire row | Entire row | W | PRV47 | WARNING. A potential double reporting was detected. The number of units reported for a matrix category is the same as the sum of units reported in other rows containing subcategories of the same matrix |
| PRV.01 | repYear | E | PRV01 | The value in repYear must be the same as the data collection reporting year |
| PRV.03 | lang | W | PRV04 | WARNING. The value in lang should be 'English' ('en') |
| PRV.04 | zoonosis | E | PRV58 | If the value in zoonosis is in level 2 'VTEC/STEC' and the value in totUnitsPos is greater than 0, then zoonosis should be reported at least at level 3 |
| PRV.04 | zoonosis | E | PRV61 | If the value in zoonosis is in level 2 'VTEC/STEC' and the value in totUnitsPos is equal to 0, then zoonosis should be reported at level 2 |
| PRV.04 | zoonosis | E | PRV62 | If the value in zoonosis is in level 1 'Listeria' and the value in 'Matrix' is in level_0 (speciesType) 'food', then zoonosis should be reported at least at level 2 |
| PRV.04 | zoonosis | E | PRV66 | If the value in zoonosis is in level 2 'VTEC' (RF-00000132-MCG), then the verotoxin pheno-genotyping (vt) must be reported and must be different from 'Not applicable' (P001V) |
| PRV.04 | zoonosis | E | PRV67 | If the value in zoonosis is not in level 2 'VTEC' (RF-00000132-MCG) the verotoxin pheno-genotyping (vt) should not be reported (the only allowed value is 'Not applicable' - P001V). |
| PRV.04 | zoonosis | E | PRV68 | If the value in verotoxin pheno-genotyping (vt) contains 'Verotoxin production, VT1' (P003V), or 'Verotoxin production, VT2' (P008V), then the value in verotoxin pheno-genotyping (vt) can only be a combination of the two values (P003V and/or P008V). |
| PRV.04 | zoonosis | E | PRV69 | If the value in verotoxin pheno-genotyping (vt) contains 'VT1, gene identified, subtype unspecified' (P004V), or 'VT2, gene identified, subtype unspecified' (P009V), then the value in verotoxin pheno-genotyping (vt) can only be a combination of the two values (P004V and/or P009V). |
| PRV.04 | zoonosis | E | PRV70 | If the value in zoonosis is in level 2 'VTEC' (RF-00000132-MCG), then adhesion genes (ag) must be reported and must be different from 'Adhesion genes investigation not applicable' (P001A) |
| PRV.04 | zoonosis | E | PRV71 | If the value in zoonosis is not in level 2 'VTEC' (RF-00000132-MCG) the adhesion genes (ag) should not be reported (the only allowed value is 'Adhesion genes investigation not applicable' - P001A). |
| PRV.04 | zoonosis | E | PRV72 | If the value in adhesion genes (ag) contains 'Adhesion genes investigation not reported' (P002A), or 'Adhesion genes not investigated' (P003A), or 'eae positive' (P004A), or 'Enterotoxigenic adhesion genes negative' (P010A), then the value in adhesion genes (ag) must be one of the following combination: P002A, P003A, P004A, P010A, P004A and P010A, P009A and P010A. |
| PRV.04 | zoonosis | E | PRV73 | If the value in zoonosis is not in level 2 'VTEC' (RF-00000132-MCG), then antigenH (antH) must not be reported. |
| PRV.05 | matrix | W | PRV25 | WARNING. For data interpretation purposes, it is advised not to use general categories. The value in matrix should not be 'Gallus gallus (fowl) - unspecified' ('A031721A'), or 'Compound feedingstuffs, not |

| Element code | Element name | Error type | Error code | Rule |
|--------------|---|------------|------------|---|
| | | | | specified' ('A001421A') |
| PRV.05 | matrix | E | PRV60 | If zoonosis is in level_2 'Listeria monocytogenes' and matrix is in level_0 (speciesType) 'food', then matrix should be reported at least at level 3 |
| PRV.05 | matrix | E | PRV59 | If the value in zoonosis is in level_1 'Toxoplasma' (RF-00002512-MCG), then the value in matrix should be different from 'Crocodile' (A041316A), 'Crocodile - zoo animals' (A041319A0), 'Reptiles - wild' (A013221A), 'Reptiles - farmed' (A013241A), 'Reptiles' (A000101A), 'Reptiles - zoo animal' (A000421A), 'Reptiles - pet animals' (A022681A), 'Salamander' (A041315A), 'Salamander - zoo animals' (A041320A), 'Salamander - wild' (A041321A), 'Snakes - pet animals' (A013281A), 'Snakes - zoo animal' (A001341A), 'Fish - farmed - carp' (A012761A), 'Fish - aquarium fish' (A012781A), 'Fish - farmed - salmon' (A000201A), 'Fish' (A008601A), 'Fish - farmed' (A024121A), 'Fish - wild' (A027961A), 'Turtles' (A003321A), 'Turtles - wild' (A013121A), 'Turtles - pet animals' (A032541A), 'Turtles - zoo animals' (A040961A), 'Shellfish - wild' (A012821A), 'Shellfish' (A011321A), 'Shrews' (A013841A), 'Shrews - zoo animal' (A029181A), 'Shellfish - farmed' (A012801A), 'Snakes' (A013261A), 'Snakes - wild' (A029141A); |
| PRV.06 | sampStage | W | PRV21 | WARNING. For data interpretation purposes, a value in sampStage should be reported and should not be 'Unspecified' ('E098A') |
| PRV.09 | sampContext | W | PRV22 | WARNING. For data interpretation purposes, a value in sampContext should be reported and should not be 'Unspecified' ('K029A') |
| PRV.10 | sampler | W | PRV23 | WARNING. For data interpretation purposes, a value in sampler should be reported and should not be 'Not applicable' ('CX99A') |
| PRV.10 | sampler | E | PRV27 | In sampler, the value 'Official and industry sampling' ('CX03A') can be only reported when reporting on <i>Salmonella</i> in <i>Gallus gallus</i> (fowl) and Turkeys categories under control programmes ('target verification' equal to 'yes') |
| | sampUnit & sampler & progSampStrategy & sampContext | E | PRV63 | If the value in 'Target verification' (target) is 'YES' (Y), then the value in 'Zoonotic agent' (zoonosis) must be in level_1 'Salmonella' (RF-00000304-MCG), the value in 'Matrix' (matrix) must be 'Gallus gallus (fowl) - breeding flocks for broiler production line - adult' ('A041001A'), or 'Gallus gallus (fowl) - breeding flocks for egg production line - adult' ('A041019A'), or 'Gallus gallus (fowl) - breeding flocks, unspecified - adult' ('A041021A'), or 'Gallus gallus (fowl) - broilers - before slaughter' ('A000041A'), or 'Gallus gallus (fowl) - elite breeding flocks for broiler production line - adult' ('A041004A'), or 'Gallus gallus (fowl) - elite breeding flocks for egg production line - adult' ('A041022A'), or 'Gallus gallus (fowl) - elite breeding flocks, unspecified - adult' ('A041024A'), or 'Gallus gallus (fowl) - grandparent breeding flocks for broiler production line - adult' ('A041005A'), or 'Gallus gallus (fowl) - grandparent breeding flocks for egg production line - adult' ('A041025A'), or 'Gallus gallus (fowl) - grandparent breeding flocks, unspecified - adult' ('A041027A'), or 'Gallus gallus (fowl) - laying hens - adult' ('A041031A'), or 'Gallus gallus (fowl) - parent breeding flocks for broiler production line - adult' ('A041006A'), or 'Gallus gallus (fowl) - parent breeding flocks for egg production line - adult' ('A041028A'), or 'Gallus gallus (fowl) - parent breeding flocks, unspecified - adult' ('A041030A'), or |

| Element code | Element name | Error type | Error code | Rule |
|--------------------------------|---------------------------------------|------------|------------|---|
| | | | | 'Turkeys - breeding flocks, unspecified - adult' ('A041033A'), or 'Turkeys - elite breeding flocks - adult' ('A041034A'), or 'Turkeys - grandparent breeding flocks - adult' ('A041035A'), or 'Turkeys - parent breeding flocks - adult' ('A041036A'), or 'Turkeys - fattening flocks - before slaughter' ('A041278A'), the value in 'Sampling unit' (sampUnit) must be 'herd/flock' (G202A), the value in 'Sampler' (sampler) must be 'Official and industry sampling' (CX03A), the value in 'Sampling strategy' (progSampStrategy) must be 'Census' (ST50A) and the value in 'Sampling context' (sampContext) must be 'Control and eradication programmes' (K021A) |
| | sampStage | E | PRV64 | If the value in 'Zoonotic agent' (zoonosis) is in level_1 'Salmonella' ('RF-00000304-MCG') and the value in 'Target verification' (target) is 'YES' (Y) and the value in 'Matrix' (matrix) is 'Gallus gallus (fowl) - breeding flocks for broiler production line - adult' ('A041001A'), or 'Gallus gallus (fowl) - breeding flocks for egg production line - adult' ('A041019A'), or 'Gallus gallus (fowl) - breeding flocks, unspecified - adult' ('A041021A'), or 'Gallus gallus (fowl) - elite breeding flocks for broiler production line - adult' ('A041004A'), or 'Gallus gallus (fowl) - elite breeding flocks for egg production line - adult' ('A041022A'), or 'Gallus gallus (fowl) - elite breeding flocks, unspecified - adult' ('A041024A'), or 'Gallus gallus (fowl) - grandparent breeding flocks for broiler production line - adult' ('A041005A'), or 'Gallus gallus (fowl) - grandparent breeding flocks for egg production line - adult' ('A041025A'), or 'Gallus gallus (fowl) - grandparent breeding flocks, unspecified - adult' ('A041027A'), or 'Gallus gallus (fowl) - parent breeding flocks for broiler production line - adult' ('A041006A'), or 'Gallus gallus (fowl) - parent breeding flocks for egg production line - adult' ('A041028A'), or 'Gallus gallus (fowl) - parent breeding flocks, unspecified - adult' ('A041030A'), then the value in 'Sampling stage' (sampStage) must be 'Farm' (E101A), or 'Unspecified' (E098A), or 'Hatchery' (E160A) |
| | sampStage | E | PRV65 | If the value in 'Zoonotic agent' (zoonosis) is in level_1 'Salmonella' ('RF-00000304-MCG') and the value in 'Target verification' (target) is 'YES' (Y) and the value in 'Matrix' (matrix) is 'Gallus gallus (fowl) - laying hens - adult' ('A041031A'), or 'Gallus gallus (fowl) - broilers - before slaughter' ('A000041A'), or 'Turkeys - breeding flocks, unspecified - adult' ('A041033A'), or 'Turkeys - elite breeding flocks - adult' ('A041034A'), or 'Turkeys - grandparent breeding flocks - adult' ('A041035A'), or 'Turkeys - parent breeding flocks - adult' ('A041036A'), or 'Turkeys - fattening flocks - before slaughter' ('A041278A'), then the value in 'Sampling stage' (sampStage) must be 'Farm' (E101A), or 'Unspecified' (E098A) |
| PRV.11 | progSampStrategy | W | PRV24 | WARNING. For data interpretation purposes, a value in progSampStrategy should be reported and should not be 'Unspecified' ('STXXA') |
| PRV.12 & PRV.17 & PRV.27 | sampDetails & sourceInfo & resComm | W | PRV41 | Following term in free text data element should be revised and inserted in an appropriate data element where applicable: 'import' |
| PRV.12 & PRV.17 & | sampDetails & sourceInfo & resComm | W | PRV42 | Following term in free text data element should be revised and inserted in an appropriate data element where applicable: 'HACCP' |

| Element code | Element name | Error type | Error code | Rule |
|--------------------------|------------------------------------|------------|------------|--|
| PRV.27 | | | | |
| PRV.12 & PRV.17 & PRV.27 | sampDetails & sourceInfo & resComm | W | PRV43 | Following term in free text data element should be revised and inserted in an appropriate data element where applicable: 'baseline' |
| PRV.12 & PRV.17 & PRV.27 | sampDetails & sourceInfo & resComm | W | PRV44 | Following terms in free text data element should be revised and inserted in an appropriate data element where applicable: 'suspect', 'clinical' |
| PRV.13 | sampArea | W | PRV53 | WARNING: For analysis purposes, it is highly recommended to also provide regional data for E. multilocularis in foxes and other wildlife in addition to country data. |
| PRV.13 | sampArea | W | PRV54 | WARNING: For analysis purposes, it is highly recommended to also provide regional data for West Nile virus in animals in addition to country data. |
| PRV.14 | sampUnit | E | PRV20 | If the value in 'Matrix' is in level_0 (speciesType) 'animal', then the value in sampUnit must be 'herd/flock' ('G202A'), or 'animal' ('G199A'), or 'holding' ('G198A'), or 'slaughter batch' ('G200A'); and if the value in 'Matrix' is in level_0 (speciesType) 'food' or 'feed' then the value in sampUnit must be 'single (food/feed)' ('G203A'), or 'batch (food/feed)' ('G204A') |
| PRV.15 | sampWeight | E | PRV08 | The value in sampWeight must be greater than '0' |
| PRV.15 | sampWeight | E | PRV09 | If the value in sampUnit is 'single (food/feed)' ('G203A') or 'batch (food/feed)' ('G204A'), then a value in sampWeight must be reported |
| PRV.16 | sampWeightUnit | E | PRV10 | If a value in sampWeight is reported, then a value in sampWeightUnit must be reported |
| PRV.18 | target | E | PRV02 | If the value in zoonosis is in level_1 ' <i>Salmonella</i> ' ('RF-00000304-MCG') and the value in matrix is ' <i>Gallus gallus</i> (fowl) - breeding flocks for broiler production line - adult' ('A041001A'), or ' <i>Gallus gallus</i> (fowl) - breeding flocks for egg production line - adult' ('A041019A'), or ' <i>Gallus gallus</i> (fowl) - breeding flocks, unspecified - adult' ('A041021A'), or ' <i>Gallus gallus</i> (fowl) - broilers - before slaughter' ('A000041A'), or ' <i>Gallus gallus</i> (fowl) - elite breeding flocks for broiler production line - adult' ('A041004A'), or ' <i>Gallus gallus</i> (fowl) - elite breeding flocks for egg production line - adult' ('A041022A'), or ' <i>Gallus gallus</i> (fowl) - elite breeding flocks, unspecified - adult' ('A041024A'), or ' <i>Gallus gallus</i> (fowl) - grandparent breeding flocks for broiler production line - adult' ('A041005A'), or ' <i>Gallus gallus</i> (fowl) - grandparent breeding flocks for egg production line - adult' ('A041025A'), or ' <i>Gallus gallus</i> (fowl) - grandparent breeding flocks, unspecified - adult' ('A041027A'), or ' <i>Gallus gallus</i> (fowl) - laying hens - adult' ('A041031A'), or ' <i>Gallus gallus</i> (fowl) - parent breeding flocks for broiler production line - adult' ('A041006A'), or ' <i>Gallus gallus</i> (fowl) - parent breeding flocks for egg production line - adult' ('A041028A'), or ' <i>Gallus gallus</i> (fowl) - parent breeding flocks, unspecified - adult' ('A041030A'), or 'Turkeys - breeding flocks, unspecified - adult' ('A041033A'), or 'Turkeys - elite breeding flocks - adult' ('A041034A'), or 'Turkeys - grandparent breeding flocks - adult' ('A041035A'), or 'Turkeys - parent breeding flocks - adult' ('A041036A'), or 'Turkeys - fattening flocks - before slaughter' ('A041278A'), |

| Element code | Element name | Error type | Error code | Rule |
|--------------|----------------|------------|------------|--|
| PRV.19 | contrFlocks | E | PRV03 | then a value in target must be reported If the value in zoonosis is in level 1 ' <i>Salmonella</i> ' ('RF-00000304-MCG') and the value in matrix is ' <i>Gallus gallus</i> (fowl) - breeding flocks for broiler production line - adult' ('A041001A'), or ' <i>Gallus gallus</i> (fowl) - breeding flocks for egg production line - adult' ('A041019A'), or ' <i>Gallus gallus</i> (fowl) - breeding flocks, unspecified - adult' ('A041021A'), or ' <i>Gallus gallus</i> (fowl) - elite breeding flocks for broiler production line - adult' ('A041004A'), or ' <i>Gallus gallus</i> (fowl) - elite breeding flocks for egg production line - adult' ('A041022A'), or ' <i>Gallus gallus</i> (fowl) - elite breeding flocks, unspecified - adult' ('A041024A'), or ' <i>Gallus gallus</i> (fowl) - grandparent breeding flocks for broiler production line - adult' ('A041005A'), or ' <i>Gallus gallus</i> (fowl) - grandparent breeding flocks for egg production line - adult' ('A041025A'), or ' <i>Gallus gallus</i> (fowl) - grandparent breeding flocks, unspecified - adult' ('A041027A'), or ' <i>Gallus gallus</i> (fowl) - laying hens - adult' ('A041031A'), or ' <i>Gallus gallus</i> (fowl) - parent breeding flocks for broiler production line - adult' ('A041006A'), or ' <i>Gallus gallus</i> (fowl) - parent breeding flocks for egg production line - adult' ('A041028A'), or ' <i>Gallus gallus</i> (fowl) - parent breeding flocks, unspecified - adult' ('A041030A'), or 'Turkeys - breeding flocks, unspecified - adult' ('A041033A'), or 'Turkeys - elite breeding flocks - adult' ('A041034A'), or 'Turkeys - grandparent breeding flocks - adult' ('A041035A'), or 'Turkeys - parent breeding flocks - adult' ('A041036A'), or 'Turkeys - fattening flocks - before slaughter' ('A041278A'), then a value in contrFlocks must be reported |
| PRV.19 | contrFlocks | E | PRV15 | The value in contrFlocks must be numeric |
| PRV.20 | affectHerds | E | PRV16 | The value in affectHerds must be numeric |
| PRV.20 | affectHerds | E | PRV28 | If zoonosis level_1 is ' <i>Coxiella</i> (Q fever)' ('RF-00000083-MCG'), then a value in affectHerds must be reported |
| PRV.20 | affectHerds | E | PRV56 | If the value in zoonosis is in level_1 ' <i>Coxiella</i> (Q fever)' ('RF-00000083-MCG') and the value in sampUnit is 'animal' (G199A), then affectHerds should not be reported |
| PRV.20 | affectHerds | E | PRV57 | If the value in zoonosis is in level_1 ' <i>Coxiella</i> (Q fever)' ('RF-00000083-MCG') and the value in sampUnit is 'holding' (G198A) or 'herd/flock' (G202A) and affectHerds is greater than 0, then totUnitsPos must be greater than 0 |
| PRV.21 | totUnitsTested | E | PRV05 | The value in totUnitsTested must be greater than '0' |
| PRV.21 | totUnitsTested | E | PRV06 | The value in totUnitsTested must be greater than or equal to the value in totUnitsPositive |
| PRV.21 | totUnitsTested | E | PRV12 | The value in totUnitsTested must be numeric |
| PRV.21 | totUnitsTested | E | PRV32 | The value in totUnitsTested must be greater than or equal to the value in unitsTested |
| PRV.21 | totUnitsTested | E | PRV36 | The value in totUnitsTested must be less than or equal to the sum of unitsTested of the same context |
| PRV.21 | totUnitsTested | E | PRV55 | If the value in zoonosis is in level 1 ' <i>Salmonella</i> ' ('RF-00000304-MCG') and the value in matrix is ' <i>Gallus gallus</i> (fowl) - breeding flocks for broiler production line - adult' ('A041001A'), or ' <i>Gallus gallus</i> (fowl) - breeding flocks for egg production line - adult' ('A041019A'), or |

| Element code | Element name | Error type | Error code | Rule |
|--------------|------------------|------------|------------|--|
| | | | | <p>`Gallus gallus (fowl) - breeding flocks, unspecified - adult' ('A041021A'), or `Gallus gallus (fowl) - elite breeding flocks for broiler production line - adult' ('A041004A'), or `Gallus gallus (fowl) - elite breeding flocks for egg production line - adult' ('A041022A'), or `Gallus gallus (fowl) - elite breeding flocks, unspecified - adult' ('A041024A'), or `Gallus gallus (fowl) - grandparent breeding flocks for broiler production line - adult' ('A041005A'), or `Gallus gallus (fowl) - grandparent breeding flocks for egg production line - adult' ('A041025A'), or `Gallus gallus (fowl) - grandparent breeding flocks, unspecified - adult' ('A041027A'), or `Gallus gallus (fowl) - laying hens - adult' ('A041031A'), or `Gallus gallus (fowl) - parent breeding flocks for broiler production line - adult' ('A041006A'), or `Gallus gallus (fowl) - parent breeding flocks for egg production line - adult' ('A041028A'), or `Gallus gallus (fowl) - parent breeding flocks, unspecified - adult' ('A041030A'), or `Turkeys - breeding flocks, unspecified - adult' ('A041033A'), or `Turkeys - elite breeding flocks - adult' ('A041034A'), or `Turkeys - grandparent breeding flocks - adult' ('A041035A'), or `Turkeys - parent breeding flocks - adult' ('A041036A'), or `Turkeys - fattening flocks - before slaughter' ('A041278A'), and the value in target is 'yes', then the value in totUnitsTested must be less than or equal to the value in contrFlocks</p> |
| PRV.22 | totUnitsPositive | E | PRV07 | The value in totUnitsPositive must be greater than or equal to '0' |
| PRV.22 | totUnitsPositive | E | PRV13 | The value in totUnitsPositive must be numeric |
| PRV.22 | totUnitsPositive | E | PRV35 | The value in totUnitsPositive must be less than or equal to the sum of unitsPositive of the same context |
| PRV.22 | totUnitsPositive | E | PRV52 | The value in totUnitsPositive must be greater than or equal to the value in unitsPositive |
| PRV.23 | anMethCode | W | PRV11 | <p>WARNING. For data interpretation purposes,if the value in zoonosis is in level 1 `Coxiella (Q fever)' ('RF-00000083-MCG'), or `Escherichia coli, pathogenic' ('RF-00003550-MCG'), or `Mycobacterium' ('RF-00000273-MCG'), or `Toxoplasma' ('RF-00002512-MCG'), or `West Nile virus' ('RF-00002664-MCG'), then a value in anMethCode should be reported</p> |
| PRV.23 | anMethCode | E | PRV49 | <p>If the value in zoonosis is in level 1 `Listeria' ('RF-00000245-MCG') and if the value in 'Matrix' is in level_0 (speciesType) 'food', then the value in anMethCode must be `Enumeration/Quantitative method' ('F141A'), or `Detection method—presence in x g' ('F145A')</p> |
| PRV.23 | anMethCode | E | PRV50 | <p>If the value in 'Zoonotic agent' (zoonosis) is 'Histamine' (RF-00000003-BGA), then the value in `Analytical method' (anMethCode) must be 'High Performance Liquid Chromatography (HPLC)' (F018A)</p> |
| PRV.23 | anMethCode | E | PRV62 | <p>if the value in zoonosis is in level 2 VTEC, then a value in anMethCode should be reported</p> |
| PRV.24 | quantity | E | PRV29 | <p>If the value in anMethCode is `Enumeration/Quantitative method' ('F141A'), or HPLC ('F018A') then the value in quantity must be reported</p> |

| Element code | Element name | Error type | Error code | Rule |
|--------------|---------------|------------|------------|---|
| PRV.25 | unitsTested | E | PRV18 | The value in unitsTested must be numeric |
| PRV.25 | unitsTested | E | PRV30 | If the value in zoonosis is in level 1 ' <i>Listeria</i> ' ('RF-00000245-MCG') and the value in 'Matrix' is in level_0 (speciesType) 'food', then a value in unitsTested must be reported |
| PRV.26 | unitsPositive | E | PRV14 | The value in unitsPositive must be numeric |
| PRV.26 | unitsPositive | E | PRV31 | If the value in zoonosis is in level 1 ' <i>Listeria</i> ' ('RF-00000245-MCG') and the value in 'Matrix' is in level_0 (speciesType) 'food', then a value in unitsPositive must be reported |
| PRV.26 | unitsPositive | E | PRV33 | If the value in unitsTested is reported, then a value in unitsPositive must be reported |
| PRV.26 | unitsPositive | W | PRV34 | WARNING. If the value in anMethCode is 'Enumeration/Quantitative method' ('F141A') and the value in unitsPositive is the same as the value in unitsTested, then this suggests that only positive results are reported |
| PRV.26 | unitsPositive | E | PRV40 | If the value in totUnitsPositive is greater than '0', then the value in unitsPositive must be greater than or equal to '0' |

Table 37: Example on how to report data on prevalence for *Salmonella*

| Context | | | | | | | | |
|---------|---|--------------------------|-------------------|---|----------------|------------------|---------------|-------------------------------------|
| repYear | matrix | sampStage, sampType, ... | zoonosis_L1 | zoonosis | totUnitsTested | totUnitsPositive | unitsPositive | resComm |
| 2015 | <i>Gallus gallus</i> (fowl) - laying hens - adult | Farm | <i>Salmonella</i> | <i>Salmonella</i> - <i>Salmonella</i> spp., unspecified | 10 | 8 | 1 | |
| 2015 | <i>Gallus gallus</i> (fowl) - laying hens - adult | Farm | <i>Salmonella</i> | <i>Salmonella</i> - <i>S. Enteritidis</i> | 10 | 8 | 1 | |
| 2015 | <i>Gallus gallus</i> (fowl) - laying hens - adult | Farm | <i>Salmonella</i> | <i>Salmonella</i> - <i>S. Enteritidis</i> - PT 12 | 10 | 8 | 2 | |
| 2015 | <i>Gallus gallus</i> (fowl) - laying hens - adult | Farm | <i>Salmonella</i> | <i>Salmonella</i> - <i>S. Tennessee</i> | 10 | 8 | 3 | |
| 2015 | <i>Gallus gallus</i> (fowl) - laying hens - adult | Farm | <i>Salmonella</i> | <i>Salmonella</i> - <i>S. Typhimurium</i> | 10 | 8 | 1 | |
| 2015 | Meat from pig - fresh | Cutting plant | <i>Salmonella</i> | <i>Salmonella</i> - <i>Salmonella</i> spp., unspecified | 1 529 | 0 | | |
| 2015 | <i>Gallus gallus</i> (fowl) - breeding flocks | Farm | <i>Salmonella</i> | <i>Salmonella</i> - <i>S. Typhimurium</i> | 50 | 1 | 1 | 2 serovars found in the same sample |
| 2015 | <i>Gallus gallus</i> (fowl) - breeding flocks | Farm | <i>Salmonella</i> | <i>Salmonella</i> - <i>S. Enteritidis</i> | 50 | 1 | 1 | 2 serovars found in the same sample |

Table 38: Example on how to report data on prevalence for *Listeria monocytogenes*

| Context | | | | | | | | | | | |
|----------------|--|-----------------------------|--|--|--------------------|----------------------|---------------------------------------|----------------|----------|-----------------|-------------------|
| repYear | matrix | sampStage, sampType, ... | zoonosis_L2 | zoonosis | totUnits Tested | totUnits Positive | anMethCode | Samp Weight | quantity | units Tested | units Positive |
| 2015 | Fishery products, unspecified | Retail | <i>Listeria - L. monocytogenes</i> | <i>Listeria - L. monocytogenes</i> | 63 | 10 | Detection method - presence in x g | 25 | | 63 | 10 |
| 2015 | Fishery products, unspecified | Retail | <i>Listeria - L. monocytogenes</i> | <i>Listeria - L. monocytogenes</i> | 63 | 10 | Enumeration method | 1 | <=100 | 50 | 9 |
| 2015 | Fishery products, unspecified | Retail | <i>Listeria - L. monocytogenes</i> | <i>Listeria - L. monocytogenes</i> | 63 | 10 | Enumeration method | 1 | > 100 | 50 | 1 |
| 2015 | Cheeses made from cows' milk | Retail | <i>Listeria - L. monocytogenes</i> | <i>Listeria - L. monocytogenes</i> | 25 | 13 | Detection method - presence in x g | 25 | | 25 | 11 |
| 2015 | Cheeses made from cows' milk | Retail | <i>Listeria - L. monocytogenes</i> | <i>Listeria - L. monocytogenes</i> | 25 | 13 | Enumeration method | 1 | <=100 | 25 | 12 |
| 2015 | Cheeses made from cows' milk | Retail | <i>Listeria - L. monocytogenes</i> | <i>Listeria - L. monocytogenes</i> | 25 | 13 | Enumeration method | 1 | > 100 | 25 | 1 |
| 2015 | Vegetables - pre-cut - ready- to-eat | Retail | <i>Listeria - L. monocytogenes</i> | <i>Listeria - L. monocytogenes</i> | 80 | 9 | Enumeration method | 1 | <=100 | 80 | 8 |
| 2015 | Vegetables - pre-cut - ready- to-eat | Retail | <i>Listeria - L. monocytogenes</i> | <i>Listeria - L. monocytogenes</i> | 80 | 9 | Enumeration method | 1 | > 100 | 80 | 1 |
| 2015 | Bakery products - cakes | Retail | <i>Listeria - L. monocytogenes</i> | <i>Listeria - L. monocytogenes</i> | 120 | 3 | Detection method - presence in x g | 25 | | 120 | 3 |

Note: the last two examples included in this table refer to the possibility of reporting information from only detection or enumeration tests.

Table 39: Example on how to report data on prevalence for histamine

| Context | | | | | | | | | |
|----------------|---|-----------------------------|------------------|----------------|--------------------|-------------------------------------|------------|------------------|-------------------|
| repYear | matrix | sampStage, sampType, ... | Sampling Unit | Zoonosis L1 | totUnits Tested | totUnits Positive ^(a) | anMethCode | quantity | units Positive |
| 2015 | Fish - Fishery products from fish species associated with a high amount of histidine - not enzyme matured | Retail | batch | Histamine | 5 | 1 | HPLC | <=100 | 3 |
| 2015 | Fish - Fishery products from fish species associated with a high amount of histidine - not enzyme matured | Retail | batch | Histamine | 5 | 1 | HPLC | > 100 to<=200 | 0 |
| 2015 | Fish - Fishery products from fish species associated with a high amount of histidine - not enzyme matured | Retail | batch | Histamine | 5 | 1 | HPLC | > 200 | 1 |
| 2015 | Fish - Fishery products which have undergone enzyme maturation treatment in brine | Retail | batch | Histamine | 6 | 1 | HPLC | <=200 | 4 |
| 2015 | Fish - Fishery products which have undergone enzyme maturation treatment in brine | Retail | batch | Histamine | 6 | 1 | HPLC | > 200 to<=400 | 0 |
| 2015 | Fish - Fishery products which have undergone enzyme maturation treatment in brine | Retail | batch | Histamine | 6 | 1 | HPLC | > 400 | 1 |

(a): The total units positive (number of unsatisfactory samples) should be calculated based on the food safety criteria of Regulation (EC) 2073/2005, three classes sampling plan, or according to the national sampling plan.

Table 40: Example on how to report data on prevalence of VTEC

| Context | | | | | | | | |
|----------------|--|--------------------------------|--|--|---|--------------------|----------------------|-------------------|
| repYear | matrix | sampStage, sampType, ... | anMethCode | zoonosis_L2 | zoonosis | totUnits Tested | totUnits Positive | units Positive |
| 2015 | Vegetables - pre-cut - ready-to-eat | Retail | ISO 16654:2001 or NMKL 164:2005 or DIN 10167 ^(a) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) - VTEC O157 | 180 | 12 | 12 |
| 2015 | Seeds, sprouted - ready-to-eat | Retail | ISO/TS 13136:2012 (including the EU-RL adaptation for O104:H4) ^(b) ^(c) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | 130 | 0 | 0 |
| 2015 | Cheeses made from cows' milk - soft and semi-soft - made from raw or low heat-treated milk | Retail | ISO/TS 13136:2012 (including the EU-RL adaptation for O104:H4) ^(b) ^(c) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) - VTEC O157 | 320 | 28 | 17 |
| 2015 | Cheeses made from cows' milk - soft and semi-soft - made from raw or low heat-treated milk | Retail | ISO/TS 13136:2012 (including the EU-RL adaptation for O104:H4) ^(b) ^(c) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) - VTEC O88 | 320 | 28 | 2 |
| 2015 | Cheeses made from cows' milk - soft and semi-soft - made from raw or low heat-treated milk | Retail | ISO/TS 13136:2012 (including the EU-RL adaptation for O104:H4) ^(b) ^(c) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) - VTEC O103 | 320 | 28 | 9 |
| 2015 | Meat from bovine animals - fresh | Processing plant | ISO/TS 13136:2012 (including the EU-RL adaptation for O104:H4) ^(b) ^(c) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) - VTEC O26 | 75 | 3 | 2 |
| 2015 | Meat from bovine animals - fresh | Processing plant | ISO/TS 13136:2012 (including the EU-RL adaptation for O104:H4) ^(b) ^(c) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) - VTEC non (O157, O26, O103, O111, O145) | 75 | 3 | 1 |
| 2015 | Meat from sheep - fresh | Retail | Other methods based on PCR detection of vtx genes | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) - VTEC non-O157 | 67 | 3 | 1 |
| 2015 | Meat from sheep - fresh | Retail | Other methods based on PCR detection of vtx genes | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) - VTEC O26 | 67 | 3 | 2 |

| Context | | | | | | | | |
|---------|-------------------------|--------------------------------|--|--|---|--------------------|----------------------|-------------------|
| repYear | matrix | sampStage, sampType, ... | anMethCode | zoonosis_L2 | zoonosis | totUnits Tested | totUnits Positive | units Positive |
| 2015 | Cattle (bovine animals) | Farm | In house real time PCR methods based on ISO/TS 13136:2012 ^(e) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) - VTEC O157 | 237 | 16 | 9 |
| 2015 | Cattle (bovine animals) | Farm | In house real time PCR methods based on ISO/TS 13136:2012 ^(e) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) - VTEC O145 | 237 | 16 | 5 |
| 2015 | Cattle (bovine animals) | Farm | In house real time PCR methods based on ISO/TS 13136:2012 ^(e) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) - VTEC non (O157, O26, O103, O111, O145) | 237 | 16 | 2 |
| 2015 | Sheep | Farm | Other methods based on the immunochemical detection of VT ^(f) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) | <i>Escherichia coli</i> , pathogenic - Verotoxigenic <i>E. coli</i> (VTEC) - VTEC, unspecified | 33 | 1 | 1 |

(a): These methods are specific for VTEC O157. Please note that any alternative method validated against these methods, according to the ISO 161401, is to be reported using the term 'ISO 16654:2001 or NMKL 164:2005 or DIN 10167'.

(b): Methods aiming at detecting any VTEC, regardless of the serotype.

(c): Any alternative method validated against method ISO/TS 13136:2012, according to the ISO 16140, is to be reported using the term 'ISO/TS 13136:2012 (including the EU-RL adaptation for O104:H4)'

(d): OIE recommended method for the detection of *E. coli* O157 in animal faeces or any other cultural methods based on ISO 16654/2001 adapted to animal samples

(e): PCR methods based on ISO/TS 13136:2012, adapted to animal samples are to be reported under this term 'in house real time PCR methods based on ISO/TS 13136:2012'. These methods aim at detecting any VTEC, regardless of the serotype.

(f): ELISA-based methods able to detect any VTEC by detection of VT toxin

Note : Example 1 - Vegetables: example on how to report results from testing using methods able to detect only VTEC O157 (ISO 16654:2001 or NMKL 164:2005 or DIN 10167 or any alternative method validated against these methods, according to the ISO 161401)

Example 2 - Seeds, sprouted: example on how to report negative results for testing using all types of methods. Please note that information on the negative findings is to be reported for '*Escherichia coli*, pathogenic - Verotoxigenic *E. coli*' (VTEC) (zoonosis level 2) and not for the different VTEC serogroups.

Example 3 - Cheese: example on how to report results from testing using methods aiming at detecting any VTEC serogroups (ISO/TS 13136:2012 (including the EU-RL adaptation for O104:H4) and any alternative method validated against these methods, according to the ISO 16140). Information on the following serogroups was provided: VTEC O157, VTEC O88 and VTEC O103.

Example 4 - Meat from bovine animals: example on how to report results from testing using methods aiming at detecting any VTEC serogroups (ISO/TS 13136:2012 (including the EU-RL adaptation for O104:H4) and any alternative method validated against these methods, according to the ISO 16140). Information on the following serogroups was provided: VTEC O157, VTEC O26 and VTEC non-(O157, O26, O103, O111, O145). Information on VTEC non-(O157, O26, O111, O103, O145) is reported when the laboratory is able to isolate a strain carrying the *vtx* genes but its serogroup belongs neither to O157, O26, O103, O111, O145 (the serogroups identified by the ISO/TS13136:2012) nor to any of the other serogroups the laboratory is able to detect.

Example 5 - Meat from sheep: example on how to report results on VTEC non-O157 using 'other methods based on PCR detection of *vtx* genes' that are not based on the ISO/TS 13136:2012. In this example, the typing attempt included only O157 and O26. Three units were positive for VTEC and the serogroup was identified for two units as VTEC O26. For the remaining positive unit, the serogroup was neither O157 nor O26 and therefore it was reported as 'VTEC, non-O157'.

Example 6 - Goat: example on how to report results from testing animal samples using the OIE recommended method for the detection of *E. coli* O157 in animal faeces or any other cultural methods based on ISO 16654/2001 adapted to animal samples.

Example 7 - Cattle (bovine animals): example on how to report results from testing using in house real time PCR methods based on ISO/TS 13136:2012, belonging to the category of analytical methods aiming at detecting any VTEC serogroups. Information on the following serogroups was provided: VTEC O157, VTEC O145 and VTEC non-(O157, O26, O111, O103, O145).

Example 8 - Sheep: example on how to report results from testing using ELISA-based methods able to detect any VTEC serogroups by detection of VT toxin. In this case, a strain producing VT toxin is detected, but no information on the VTEC serogroup is available, therefore the results are to be reported for '*Escherichia coli*, pathogenic - Verotoxigenic *E. coli* (VTEC)' (zoonosis level 2).

8. Text forms data model 2015

8.1. Introduction

This data dictionary provides guidance for reporting on text forms for zoonoses, zoonotic agents and antimicrobial resistance under the framework of Directive 2003/99/EC. The EFSA data model for text forms is summarised in Table 42.

8.2. General information and identification of the data

8.2.1. Reporting year (*repYear TXF.01*)

This data element is **mandatory**. It is a numerical data element consisting of four digits. It is the reporting year, which is the year to which reported data refer.

8.2.2. Reporting country (*repCountry TXF.02*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_COUNTRY, domain: D_ALL_repCountry). The list includes the 28 EU MSs, as well as Norway, Switzerland and Iceland.

8.2.3. Language (*lang TXF.03*)

This data element is **mandatory**. It contains codes linked to a catalogue (ZOO_CAT_LANG, domain: D_ALL_lang); however, **only the code 'en' for 'English' should be used**, as text in the free text data element (data element TXF.05 Value) should be provided in English.

8.2.4. Zoonotic agent (*zoonosis TXF.04*)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_PARAM_ZOO). It allows for the reporting on zoonoses, zoonotic agents and food-borne pathogens. This catalogue allows reporting at different speciation levels (agent species, serovars/serotypes, phagetypes and virulence factors). The zoonosis will be displayed in the title text of the text form.

8.2.5. Matrix (*matrix TXF.05*)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_MATRIX, domain: D_PRV_matrix). It represents specific detail on the food, animal species or feed category reported on. In addition, more detailed breakdown information is included at levels 2–4, such as the type of animals (wild, farmed, pet), production category (breeding, fattening animals), subcategory of food (minced meat, hard cheese) and type of food (frozen, ready-to-eat, etc.). It is recommended that relevant animal, food or feed subcategories (corresponding to level 2, 3 and 4 terms) are selected, as far as the available information makes this possible and as enabled by the detailed catalogue. For example: Cattle (bovine animals) - calves (under 1 year) - veal calves (code A004721A), Milk, goats - raw milk (code A001821A). The matrix will be displayed in the title text of the text form.

8.3. Information about the sampling

8.3.1. Sampling stage (*sampStage TXF.06*)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_SMPNT, domain: D_PRV_sampStage). The sampling stage is the stage along the food chain where the sample has been collected, e.g. Farm (code E101A), Slaughterhouse (code E311A), Retail (code E520A). The sampling stage will be displayed in the title text of the text form.

8.3.2. Sample type (*sampType TXF.07*)

This data element is **optional**. It describes the type of sample (specimen) taken for the analyses, e.g. animal sample - caecum (code S002A), food sample - neck skin (code S024A). The sample type will be displayed in the title text of the text form.

8.3.3. Sampling context (*sampContext* TXF.08)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_SRCTYP, domain: D_ALL_sampContext). It identifies the type of programme in the framework of which samples have been collected. It is possible to distinguish between different types of sampling schemes used, e.g. Surveillance (code K026A), Monitoring - EFSA specifications (code K025A), Survey - national survey (code K028A). In the case of clinical examinations of animals, the item Clinical investigations (code K020A) has to be used. The sampling context will be displayed in the title text of the text form.

8.3.4. Sampler (*sampler* TXF.09)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_SMPLR). It indicates the type of body that performed the sampling, e.g. Industry sampling (code CX01A), Official sampling (code CX02A). The sampler will be displayed in the title text of the text form.

8.3.5. Sampling strategy (*progSampStrategy* TXF.10)

This data element is **optional**. It contains codes linked to a catalogue (ZOO_CAT_SAMPSTR). It is the sampling strategy performed in the programme or project identified by Programme code, e.g. Objective sampling (code ST10A), Census (code ST50A). The sampling strategy will be displayed in the title text of the text form.

8.4. Information about paragraph

8.4.1. Paragraph type (*paragraph* TXF.11)

This data element is **mandatory**. It contains codes linked to a catalogue listing the available type of paragraphs to be reported on (ZOO_CAT_PARAGRAPHTYPE). For example, 'Text form Antimicrobial resistance animal' (code 'TF25A').

Please note that subparagraphs required by Decision 652/2013/EU and Regulation (EU) 1375/2015 have been added.

For this data element there are text form terms which can be selected based on the different data models (for example: antimicrobial, animal population, disease status). For *Salmonella* and *Trichinella* there are specific text forms which should be selected based on the Matrix that is being reported upon (for example: 'Salmonella in Gallus gallus - breeding flocks for egg production and flocks of laying hens, code 'TF17A', 'Trichinella in pigs', code 'TF21A'). For reporting more detail concerning the sampling stage, the paragraph title 'Animal text form' (code 'TF10A') and 'Food text form' (code 'TF9A') should be used rather than the available 'Animal general text form' (code 'TF7A') and 'Food general text forms' (code 'TF71A'). Please see Table 41 as example on how to report text forms for antimicrobial resistance of *E. coli* isolates from fattening pigs.

8.4.2. Subparagraph title order (*subTitleOrder* TXF.12)

This data element is **mandatory**. It provides the order for the subtitles in a selected paragraph type. It is a linear sequence of numbers ranging from 1 to N number of subtitles defined in the paragraph type. It contains codes linked to a catalogue (ZOO_CAT_SUBPARAGRAH_ORDER).

8.4.3. Sampling details (*sampDetails* TXF.13)

This data element is **optional**. This is a free text of maximum 100 alphanumerical characters. It can be used to give more information on the sampling design, stage or context, when needed. It should be completed in English, and must be repeated for every subtitle in the text form. The sampling details text will be displayed in the title text of the text form.

8.4.4. Value (*value TXF.14*)

This data element is **mandatory**. This is a free text element of a maximum of 4 000 alphanumeric characters. It contains the text related to the paragraph title selected in the previous data element. It should be completed in English (see data element *TXF.03* Language).

Table 41: Example on how to report text forms for antimicrobial resistance of *E. coli* isolates from fattening pigs

| repYear | zoonosis | matrix | sampStage | sampType | sampContext | sampler | rogSampStrategy | paragraph | subTitleOrder | values |
|---------|----------------------------------|-----------------------|----------------|------------------------|-------------|-------------------|---------------------|---|--|---|
| 2015 | Escherichia coli, non-pathogenic | Pigs - fattening pigs | Slaughterhouse | animal sample - caecum | Monitoring | Official sampling | Objective sampling' | Text form Antimicrobial resistance animal | 1 (Description of sampling designs) | the text related to the paragraph title selected in the previous data element |
| 2015 | Escherichia coli, non-pathogenic | Pigs - fattening pigs | Slaughterhouse | animal sample - caecum | Monitoring | Official sampling | Objective sampling' | Text form Antimicrobial resistance animal | 2 (Stratification procedures per animal populations and food categories) | the text related to the paragraph title selected in the previous data element |
| 2015 | Escherichia coli, non-pathogenic | Pigs - fattening pigs | Slaughterhouse | animal sample - caecum | Monitoring | Official sampling | Objective sampling' | Text form Antimicrobial resistance animal | 3 (Randomisation procedures per animal populations and food categories) | the text related to the paragraph title selected in the previous data element |

If information is available for any of the sub-titles then they should be reported as indicated in the example above. The reporting tool allows for the omission of a sub-title in case no information is available.

Table 42: EFSA data model for text forms data reporting

| Element code | Element label | Element name (for XML/Excel transfer) | Constraint | Type | Catalogue | Domain |
|--------------|--------------------------|---------------------------------------|------------|-----------------|-----------------------|-------------------------|
| TXF.01 | Reporting year | repYear | Mandatory | xs:integer(4) | | |
| TXF.02 | Reporting country | repCountry | Mandatory | xs:string(2) | ZOO_CAT_COUNTRY | D_ALL_repCountry |
| TXF.03 | Language | lang | Mandatory | xs:string(2) | ZOO_CAT_LANG | D_ALL_lang |
| TXF.04 | Zoonotic agent | zoonosis | Optional | xs:string(15) | ZOO_CAT_PARAM_ZOO | |
| TXF.05 | Matrix | matrix | Optional | xs:string(4000) | ZOO_CAT_MATRIX | |
| TXF.06 | Sampling stage | sampStage | Optional | xs:string(5) | ZOO_CAT_SMPNT | domain: D_PRV_sampStage |
| TXF.07 | Sample type | sampType | Optional | xs:string(5) | ZOO_CAT_SMPTYP | |
| TXF.08 | Sampling context | sampContext | Optional | xs:string(5) | ZOO_CAT_SRCTYP | D_ALL_sampContext |
| TXF.09 | Sampler | sampler | Optional | xs:string(5) | ZOO_CAT_SMPLR | |
| TXF.10 | Sampling strategy | progSampStrategy | Optional | xs:string(5) | ZOO_CAT_SAMPSTR | |
| TXF.11 | Paragraph type | paragraphtype | Mandatory | xs:string(5) | ZOO_CAT_PARAGRAPHTYPE | |
| TXF.12 | Subparagraph title order | subTitleOrder | Mandatory | | | |
| TXF.13 | Species note | speciesNote | Optional | | | |
| TXF.14 | Value | value | Mandatory | xs:string(4000) | | |

References

- EFSA (European Food Safety Authority), 2012. Technical specifications for the harmonised monitoring and reporting of antimicrobial resistance in MRSA in food-producing animals and food. EFSA Journal 2012;10(10):2897, 56 pp. doi:10.2903/j.efsa.2012.2897
- EFSA (European Food Safety Authority), 2014a. Update of the technical specifications for harmonised reporting of food-borne outbreaks through the European Union reporting systems in accordance with Directive 2003/99/EC. EFSA Journal 2014;12(3):3598, 25 pp. doi:10.2903/j.efsa.2014.3598
- EFSA (European Food Safety Authority), 2014b. Technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria. EFSA Journal 2014;12(5):3686, 33 pp. doi:10.2903/j.efsa.2014.3686
- EFSA (European Food Safety Authority), 2016a. Manual for reporting on zoonoses and zoonotic agents, within the framework of Directive 2003/99/EC, and on some other pathogenic microbiological agents for information deriving from the year 2015. EFSA supporting publication 2016:EN-991. 96 pp.
- EFSA (European Food Safety Authority), 2016b. Manual for reporting on antimicrobial resistance within the framework of Directive 2003/99/EC and Decision 2013/652/EU for information deriving from the year 2015. EFSA supporting publication 2016:EN-990. 35 pp.
- EFSA (European Food Safety Authority), 2016c. Manual for reporting on food-borne outbreaks in accordance with Directive 2003/99/EC for information deriving from the year 2015. EFSA supporting publication 2016:EN-989. 43 pp.
- Sidi-Boumedine K, Rousset E, Henning K, Ziller M, Niemczuk K, Roest HIJ and Thiéry R, 2010. Development of harmonised schemes for the monitoring and reporting of Q-fever in animals in the European Union. Available online: <http://www.efsa.europa.eu/en/search/doc/48e.pdf>

Abbreviations

| | |
|-------|--|
| AMR | antimicrobial resistance |
| AMPC | AmpC β -lactamases |
| BST | brucellosis skin test |
| DCF | Data Collection Framework |
| cfu | colony-forming units |
| EC | European Commission |
| ECDC | European Centre for Disease Prevention and Control |
| ECOFF | epidemiological cut-off |
| EEC | European Economic Community |
| EFSA | European Food Safety Authority |
| EMA | European Medicines Agency |
| ESBL | extended-spectrum β -lactamases |
| EU | European Union |
| FBO | food-borne outbreak |
| IZD | inhibition zone diameter |
| MIC | minimum inhibitory concentration |
| MLST | multi-locus sequence typing |
| MRSA | meticillin-resistant <i>Staphylococcus aureus</i> |
| MS | Member State of the European Union |
| NUTS | Nomenclature of Territorial Units for Statistics |
| Spa | <i>Staphylococcus</i> protein A |
| VTEC | verotoxigenic <i>Escherichia coli</i> |
| XML | extensible markup language |

Abbreviations used in codes of data elements and business rules that refer to a data model:

| | |
|------|--|
| AMR | AMR isolate-based data model |
| ESBL | specific monitoring of ESBL-/AmpC-/carbapenemase-producing bacteria, in the absence of isolate detected data model |
| POP | animal population data model |
| DST | disease status data model |
| FBO | food-borne outbreaks data model |
| PRV | prevalence data model |
| TXF | text forms data model |