

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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Correspondence: zoonoses_support@efsa.europa.eu

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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).

Table of contents

Abstract.....	1
Summary	3
1. Introduction.....	8
1.1. Background and Terms of Reference as provided by EFSA.....	8
2. Antimicrobial resistance isolate-based data model 2015.....	9
2.1. Introduction.....	9
2.1.1. Illustrative example of how to use the data model	9
2.1.2. How to report the minimum inhibitory concentration	12
2.2. General information and identification of the isolate/result	13
2.2.1. Result code (<i>resultCode</i> AMR.01)	13
2.2.2. Reporting year (<i>repYear</i> AMR.02).....	13
2.2.3. Reporting country (<i>repCountry</i> AMR.03)	13
2.2.4. Language (<i>lang</i> AMR.04)	13
2.3. Information about type and source of samples and isolates	13
2.3.1. Zoonotic agent (<i>zoonosis</i> AMR.05)	13
2.3.2. Matrix (<i>matrix</i> AMR.06)	14
2.4. Information about the sampling performed.....	14
2.4.1. Total units tested (<i>totUnitsTested</i> AMR.07).....	14
2.4.2. Total units positive (<i>totUnitsPositive</i> AMR.09)	15
2.4.3. Total samples tested (<i>totSampUnitsTested</i> AMR.44).....	15
2.4.4. Total samples positive (<i>totSampUnitsPositive</i> AMR.50)	15
2.4.5. Sampling unit type (<i>sampUnitType</i> AMR.45)	16
2.4.6. Sampling stage (<i>sampStage</i> AMR.08)	16
2.4.7. Sample origin (<i>sampOrig</i> AMR.46).....	16
2.4.8. Sample type (<i>sampType</i> AMR.09)	16
2.4.9. Sampling context (<i>sampContext</i> AMR.10)	16
2.4.10. Sampler (sampler AMR.11)	16
2.4.11. Programme code (<i>progCode</i> AMR.12).....	17
2.4.12. Sampling strategy (<i>progSampStrategy</i> AMR.13).....	17
2.4.13. Sampling details (<i>sampDetails</i> AMR.14)	17
2.4.14. Area of sampling (<i>sampArea</i> AMR.15)	18
2.5. Information about the laboratory	18
2.5.1. Laboratory identification code (<i>labCode</i> AMR.16)	18
2.5.2. Laboratory isolate code (<i>labIsolCode</i> AMR.17)	18
2.5.3. Total number of isolates in the laboratory (<i>labTotIsol</i> AMR.18)	18
2.6. Information about the sampling and testing for AMR.....	18
2.6.1. Sampling year/month/day (<i>sampY/sampM/sampD</i> AMR.19/AMR.20/ AMR.21)	18
2.6.2. Isolation year/month/day (<i>isolY/isoM/isoD</i> AMR.22/AMR.23/AMR.24).....	18
2.6.3. Susceptibility test year/month/day (<i>analysisY/analysisM/analysisD</i> AMR.25/AMR.26/AMR.27)	18
2.7. Information about the method and the antimicrobials	19
2.7.1. Method (<i>anMethCode</i> AMR.28)	19
2.7.2. Antimicrobial substance (<i>substance</i> AMR.29)	19
2.7.3. Cut-off value (<i>cutoffValue</i> AMR.30)	20
2.8. Information about the dilution method	20
2.8.1. Lowest limit (<i>lowest</i> AMR.31).....	20
2.8.2. Highest limit (<i>highest</i> AMR.32).....	20
2.8.3. Minimum inhibitory concentration value (mg/L) (<i>MIC</i> AMR.33).....	21
2.9. Information about the diffusion method	21
2.9.1. Disc concentration (microg) (<i>diskConc</i> AMR.34)	21
2.9.2. Disc diameter (mm) (<i>diskDiam</i> AMR.35)	21
2.9.3. IZD value (mm) (<i>IZD</i> AMR.36).....	21
2.10. Information about further isolate characterisation	21
2.10.1. ESBL genotype (<i>esbl</i> AMR.38).....	21
2.10.2. AmpC genotype (<i>ampC</i> AMR.39)	21
2.10.3. Carbapenemase genotype (<i>carbapenem</i> AMR.40)	21

2.10.4. Ceftazidime synergy test (<i>synTestCAZ AMR.41</i>)	22
2.10.5. Cefotaxime synergy test (<i>synTestCTX AMR.42</i>)	22
2.10.6. Cefepime synergy test (<i>synTestFEP AMR.43</i>)	22
2.10.7. Performed CC MRSA characterisation (<i>perCC AMR.47</i>)	22
2.10.8. Performed MLST MRSA characterisation (<i>perMLST AMR.48</i>)	22
2.11. Additional information	22
2.11.1. Comment (<i>resComm AMR.37</i>)	22
3. 2015 data model used for reporting specific monitoring of ESBL-/AmpC-/carbapenemase-producing bacteria, in the absence of isolate detected	31
3.1. Introduction	31
3.2. General information	31
3.2.1. Reporting year (<i>repYear ESBL.01</i>)	31
3.2.2. Reporting country (<i>repCountry ESBL.02</i>)	31
3.3. Information about type and source of samples	31
3.3.1. Zoonotic agent (<i>zoonosis ESBL.03</i>)	31
3.3.2. Matrix (<i>matrix ESBL.04</i>)	31
3.4. Information about the sampling performed	32
3.4.1. Total units tested (<i>totUnitsTested ESBL.05</i>)	32
3.4.2. Total units positive (<i>totUnitsPositive ESBL.06</i>)	32
3.4.3. Sampling unit type (<i>sampUnitType ESBL.07</i>)	32
3.4.4. Sampling stage (<i>sampStage ESBL.08</i>)	32
3.4.5. Sample origin (<i>sampOrig ESBL.09</i>)	32
3.4.6. Sample type (<i>sampType ESBL.10</i>)	32
3.4.7. Sampling context (<i>sampContext ESBL.11</i>)	32
3.4.8. Sampler (<i>sampler ESBL.12</i>)	33
3.4.9. Programme code (<i>progCode ESBL.13</i>)	33
3.4.10. Sampling strategy (<i>progSampStrategy ESBL.14</i>)	33
3.4.11. Sampling details (<i>sampDetails ESBL.15</i>)	33
3.1. Additional information	33
3.1.1. Comment (<i>resComm ESBL.16</i>)	33
4. Animal population data model 2015	36
4.1. Introduction	36
4.2. General information and identification of the data	36
4.2.1. Reporting year (<i>repYear POP.01</i>)	36
4.2.2. Reporting country (<i>repCountry POP.02</i>)	36
4.2.3. Language (<i>lang POP.03</i>)	36
4.3. Information about type and source of data	36
4.3.1. Matrix (<i>matrix POP.04</i>)	36
4.3.2. Source year (<i>sourceYear POP.05</i>)	36
4.3.3. Unit (<i>unit POP.06</i>)	36
4.3.4. Population (<i>population POP.07</i>)	36
4.4. Additional information	37
4.4.1. Comment (<i>resComm POP.08</i>)	37
5. Disease status data model 2015	39
5.1. Introduction	39
5.2. General information and identification of the sample	39
5.2.1. Reporting year (<i>repYear DST.01</i>)	39
5.2.2. Reporting country (<i>repCountry DST.02</i>)	39
5.2.3. Region (<i>sampArea DST.03</i>)	39
5.2.4. Language (<i>lang DST.04</i>)	39
5.3. Information about type and source of data	39
5.3.1. Zoonotic agent (<i>zoonosis DST.05</i>)	39
5.3.2. Matrix (<i>matrix DST.06</i>)	39
5.3.3. Disease status unit (<i>unitDS DST.07</i>)	40
5.3.4. Number of units (<i>numUnits DST.08</i>)	40
5.3.5. Table name (<i>tableName DST.09</i>)	40
5.4. Additional information	40
5.4.1. Comment (<i>resComm DST.10</i>)	40

6.	Food-borne outbreaks data model 2015	57
6.1.	Introduction.....	57
6.2.	General constraints	57
6.2.1.	Context and uniqueness of information for food-borne outbreak reporting.....	57
6.3.	General information and identification of the isolate	57
6.3.1.	Reporting year (<i>repYear FBO.01</i>)	57
6.3.2.	Reporting country (<i>repCountry FBO.02</i>).....	57
6.3.3.	Language (<i>lang FBO.03</i>).....	57
6.4.	Information about type of food-borne outbreak	58
6.4.1.	Outbreak strength (<i>fboStrengthStrong FBO.04</i>)	58
6.4.2.	Causative agent group (<i>fboAgentGroup FBO.05</i>).....	58
6.4.3.	Causative agent (<i>fboAgent FBO.06</i>)	58
6.5.	Information about the outbreak	58
6.5.1.	FBO national code (<i>fboCodeFBO.07</i>)	58
6.5.2.	Mixed outbreaks (<i>fboOtherAgents FBO.08</i>)	58
6.5.3.	Extent of outbreak (<i>fboType FBO.09</i>)	58
6.5.4.	Food vehicle (<i>fboVehicle FBO.10</i>).....	58
6.5.5.	More food vehicle information (<i>fboVehicleInfo FBO.11</i>)	58
6.5.6.	Nature of evidence (<i>fboEvidence FBO.12</i>).....	59
6.5.7.	Place of exposure (<i>fboSetting FBO.13</i>)	59
6.5.8.	Place of origin of problem (<i>fboPlaceOrigin FBO.14</i>)	59
6.5.9.	Origin of food vehicle (<i>fboVehicleOrigin FBO.15</i>).....	59
6.5.10.	Contributory factors (<i>fboFactor FBO.16</i>)	59
6.5.11.	Number of outbreaks (<i>numOutbreaks FBO.17</i>).....	59
6.5.12.	Number of human cases (<i>numHumanCases FBO.18</i>).....	59
6.5.13.	Number of hospitalised (<i>numHospitalised FBO.19</i>)	59
6.5.14.	Number of deaths (<i>numDeaths FBO.20</i>)	59
6.6.	Additional information	60
6.6.1.	Comment (<i>resComm FBO.21</i>)	60
7.	Prevalence data model 2015	63
7.1.	Introduction.....	63
7.2.	General constraints	63
7.2.1.	Context for aggregated data elements.....	63
7.2.2.	Reporting units positive at different levels of detail (zoonosis level 2 and above)	65
7.2.3.	Reporting data at various levels of the <i>matrix</i> and <i>sampArea</i> data elements	65
7.2.4.	Comparison with the Zoonoses Web Application.....	65
7.2.5.	Reporting VTEC and MRSA using facets.....	66
7.3.	General information and identification of the sample	69
7.3.1.	Reporting year (<i>repYear PRV.01</i>)	69
7.3.2.	Reporting country (<i>repCountry PRV.02</i>).....	69
7.3.3.	Language (<i>lang PRV.03</i>).....	69
7.3.4.	Zoonotic agent (<i>zoonosis PRV.04</i>)	69
7.3.5.	Matrix (<i>matrix PRV.05</i>)	71
7.4.	Information about the sampling	71
7.4.1.	Sampling stage (<i>sampStage PRV.06</i>).....	71
7.4.2.	Sample origin (<i>sampOrig PRV.07</i>)	71
7.4.3.	Sample type (<i>sampType PRV.08</i>)	71
7.4.4.	Sampling context (<i>sampContext PRV.09</i>).....	71
7.4.5.	Sampler (<i>sampler PRV.10</i>).....	72
7.4.6.	Sampling strategy (<i>progSampStrategy PRV.11</i>).....	72
7.4.7.	Sampling details (<i>sampDetails PRV.12</i>).....	72
7.4.8.	Area of sampling (<i>sampArea PRV.13</i>)	72
7.4.9.	Sampling unit (<i>sampUnit PRV.14</i>)	73
7.4.10.	Source of information (<i>sourceInfo PRV.17</i>)	73
7.5.	Information about the herd/flock	73
7.5.1.	Target verification (<i>target PRV.18</i>)	73
7.5.2.	Number of flocks under control programme (<i>contrFlocks PRV.19</i>)	74
7.5.3.	Number of clinically affected herds (<i>affectHerds PRV.20</i>).....	74

7.5.4. Vaccination status (<i>vaccination PRV.29</i>)	74
7.6. Information about the result	74
7.6.1. Total units tested (<i>totUnitsTested PRV.21</i>)	74
7.6.2. Total units positive (<i>totUnitsPositive PRV.22</i>)	75
7.6.3. Quantity (<i>quantity PRV.24</i>)	75
7.6.4. Number of units tested (<i>unitsTested PRV.25</i>)	75
7.6.5. Number of units positive (<i>unitsPositive PRV.26</i>)	75
7.7. Information about the test method	76
7.7.1. Method (<i>anMethCode PRV.23</i>)	76
7.7.2. Sample weight (<i>sampWeight PRV.15</i>)	77
7.7.3. Sample weight unit (<i>sampWeightUnit PRV.16</i>)	77
7.8. Additional information	77
7.8.1. Comment (<i>resComm PRV.27</i>)	77
8. Text forms data model 2015	92
8.1. Introduction	92
8.2. General information and identification of the data	92
8.2.1. Reporting year (<i>repYear TXF.01</i>)	92
8.2.2. Reporting country (<i>repCountry TXF.02</i>)	92
8.2.3. Language (<i>lang TXF.03</i>)	92
8.2.4. Zoonotic agent (<i>zoonosis TXF.04</i>)	92
8.2.5. Matrix (<i>matrix TXF.05</i>)	92
8.3. Information about the sampling	92
8.3.1. Sampling stage (<i>sampStage TXF.06</i>)	92
8.3.2. Sample type (<i>sampType TXF.07</i>)	92
8.3.3. Sampling context (<i>sampContext TXF.08</i>)	93
8.3.4. Sampler (<i>sampler TXF.09</i>)	93
8.3.5. Sampling strategy (<i>progSampStrategy TXF.10</i>)	93
8.4. Information about paragraph	93
8.4.1. Paragraph type (<i>paragraph TXF.11</i>)	93
8.4.2. Subparagraph title order (<i>subTitleOrder TXF.12</i>)	93
8.4.3. Sampling details (<i>sampDetails TXF.13</i>)	93
8.4.4. Value (<i>value TXF.14</i>)	94
References	97
Abbreviations	98

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.

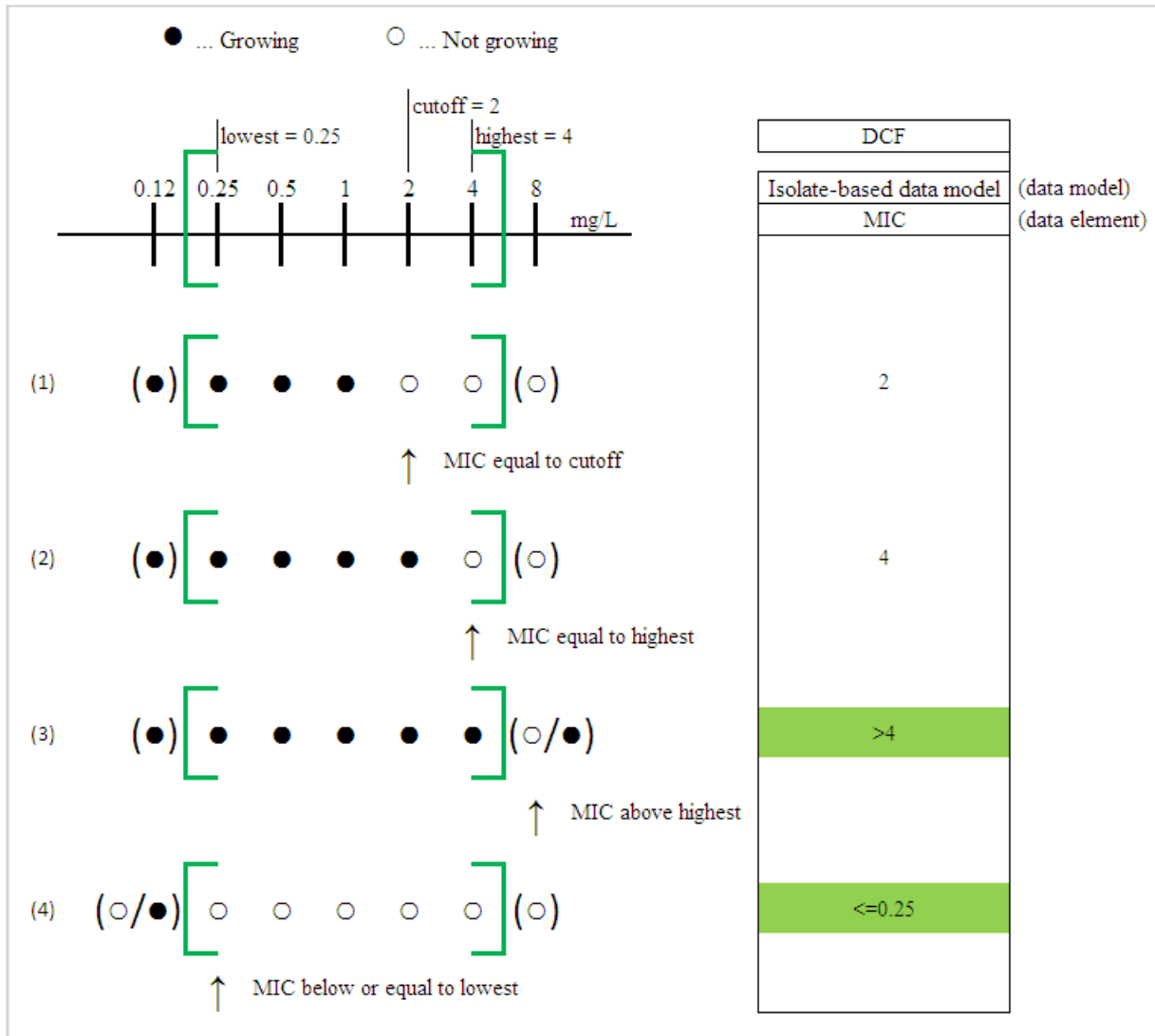


Figure 2: MIC in the isolate-based data model. The right-hand column displays which MIC values should be reported for the respective test results in the data element *MIC* (MIC values have to be coded before transmission to DCF)

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 methicillin-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 carcass 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 carcass 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_CARBAPENEM). 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

Histamine														
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
				then a value in target must be reported
PRV.19	contrFlocks	E	PRV03	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	if the value in zoonosis is in level 2 VTEC, then a value in anMethCode should be reported
PRV.24	quantity	E	PRV29	If the value in anMethCode is `Enumeration/Quantitative method' ('F141A'), or HPLC ('F018A') then the value in quantity must be reported

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 alphanumeric 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