TECHNICAL REPORT

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 2014, for 2013 data[1]

European Food Safety Authority [2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

EFSA is tasked with coordinating the reporting of zoonoses, zoonotic agents, animal population, antimicrobial resistance and food-borne outbreaks in the European Union under the Directive 2003/99/EC as well as analysing and summarising the data collected. For data collection purposes EFSA has created the Data Collection Framework application. To support reporting countries in data submission using XML/Excel/CSV data transfer, specific guidelines are given in this report covering the reporting of qualitative, quantitative and isolate-based quantitative antimicrobial resistance data in food, animals and feed as well as of prevalence data on zoonoses and food-borne contaminants, *Salmonella* serovar sand phagetypes, food-borne outbreak data, animal population data, disease status data and sample-based food data and text forms. The specific aim of these data dictionaries is to guide the reporting of information deriving from the year 2013 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 models to be used for the XML/Excel/CSV data transmission through the Data Collection Framework. 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.

© European Food Safety Authority, 2014

KEY WORDS

antimicrobial resistance, prevalence, food-borne outbreak, Data Collection Framework, data models

[1] On request from EFSA, Question No EFSA-Q-2014-00053, approved on 25 March 2014.

[2] Correspondence: zoonoses_support@efsa.europa.eu

[3] Acknowledgement: EFSA wishes to thank the members of the Scientific Nework for Zoonoses Monitoring Data that reviewed this report, and EFSA staff members: Francesca Riolo, Kenneth Mulligan, Verena Spiteller, Mario Monguidi, Mary Gilsenan, Valentina Rizzi, Pierre-Alexandre Beloeil, Anca Stoicescu, Frank Boelaert, Doreen Dolores Russell and Chiara Guescini for the preparation work on this technical output.

Suggested citation: European Food Safety Authority, 2014; 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 2014, for 2013 data. EFSA supporting publication 2014:EN-577. 102 pp.

Available online: www.efsa.europa.eu/publications

© European Food Safety Authority, 2014

SUMMARY

The Directive 2003/99/EC[4] lays down the European Union (EU) system for monitoring and reporting of information on zoonoses, which obligates the EU Member States to collect data on zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks. The European Food Safety Authority is assigned the tasks of examining the data collected and preparing the European Union Summary Reports in collaboration with the European Centre for Disease Prevention and Control (ECDC).

For the reporting of the annual data, EFSA currently provides a manual web-based reporting application (Zoonoses Web Application) and a Data Collection Framework (DCF) that allows data providers to submit data in XML/Excel/CSV formats through a web interface or a web service, respectively. 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/CSV data transfer, specific guidelines are given in this report covering the reporting of qualitative, quantitative and isolate-based quantitative antimicrobial resistance data in food, animals and feed as well as of prevalence data on zoonoses and food-borne contaminants, food-borne outbreak data, animal population data, disease status data and sample-based food data and text forms. These data dictionaries are specifically aimed at guiding the reporting of information deriving from the year 2013 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 models to be used for the XML/Excel/CSV data transmission through the Data Collection Framework (DCF). In particular the data elements to be reported on 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 (pick lists 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 pick list the name of the pick list 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 pick list that apply to a specific data element and are documented in the form of columns indicating if a term belongs (TRUE) or not (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 and disease status tables and text forms are given in the sections A-G.

Further information on the scientific aspects of the data to be reported can be found in 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 2013 (EFSA, 2014a), Manual for reporting on antimicrobial resistance in the framework of Directive 2003/99/EC and indicator bacteria for information derived from the year 2013 (EFSA, 2014b) and in the Manual for Reporting on food-borne outbreaks in accordance with Directive 2003/99/EC from the year 2013 (EFSA, 2014c). Detailed guidelines for reporting on antimicrobial resistance data have been issued by EFSA for specific pathogens (*Salmonella* and *Campylobacter*), indicator bacteria (commensal *Escherichia coli* and *Enterococcus* spp.) and methicillin-resistant *Staphylococcus aureus* (MRSA) (EFSA, 2012a, b, c).

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

TABLE OF CONTENTS

Abstract 1
Summary 2
Table of contents 3
Background as provided by EFSA 8
Terms of reference as provided by EFSA 8
A) AMR isolate-based data model 2013 9
1. Introduction 9
2. Illustrative example of how to use the data model 9
2.1. How to report the Minimum Inhibitory Concentration (MIC) 12
3. General information and identification of the isolate 13
3.1. Result code (*resultCode AMR.01*) 13
3.2. Reporting year (*repYear AMR.02*) 13
3.3. Reporting country (*repCountry AMR.03*) 13
3.4. Language (*lang AMR.04*) 13
4. Information about type and source of samples and isolates 13
4.1. Zoonotic agent (*zoonosis AMR.05*) 13
4.2. Matrix (*matrix AMR.06*) 14
5. Information about the sampling performed 15
5.1. Total units tested (*totUnitsTested AMR.07*) 15
5.2. Total units positive (*totUnitsPositive AMR.49*) 15
5.3. Total samples tested (*totSampUnitsTested AMR.44*) 16
5.4. Total samples positive (*totSampUnitsPositive AMR.50*) 16
5.5. Sampling unit type (*sampUnitType AMR.45*) 16
5.6. Sampling stage (*sampStage AMR.08*) 16
5.7. Sample origin (*sampOrig AMR.46*) 16
5.8. Sample type (*sampType AMR.09*) 16
5.9. Sampling context (*sampContext AMR.10*) 17
5.10. Sampler (*sampler AMR.11*) 17
5.11. Programme code (*progCode AMR.12*) 17
5.12. Sampling strategy (*progSampStrategy AMR.13*) 17
5.13. Sampling details (*sampDetails AMR.14*) 17
5.14. Area of sampling (*sampArea AMR.15*) 17
6. Information about the laboratory 17
6.1. Laboratory identification code (*labCode AMR.16*) 17
6.2. Laboratory isolate code (*labIsolCode AMR.17*) 18
6.3. Total number of isolates in the laboratory *(labTotIsol AMR.18)* 18
7. Information about the sampling and testing for antimicrobial susceptibility 18
7.1. Sampling year/month/day (*sampY/sampM/sampD AMR.19/AMR.20/AMR.21*) 18
7.2. Isolation year/month/day *(isolY/isolM/isolD AMR.22/AMR.23/AMR.24*) 18
7.3. Susceptibility test year/month/day (*analysisY/analysisM/analysisD AMR.25/AMR.26/ AMR.27*) 18
8. Information about the method and the antimicrobial 18
8.1. Method (*anMethCode AMR.28*) 18
8.2. Antimicrobial substance (*substance AMR.29*) 18
8.3. Cut-off value (*cutoffValue AMR.30*) 19
9. Information about dilution method 20
9.1. Lowest limit (*lowest AMR.31*) 20
9.2. Highest limit (*highest AMR.32*) 20
9.3. MIC value (mg/L) (*MIC AMR.33*) 20
10. Information about diffusion method 20
10.1. Disc concentration (microg) (*diskConc AMR.34*) 20
10.2. Disc diameter (mm) (*diskDiam AMR.35*) 20
10.3. IZD value (mm) (*IZD AMR.36*) 21

11. Information about further isolate characterisation 21
11.1. ESBL phenotype (*esbl AMR.38*) 21
11.2. AmpC phenotype (*ampC AMR.39*) 21
11.3. Carbapenemase phenotype (*carbapenem AMR.40*) 21
11.4. Ceftazidime synergy test (*synTestCAZ AMR.41*) 21
11.5. Cefotaxime synergy test (*synTest CTX AMR.42*) 21
11.6. Cefepime synergy test (*synTest FEP AMR.43*) 21
11.7. Performed CC MRSA characterisation (*perCC AMR.47*) 21
11.8. Performed MLST MRSA characterisation (*perMLST AMR.48*) 21
12. Additional information 22
12.1. Comment (*resComm AMR.37*) 22
B) AMR qualitative data model 2013 27
13. Introduction 27
14. Illustrative example of how to use the data model 27
15. General information 28
15.1. Reporting year (*repYear AQL.01*) 28
15.2. Reporting country (*repCountry AQL.02*) 28
15.3. Language (*lang AQL.03*) 28
16. Information about type and source of samples and isolates 28
16.1. Zoonotic agent (*zoonosis AQL.04*) 28
16.2. Matrix (*matrix AQL.05*) 30
17. Information about the sampling performed 31
17.1. Sampling stage (*sampStage AQL.06*) 31
17.2. Sample type (*sampType AQL.07*) 31
17.3. Sampling context (*sampContext AQL.08*) 31
17.4. Sampler (*sampler AQL.09*) 31
17.5. Sampling strategy (*progSampStrategy AQL.10*) 31
17.6. Sampling details (*sampDetails AQL.11*) 31
17.7. Monitoring programme (*monitProgr AQL.13*) 31
17.8. Tested (*tested AQL.15*) 32
17.9. Resistant (*resistant AQL.16*) 32
18. Information about the laboratory 32
18.1. Total number of isolates in the laboratory (*labTotIsol AQL.12*) 32
19. Information about the method and the antimicrobial 32
19.1. Antimicrobial substance (*substance AQL.14*) 32
C) AMR quantitative data model 2013 36
20. Introduction 36
21. Illustrative example of how to use the data model 36
21.1. How to report the Minimum Inhibitory Concentration (MIC) 39
22. General information 40
22.1. Reporting year (*repYear AQT.01*) 40
22.2. Reporting country (*repCountry AQT.02*) 40
22.3. Language (*lang AQT.03*) 40
23. Information about type and source of samples and isolates 40
23.1. Zoonotic agent (*zoonosis AQT.04*) 40
23.2. Matrix (*matrix AQT.05*) 41
24. Information about the sampling 42
24.1. Sampling stage (*sampStage AQT.06*) 42
24.2. Sample origin (*sampOrig AQT.22*) 42
24.3. Sample type (*sampType AQT.07*) 42
24.4. Total units tested (*totUnitsTested AQT.23*) 43
24.5. Total samples tested (*totSampUnitsTested AQT.24*) 43
24.6. Sampling unit type (*sampUnitType AQT.25*) 43
24.7. Sampling context (*sampContext AQT.08*) 43
24.8. Sampler (*sampler AQT.09*) 43

24.9. Programme code (*progCode AQT.26*) ... 43
24.10. Sampling strategy (*progSampStrategy AQT.10*) ... 44
24.11. Sampling details (*sampDetails AQT.11*) ... 44
24.12. Monitoring programme (*monitProgr AQT.14*) ... 44
25. Information about the laboratory ... 44
25.1. Total number of isolates in the laboratory (*labTotIsol AQT.12*) ... 44
26. Information about the method and the antimicrobials ... 44
26.1. Method (*anMethCode AQT.13*) ... 44
26.2. Antimicrobial substance (*substance AQT.15*) ... 44
26.3. Cut-off value (*cutoffValue AQT.16*) ... 45
27. Information about MIC/IZD values ... 46
27.1. Lowest limit (*lowest AQT.17*) ... 46
27.2. Highest limit (*highest AQT.18*) ... 46
27.3. Range (MIC value or IZD value, considered) (*range AQT.19*) ... 46
27.4. Number of inhibited (*inhibited AQT.20*) ... 46
D) Animal population data model 2013 ... 49
28. Introduction ... 49
29. General information and identification of the data ... 49
29.1. Reporting year (*repYear POP.01*) ... 49
29.2. Reporting country (*repCountry POP.02*) ... 49
29.3. Language (*lang POP.03*) ... 49
30. Information about type and source of data ... 49
30.1. Matrix (*matrix POP.04*) ... 49
30.2. Source year (*sourceYear POP.05*) ... 49
30.3. Unit (*unit POP.06*) ... 49
30.4. Population (*population POP.07*) ... 50
31. Additional information ... 50
31.1. Comment (*resComm POP.08)* ... 50
E) Disease status data model 2013 ... 52
32. Introduction ... 52
33. General information and identification of the sample ... 52
33.1. Reporting year (*repYear DST.01*) ... 52
33.2. Reporting country (*repCountry DST.02*) ... 52
33.3. Region (*sampArea DST.03*) ... 52
33.4. Language (*lang DST.04*) ... 52
34. Information about type and source of data ... 52
34.1. Zoonotic agent (*zoonosis DST.05*) ... 52
34.2. Matrix (*matrix DST.06*) ... 52
34.3. Disease status unit (*unitDS DST.07*) ... 53
34.4. Number of units (*numUnits DST.08*) ... 53
34.5. Table name (*tableName DST.09*) ... 53
35. Additional information ... 53
35.1. Comment (*resComm DST.10*) ... 53
F) Food-borne outbreaks data model 2013 ... 73
36. Introduction ... 73
37. General constraints ... 73
37.1. Context and uniqueness of information for weak-evidence FBO reporting ... 73
37.2. Context and uniqueness of information for strong-evidence FBO reporting ... 73
38. General information and identification of the isolate ... 74
38.1. Reporting year (*repYear FBO.01*) ... 74
38.2. Reporting country (*repCountry FBO.02*) ... 74
38.3. Language (*lang FBO.03*) ... 74
39. Information about type of food-borne outbreak ... 74
39.1. Outbreak strength (*fboStrengthStrong FBO.04*) ... 74
39.2. Causative agent group (*fboAgentGroup FBO.05*) ... 74

39.3. Causative agent (*fboAgent FBO.06*) ... 74
40. Information about the outbreak ... 75
40.1. FBO national code (*fboCodeFBO.07*) ... 75
40.2. Other agents (*fboOtherAgents FBO.08*) ... 75
40.3. Outbreak type (*fboType FBO.09*) ... 75
40.4. Food vehicle (*fboVehicle FBO.10*) ... 75
40.5. More food vehicle information (*fboVehicleInfo FBO.11*) ... 75
40.6. Nature of evidence (*fboEvidence FBO.12*) ... 75
40.7. Setting (*fboSetting FBO.13*) ... 76
40.8. Place of origin of problem (*fboPlaceOrigin FBO.14*) ... 76
40.9. Origin of food vehicle (*fboVehicleOrigin FBO.15*) ... 76
40.10. Contributory factors (*fboFactor FBO.16*) ... 76
40.11. Number of outbreaks (*numOutbreaks FBO.17*) ... 76
40.12. Number of human cases (*numHumanCases FBO.18*) ... 76
40.13. Number of hospitalised (*numHospitalised FBO.19*) ... 76
40.14. Number of deaths (*numDeaths FBO.20*) ... 77
41. Additional information ... 77
41.1. Comment (*resComm FBO.21*) ... 77
G) Prevalence data model 2013 ... 81
42. Introduction ... 81
43. General constraints ... 81
43.1. Context for aggregated data elements ... 81
43.2. Reporting units positive at different level of detail (zoonosis level 2 and above) ... 82
43.3. Reporting data at various level of the matrix and sampArea data elements ... 83
43.4. Comparison with the manual web-based reporting application ... 83
44. General information and identification of the sample ... 84
44.1. Reporting year (*repYear PRV.01*) ... 84
44.2. Reporting country (*repCountry PRV.02*) ... 84
44.3. Language (*lang PRV.03*) ... 84
44.4. Zoonotic agent (*zoonosis PRV.04*) ... 85
44.5. Matrix (*matrix PRV.05*) ... 85
45. Information about the sampling ... 86
45.1. Sampling stage (*sampStage PRV.06*) ... 86
45.2. Sample origin (*sampOrig PRV.07*) ... 86
45.3. Sample type (*sampType PRV.08*) ... 86
45.4. Sampling context (*sampContext PRV.09*) ... 86
45.5. Sampler (*sampler PRV.10)* ... 86
45.6. Sampling strategy (*progSampStrategy PRV.11*) ... 86
45.7. Sampling details (*sampDetails PRV.12*) ... 86
45.8. Area of sampling (*sampArea PRV.13*) ... 87
45.9. Sampling unit (*sampUnit PRV.14*) ... 87
45.10. Sample weight (*sampWeight PRV.15*) ... 87
45.11. Sample weight unit (*sampWeightUnit PRV.16*) ... 87
45.12. Source of information (*sourceInfo PRV.17*) ... 87
45.13. Target verification (*target PRV.18*) ... 87
45.14. Number of flocks under control programme (*contrFlocks PRV.19*) ... 88
45.15. Number of clinically affected herds (*affectHerds PRV.20*) ... 88
45.16. Vaccination status (*vaccination PRV.29*) ... 88
46. Information about the result ... 88
46.1. Total units tested (*totUnitsTested PRV.21*) ... 88
46.2. Total units positive (*totUnitsPositive PRV.22*) ... 88
46.3. Quantity (*quantity PRV.24*) ... 89
46.4. Number of units tested (*unitsTested PRV.25*) ... 89
46.5. Number of units positive (*unitsPositive PRV.26*) ... 89
47. Information about the test method ... 89

47.1. Method (*anMethCode PRV.23*) ... 89
48. Additional information ... 90
48.1. Comment (*resComm PRV.27*) ... 90
I) Text forms data model 2013 ... 99
49. Introduction ... 99
49.1. General information and identification of the data ... 99
49.2. Reporting year (*repYear TXF.01*) ... 99
49.3. Reporting country (*repCountry TXF.02*) ... 99
49.4. Language (*lang TXF.03*) ... 99
50. Information about paragraph ... 99
50.1. Paragraph (*paragraph TXF.04*) ... 99
50.2. Value (*value TXF.05*) ... 99
References ... 101
Abbreviations ... 102

BACKGROUND AS PROVIDED BY EFSA

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

Based on the data reported each year, EFSA and ECDC will jointly produce an annual EU Summary Report on zoonoses, zoonotic agents and food-borne outbreaks. Similarly, the two agencies will produce a EU Summary Report on antimicrobial resistance. To support the Member States 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 runs a web-based reporting application for the annual reporting as well as the possibility of submitting data in XML/Excel format via the Data Collection Framework (DCF). The amended web application has to be tested and new XML reporting schemas created before the start of the reporting period in April each year. This is supported by revised guidance documents.

For quality improvement purposes, the EU Summary reports will be submitted every third year to the Scientific panels of Biological Hazards and Animal Health and Welfare for their review and comment.

In addition to these EU Summary Reports, EFSA will, in collaboration with ECDC and the European Medicine Agency (EMA), prepare, in the future, joint reports combining antimicrobial resistance and consumption data. These reports will be separate from the EU Summary reports and are covered by another mandate (M-2012-0209).

TERMS OF REFERENCE AS PROVIDED BY EFSA[5]

The BIOCONTAM and DATA units[6] are invited to:

- prepare and publish the EU Summary Reports on Zoonoses, Zoonotic agents and Food-borne Outbreaks in 2012, 2013 and 2014 in close collaboration with ECDC;
- prepare and publish the EU Summary Report on Antimicrobial Resistance in 2012, 2013 and 2014 in close collaboration with ECDC;
- revise the manual for reporting on zoonoses, zoonotic agents and antimicrobial resistance each year, and publish it as an EFSA technical report;
- revise the manual for reporting on food-borne outbreaks when appropriate, and publish it as an EFSA technical report;
- to revise the user manual for the web reporting application each year and publish it as an EFSA technical report;
- to 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 sixth 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.

[5] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?mandate=M-2013-0063.
[6] Since 1st January 2014, these tasks were moved from former BIOMO unit to the new BIOCONTAM and DATA units.

A) AMR ISOLATE-BASED DATA MODEL 2013

1. Introduction

This data dictionary provides guidance for reporting on antimicrobial resistance (AMR) in animals and food at isolate level pursuant to Article 9 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/CSV transmission of isolate-based data on antimicrobial resistance through the EFSA Data Collection Framework (DCF).

The EFSA data model for isolate-based AMR data is summarised in Table 5: and the business rules are presented in Table 6: .

Although this data model allows also for reporting results of diffusion methods, Member States (MSs) are strongly recommended to report quantitative Minimum Inhibitory Concentration (MIC) data from dilution methods.

Reporting isolate-based AMR data replaces the reporting of the same data in an aggregated form (quantitative or qualitative); therefore, aggregated data should not be reported where isolate-based data are submitted.

2. Illustrative example of how to use the data model

An example of how to report results on six isolates tested by dilution method for susceptibility to gentamicin and cefotaxime by using the AMR isolate-based data model, is shown in Table 1: . It is intended to point out 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. It is noteworthy 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 Zoonoses Web Application. Figure 1: presents the data shown in Table 1: after aggregation and migration to the Zoonoses Web Application, while Figure 2: 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	Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	160	500	280	isol1	42	Aminoglycosides - Gentamicin	2	0.5	32	2
isol1_CTX	Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	160	500	280	isol1	42	Cephalosporins - Cefotaxime	0.5	0.25	4	<=0.25
isol2_GEN	Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	160	500	280	isol2	42	Aminoglycosides - Gentamicin	2	0.5	32	32
isol2_CTX	Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	160	500	280	isol2	42	Cephalosporins - Cefotaxime	0.5	0.25	4	<=0.25
isol3_GEN	Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	160	500	280	isol3	42	Aminoglycosides - Gentamicin	2	0.5	32	32
isol3_CTX	Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	160	500	280	isol3	42	Cephalosporins - Cefotaxime	0.5	0.25	4	0.5
isol4_GEN	Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	160	500	280	isol4	42	Aminoglycosides - Gentamicin	2	0.5	32	32
isol4_CTX	Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	160	500	280	isol4	42	Cephalosporins - Cefotaxime	0.5	0.25	4	4
isol5_GEN	Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	160	500	280	isol5	42	Aminoglycosides - Gentamicin	2	0.5	32	>32
isol5_CTX	Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	160	500	280	isol5	42	Cephalosporins - Cefotaxime	0.5	0.25	4	4
isol6_GEN	Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	160	500	280	isol6	42	Aminoglycosides - Gentamicin	2	0.5	32	>32
isol6_CTX	Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	160	500	280	isol6	42	Cephalosporins - Cefotaxime	0.5	0.25	4	>4

S. Saintpaul	Turkeys - fattening flocks - before slaughter - at farm - Control and eradication programmes														
Isolates out of a monitoring program (yes/no)	yes														
Number of isolates available in the laboratory	42														
Antimicrobials:	Cut-off value	N	n	0.12	0.25	0.5	1	2	4	8	16	32	64	lowest	highest
Aminoglycosides - Gentamicin	2	6	5					1				3	2	0.5	32
Cephalosporins - Cefotaxime	0.5	6	3		2	1			2	1				0.25	4

Figure 1: Example data in a quantitative AMR table (Dilution method) in the Zoonoses Web Application


```xml
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<dataset>
	<result>
		<resultCode>isol1_GEN</resultCode>
		<repYear>2013</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>SalmControl</progCode>
		<progSampStrategy>ST50A</progSampStrategy>
		<labCode>NRL-Salm</labCode>
		<labIsolCode>isol1</labIsolCode>
		<labTotIsol>42</labTotIsol>
		<sampY>2013</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 2: Example data of the first row of Table 1: in XML according to DCF's AMR isolate-based data model

2.1. How to report the Minimum Inhibitory Concentration (MIC)

Figure 3: shows how MIC values relate to the data reported in the isolate-based data model through DCF.

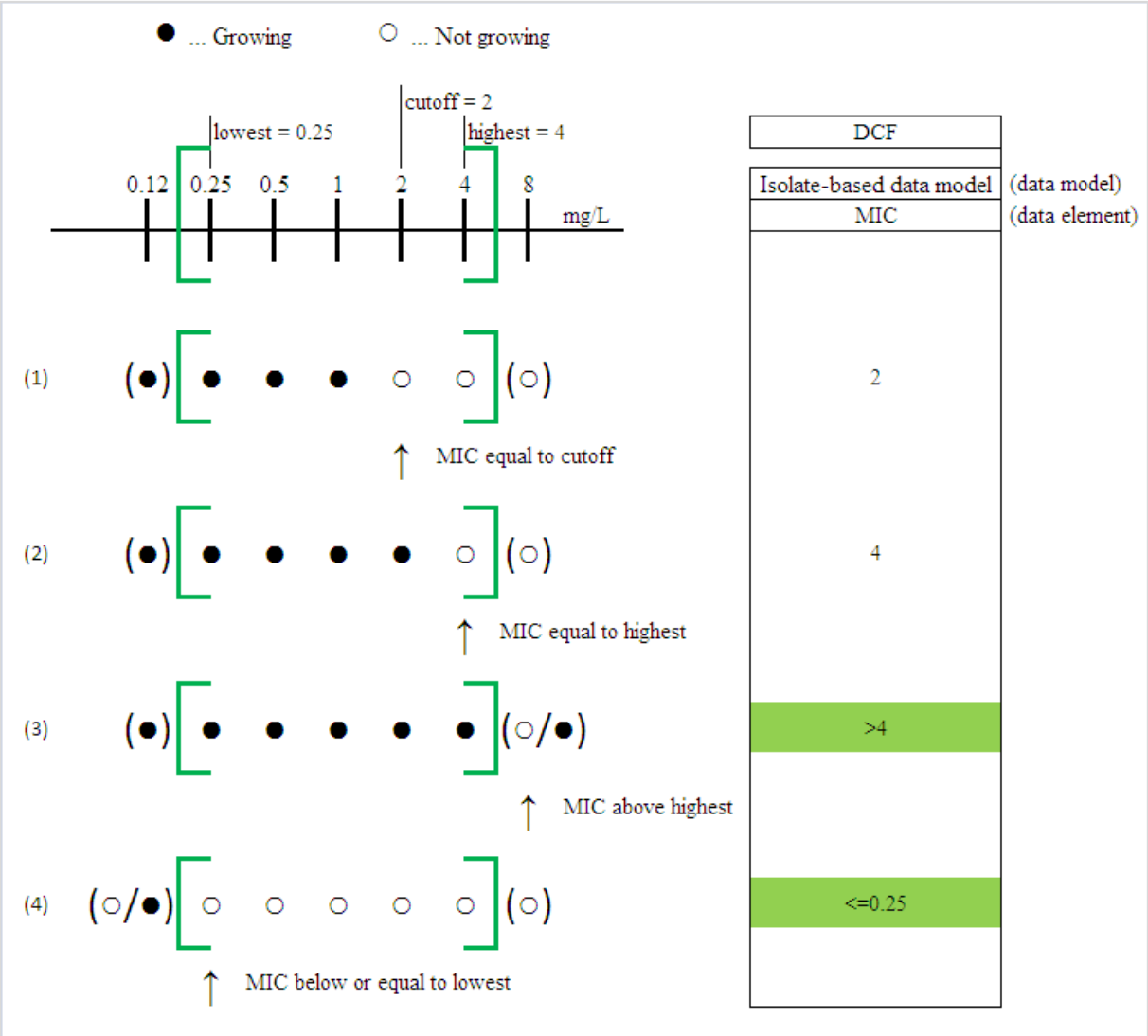

Figure 3: Minimum Inhibitory Concentration in the isolate-based data model: The right hand column displays which MIC values should be reported for the respective test results in the data element *MIC* (MIC values have to be coded before transmission to DCF)

3. General information and identification of the isolate

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

This data element is **mandatory**. It should be unique for the sender and allows identification of the record. It will be used by EFSA should an update be needed in a future data transmission or if additional clarifications are required.

3.2. 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.

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

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

3.4. Language (*lang AMR.04*)

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

4. Information about type and source of samples and isolates

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

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_PARAM_ZOO, domain: D_AMR_zoonosis). It enables reporting, when relevant, of the bacterial agents tested for antimicrobial resistance; specifying the genera, the species as well as the serovar/serotype/phagetype/*spa*-type of the bacteria in question particularly for *Salmonella* and MRSA.

It is expected that AMR data are reported for *Salmonella*, at serovar level, for *Campylobacter jejuni*, *Campylobacter coli*, indicator *Escherichia coli*, indicator *Enterococcus faecium* indicator *Enterococcus faecalis* and methicillin-resistant *Staphylococcus aureus* (MRSA).

For *Salmonella*, consistent reporting of AMR data at the serovar level (level 2 term) is recommended, 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. Certain serovars of public health importance are listed in Table 2: . If desired and for further refinement, susceptibility data can be reported at an even greater level of detail to 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').

AMR data on '*Enterococcus*, pathogenic - *E. faecium'* (code 'RF-00004078-MCG') and '*Enterococcus*, pathogenic - *E. faecalis*' (code 'RF-00004076-MCG') should also be reported separately.

Note that indicator bacteria should be reported using level 2 of the pick list 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* as '*Enterococcus*, non-pathogenic - *E. faecium'* (code 'RF-00000114-MCG') and indicator *Enterococcus faecalis* as '*Enterococcus*, non-pathogenic - *E. faecalis*' (code 'RF-00000113-MCG').

Regarding MRSA the pick list 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.

Table 2: *Salmonella* serovars of public health importance and relative codes for DCF

Animal species/food	*Salmonella* serovar (Level 2 term)	Code for DCF
All animal species and derived meat	*S.* Typhimurium	RF-00002265-MCG
	S. Typhimurium, monophasic	RF-00003051-MCG
Gallus gallus (fowl): Breeders of egg production line, breeders of meat production line, laying hens, broilers and broiler meat	*S.* Enteritidis	RF-00002135-MCG
	S. Agona	RF-00001667-MCG
	S. Virchow	RF-00001152-MCG
	S. Hadar	RF-00001843-MCG
	S. Kentucky	RF-00000640-MCG
	S. Infantis	RF-00001894-MCG
Broilers and broiler meat	*S.* Java[(a)]	RF-00001325-MCG
Turkeys and turkey meat	*S.* Enteritidis	RF-00002135-MCG
	S. Agona	RF-00001667-MCG
	S. Kentucky	RF-00000640-MCG
	S. Newport	RF-00000960-MCG
	S. Saintpaul	RF-00001234-MCG
Pigs: breeding pigs, piglets, weaners to growers, fattening pigs and swine meat	*S.* Derby	RF-00001592-MCG
	S. Agona	RF-00001667-MCG
Cattle: dairy cattle, beef cattle and bovine meat	*S.* Dublin	RF-00001517-MCG
	S. Infantis	RF-00001894-MCG

(a): Previously known as *S.* Paratyphi B var. Java.

4.2. Matrix (*matrix AMR.06*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_MATRIX). It represents the food/feed category or the animal species from which the isolate tested for AMR derives. Also 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).

As regards the reporting of the food-producing animal species 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. It is therefore recommended that AMR data are reported for the animal species/food categories listed in Table 3: .

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

Table 3: Recommended categories to be used for the reporting of the origin of the isolates

Bacteria	Animal species/Food categories
Salmonella	• Laying hens, broilers, fattening turkeys, fattening pigs, calves (under 1 year)[(a)], young bovines (1-2 years) and adult cattle (>2 years) • Broiler meat, turkey meat, pig meat and bovine meat
Campylobacter	• Broilers, fattening turkeys, fattening pigs, calves (under 1 year)[(a)], young bovines (1-2 years) and adult cattle (>2 years) • Broiler meat, turkey meat
Indicator *E. coli*	• Laying hens, broilers, fattening turkeys, fattening pigs, calves (under 1 year)[(a)], young bovines (1-2 years) and adult cattle (>2 years) • Broiler meat, turkey meat, pig meat and bovine meat
Indicator enterococci	• Laying hens, broilers, fattening pigs, fattening turkeys, calves (under 1 year)[(a)], young bovines (1-2 years) and adult cattle (>2 years) • Broiler meat, turkey meat, pig meat and bovine meat
Methicillin-resistant *Staphylococcus aureus* (MRSA)	• Broilers, breeders of *Gallus gallus*, meat sector, fattening turkeys, breeders turkeys, fattening pigs, breeders of pigs, dairy cattle, fattening veal calves (under 1 year of age), beef animals, horses • Fresh broiler meat, fresh turkey meat, fresh pig meat, fresh bovine meat, fresh veal, raw milk and/or raw milk products

(a): MSs monitoring AMR in fattening calve populations that are older than 12 months of age, and typically raised for the production of *rosé* veal, may report data under the category 'veal calves (at or above 1 year)' (code 'A0CHK').

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').

5. Information about the sampling performed

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

This data element is **optional**. 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, strains or serovars (or other zoonotic agent) 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 for all isolates coming from the same monitoring context should be reported.

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

This data element is **optional**. 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, strains or serovars (or other zoonotic agent) 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 for all isolates coming from the same monitoring context should be reported.

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

This data element is **optional**. 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 monitoring 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 (level2)) or a food category. These data may be used to assess the prevalence of resistant bacteria. Please note that the same number for all isolates coming from the same monitoring context should be reported, so that data deriving from clinical investigations, for example, are not mixed with with data deriving from epidemiological monitoring of AMR.

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

This data element is **optional**. 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 monitoring 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 (level2)) or a food category. Please note that the same number for all isolates coming from the same monitoring context should be reported so that data deriving from clinical investigations, for example, are not mixedwith data deriving from epidemiological monitoring of AMR. These data may be used to assess the prevalence of resistant bacteria, and it should less than or equal to Total number of samples tested.

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

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (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’).

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

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (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. ‘at farm’ (code ‘E101A’), ‘at slaughterhouse’ (code ‘E311A’) or ‘at retail’ (code ‘E520A’).

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

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (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’).

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

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (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’).

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

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (ZOO_CAT_SRCTYP, domain: D_ALL_sampContext). It identifies the type of programme in the framework of which samples/isolates 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 case of clinical isolates the item 'Clinical investigations' (code 'K020A') should be used. Reporting of the sampling context is recommended to enable evaluation of the representativeness of the AMR monitoring programmes.

5.10. Sampler (*sampler AMR.11*)

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (ZOO_CAT_SMPLR). It indicates the type of body who performed the sampling, e.g. 'Industry sampling' (code 'CX01A'), 'Official sampling' (code 'CX02A').

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

This data element is **optional but is recommended to be reported at national level**. Its type is alphanumeric consisting of a maximum of 20 characters. This free text data element allows reporting of a unique identification code of the programme or project in the framework of which the sample analysed has been collected. It can refer to a specific piece of EU legislation or a national or regional control or monitoring plan.

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

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (ZOO_CAT_SAMPSTR). It is the sampling strategy performed in the programme or project identified by the data element Programme code, e.g. 'Objective sampling' (code 'ST10A'), 'Census' (code 'ST50A'). Reporting of the sampling strategy is recommended to enable evaluation of the representativeness of the AMR monitoring programmes.

5.13. 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).

5.14. 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 pick list (ZOO_CAT_NUTS). It indicates the area or region or province in the country (in accordance to the 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.

6. Information about the laboratory

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

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

6.2. 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.

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

This data element is **mandatory**. This is a numerical data element (reported as '-1' if unknown). It means the total number of isolates available in the laboratory testing for AMR for the specific bacterial species or serovars in relation to the given matrix. The reporting should be made at the bacterial species level for *C. jejuni*, *C. coli*, *E. coli* and *E. faecium* and *E. faecalis*. Regarding *Salmonella*, it is recommended to report at the serovar level if the isolates available have been serotyped. Regarding MRSA, it is recommended to report 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.

7. Information about the sampling and testing for antimicrobial susceptibility

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

Sampling year and month are **mandatory**, sampling day is **optional**. 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. Reporting of the sampling date is recommended to enable evaluation of possible seasonal effects.

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

These data elements are **optional**. 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. It corresponds to the date when the isolation of the isolate in question from the biological sample was performed. The isolation date may be used as surrogate for the sampling date, if the latter is missing.

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

These data elements are **optional**. 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. It corresponds to the date when the AMR testing was performed.

8. Information about the method and the antimicrobial

8.1. Method (*anMethCode AMR.28*)

This data element is **mandatory**. It contains codes linked to a pick list (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').

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

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_PARAM_SUB). It indicates the antimicrobial substance against which the isolates were tested. Antimicrobial substances are listed within the pick list 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 4: (Please note that in the pick list you could find also other antimicrobial substance). Furthermore the lists have been extended to include all substances recommended for susceptibility testing in the 'Technical specifications on the harmonised monitoring and reporting of antimicrobial resistance in *Salmonella*, *Campylobacter* and indicator *Escherichia coli* and *Enterococcus* spp. bacteria transmitted through food' (EFSA, 2012b) 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, 2012c).

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

Recommended set: cefoxitin, chloramphenicol, ciprofloxacin, clindamycin, erythromycin, gentamicin, linezolid, mupirocin, quinupristin/dalfopristin, sulfamethoxazole/trimethoprim, tetracycline, tiamulin, vancomycin.

Optional set: ceftobiprole, kanamycin, tigecycline, fusidic acid, daptomycin.

Table 4: Recommended antimicrobials for susceptibility testing and their codes for DCF

Salmonella	***C. jejuni*/*C. coli***	**Indicator *E. coli***	**Indicator enterococci**
Ampicillin RF-00000688-VET	Erythromycin RF-00000589-VET	Ampicillin RF-00000688-VET	Ampicillin RF-00000688-VET
Cefotaxime RF-00000717-VET	Ciprofloxacin RF-00000695-VET	Cefotaxime RF-00000717-VET	Chloramphenicol RF-00000525-VET
Chloramphenicol RF-00000525-VET	Tetracyclines[(a)]	Chloramphenicol RF-00000525-VET	Erythromycin RF-00000589-VET
Ciprofloxacin RF-00000695-VET	Streptomycin RF-0899-001-PPP	Ciprofloxacin RF-00000695-VET	Gentamicin RF-00000536-VET
Gentamicin RF-00000536-VET	Gentamicin RF-00000536-VET	Gentamicin RF-00000536-VET	Linezolid RF-00000758-VET
Nalidixic acid RF-00000547-VET	-	Nalidixic acid RF-00000547-VET	Quinopristin/Dalfopristin RF-00000777-VET
Streptomycin RF-0899-001-PPP	-	Streptomycin RF-0899-001-PPP	Streptomycin RF-0899-001-PPP
Sulfonamides[(a)]	-	Sulfonamides[(a)]	Tetracyclines[(a)]
Tetracyclines[(a)]	-	Tetracyclines[(a)]	Vancomycin RF-00000569-VET
Trimethoprim RF-00000562-VET	-	Trimethoprim RF-00000562-VET	-

(a): In the case of sulphonamides and tetracyclines, these are classes of substances. Information can be reported at either the level of the class of substances, e.g. sulfonamides (code 'RF-00000690-VET'), tetracyclines (code 'RF-00000672-VET') or more in detail at the level of the actual substances tested, e.g. sulfamethoxazole (code 'RF-00000612-VET') or tetracycline (code 'RF-00000670-VET'). If known, it is recommended to report the substance for the sake of consistency.

8.3. 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 or disc diffusion methods 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. Nevertheless, MSs may prefer to use an *ad hoc* cut-off value for the interpretation of their national data.

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

9. Information about dilution method

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

This data element is **mandatory** for **dilution** method data. However, in the data model, it is marked as optional because in case of diffusion data, this data element must be left empty. It contains codes linked to a pick list (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 *Lowest limit* must be below *Highest limit*.

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

This data element is **mandatory** for **dilution** method data. However, in the data model, it is marked as optional because in case of diffusion data, this data element must be left empty. It contains codes linked to a pick list (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 *Highest limit* must be above *Lowest limit*.

9.3. MIC value (mg/L) (*MIC AMR.33*)

This data element is **mandatory** for **dilution** method data. However, in the data model, it is marked as optional because in case of diffusion data, this data element must be left empty. It represents the Minimum Inhibitory Concentration value and contains codes linked to a pick list (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 <u>lower than or equal to</u> the lowest concentration tested. If growth is still observed at the highest concentration tested, the MIC value should be reported as strictly <u>greater than</u> 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 interpret correctly the MIC due to left censoring.

10. Information about diffusion method

10.1. 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 in case of dilution data, this data element must be left empty. The data element allows entering numeric data values with floating-point decimal numbers. It corresponds to the amount of the added antimicrobial in the test disc, which is reported by default in microgram.

10.2. 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 in case of dilution data, this data element must be left empty. The data element allows entering numeric data values with floating-point decimal numbers. It corresponds to the diameter of the disc used in the testing, which is reported by default in millimeter.

10.3. 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 in case of dilution data, this data element must be left empty. It contains codes linked to a pick list (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 millimetre.

11. Information about further isolate characterisation

11.1. ESBL phenotype (*esbl AMR.38*)

This data element is **optional** and contains codes linked to a pick list (ZOO_CAT_ESBL). It allows MSs to report ESBL (Extended-spectrum beta-lactamase) phenotypes in isolates of *Salmonella* and *E. coli* through enzyme formulas (e.g. TEM-52, SHV-2, CTX-M-1) when these are known.

11.2. AmpC phenotype (*ampC AMR.39*)

This data element is **optional** and contains codes linked to a pick list (ZOO_CAT_AMPC). It allows MSs to report AmpC phenotypes in isolates of *Salmonella* and *E. coli* through enzyme formulas (e.g. CMY-2, AAC-1) when these are known.

11.3. Carbapenemase phenotype (*carbapenem AMR.40*)

This data element is **optional** and contains codes linked to a pick list (ZOO_CAT_CARBAPENEM). It allows MSs to report carbapenemase phenotypes in isolates of *Salmonella* and *E. coli* through enzyme formulas (e.g. KPC, OXA-48)when these are known.

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

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

11.5. Cefotaxime synergy test (*synTest CTX AMR.42*)

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

11.6. Cefepime synergy test (*synTest FEP AMR.43*)

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

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

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

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

This data element is **optional** and contains codes linked to a pick list (ZOO_CAT_YESNO). It allows MSs to report whether the determination of the MRSA multi-locus sequence type results from an

actually performed genetic test ('Yes' code 'Y') or inferred from other tests/online databases ('No' code 'N').

12. Additional information

12.1. Comment (*resComm AMR.37*)

This free text data element is **optional**. This is a free text of maximum 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 AMR.04 Language).

Table 5: EFSA data model for isolate-based antimicrobial resistance data reporting

Element Code	Element Name	Short Element name for XML/Excel/CSV transfer	Type	Constraint	Pick list	Domain
AMR.01	Result code	resultCode	xs:string(60)	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 number of samples tested	totUnitTested	xs:integer	Optional		
AMR.44	Total number of sampling units tested	totSampUnitsTested	xs:integer	Optional		
AMR.45	Sampling unit type	sampUnitType	xs:string(5)	Optional	ZOO_CAT_UNIT	D_AMR_sampUnitType
AMR.08	Sampling stage	sampStage	xs:string(5)	Optional	ZOO_CAT_SMPNT	D_PRV_sampStage
AMR.46	Sample origin	sampOrig	xs:string(2)	Optional	ZOO_CAT_COUNTRY	
AMR.09	Sample type	sampType	xs:string(5)	Optional	ZOO_CAT_SMPTYP	
AMR.10	Sampling context	sampContext	xs:string(5)	Optional	ZOO_CAT_SRCTYP	D_ALL_sampContext
AMR.11	Sampler	sampler	xs:string(5)	Optional	ZOO_CAT_SMPLR	
AMR.12	Programme code	progCode	xs:string(20)	Optional		
AMR.13	Sampling strategy	progSampStrategy	xs:string(5)	Optional	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	Mandatory		
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)	Optional		
AMR.22	Isolation year	isolY	xs:integer(4)	Optional		
AMR.23	Isolation month	isolM	xs:integer(2)	Optional		

Table 5 (continued): EFSA data model for isolate-based antimicrobial resistance data reporting

Element Code	Element Name	Short Element name for XML/Excel/CSV transfer	Type	Constraint	Pick list	Domain
AMR.24	Isolation day	isolD	xs:integer(2)	Optional		
AMR.25	Susceptibility test year	analisysY	xs:integer(4)	Optional		
AMR.26	Susceptibility test month	analisysM	xs:integer(2)	Optional		
AMR.27	Susceptibility test day	analisysD	xs:integer(2)	Optional		
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)	Optional	ZOO_CAT_FIXMEAS	D_AMR_number
AMR.32	Highest limit	highest	xs:string(5)	Optional	ZOO_CAT_FIXMEAS	D_AMR_number
AMR.33	MIC value (mg/L)	MIC	xs:string(5)	Optional	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 phenotype	esbl	xs:string(5)	Optional	ZOO_CAT_ESBL	
AMR.39	AmpC phenotype	ampC	xs:string(5)	Optional	ZOO_CAT_AMPC	
AMR.40	Carbapenemase phenotype	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 6: EFSA business rules for isolate-based antimicrobial resistance data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
AMR.02	repYear	E	AMR01	Value of *repYear* must be = data collection reporting year;
AMR.04	lang	W	AMR08	WARNING. Value of *lang* should be = 'English' ('en');
AMR.05	zoonosis	E	AMR34	Value of *zoonosis* must be reported at least at level_2 of the pick list (domain D_AMR_zoonosis);
AMR.06	matrix	W	AMR32	WARNING. For data interpretation purposes, it is advised not to use general categories: value of *matrix* should NOT be IN ['Gallus gallus (fowl)' ('A006921A'), 'Gallus gallus (fowl) - unspecified' ('A031721A'), 'Compound feedingstuffs, not specified' ('A001421A')];
AMR.07	totUnitsTested	E	AMR02	Value of *totUnitsTested* must be > 0;
AMR.07	totUnitsTested	E	AMR38	If provided value of *totUnitsTested* must be > 0;
AMR.08	sampStage	W	AMR28	WARNING. For data interpretation purposes, value of *sampStage* should be <> NULL;
AMR.10	sampContext	W	AMR29	WARNING. For data interpretation purposes, value of *sampContext* should be <> NULL;
AMR.11	sampler	W	AMR30	WARNING. For data interpretation purposes, value of *sampler* should be <> NULL;
AMR.13	progSampStrategy	W	AMR31	WARNING. For data interpretation purposes, *progSampStrategy* should be <> NULL;
AMR.18	labTotIsol	E	AMR17	Value of *labTotIsol* must be >= -1;
AMR.19	sampY	E	AMR04	Value of sampY must be >= 1995 AND <= data collection reporting year;
AMR.22	isolY	E	AMR05	Value of isolY must be >= 1995 AND <= data collection reporting year;
AMR.25	analysisY	E	AMR06	Value of analysisY must be >= 1995 AND <= data collection reporting year;
AMR.30	cutoffValue	E	AMR07	Value of cutoffValue must be > 0 AND <= 5000;
AMR.30	cutoffValue	E	AMR24	Value of *cutoffValue* must be >= value of *lowest* AND < value of *highest;*
AMR.30	cutoffValue	E	AMR37	Value of *cutoffValue* must be the same for each combination of values in *zoonosis* and *substance;*
AMR.31	lowest	E	AMR09	If value of *anMethCode* is in level_2 = 'dilution' then value of *lowest* must be <> NULL;
AMR.32	highest	E	AMR10	If value of *anMethCode* is in level_2 = 'dilution' then value of *highest* must be <> NULL;
AMR.33	MIC	E	AMR11	If value of *anMethCode* is in level_2 = 'dilution' then value of *MIC* must be <> NULL;
AMR.33	MIC	E	AMR18	If value of *MIC* contains '<=' then the number in the value of *MIC* must be = value of *lowest;*
AMR.33	MIC	E	AMR19	If value of *MIC* contains '>' then the number in the value of *MIC* must be = value of *highest;*

Table 6 (continued): EFSA business rules for isolate-based antimicrobial resistance data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
AMR.33	MIC	E	AMR21	If value of *MIC* is numeric then value of *MIC* must be > value of *lowest* AND <= value of *highest;*
AMR.34	diskConc	E	AMR12	Value of *diskConc* must be > 0;
AMR.34	diskConc	E	AMR13	If value of *anMethCode* is in level_2 = 'diffusion' then value of *diskConc* must be <> NULL;
AMR.35	diskDiam	E	AMR14	If value of *anMethCode* is in level_2 = 'diffusion' then value of *diskDiam* must be <> NULL;
AMR.36	IZD	E	AMR15	If value of *anMethCode* is in level_2 = 'diffusion' then value of *IZD* must be <> NULL;
AMR.44	totSampUnitsTested	E	AMR40	If provided value of *totSampUnitsTested* must be > 0;
AMR.46	sampOrig	W	AMR33	WARNING. For data interpretation purposes, value of *sampOrig* should be <> NULL;
AMR.47	perCC	E	AMR35	If value of *zoonosis* is a MRSA clonal complex then *perCC* must be <> NULL to indicate if the result was inferred or tested;
AMR.48	perMLST	E	AMR36	If value of *zoonosis* is a MRSA MLST then *perMLST* must be <> NULL to indicate if the result was inferred or tested;
AMR.49	totUnitsPositive	E	AMR39	If provided value of *totUnitsPositive* must be > 0;
AMR.49	totUnitsPositive	E	AMR42	Value of *totUnitsPositive* must be <= *value of totUnitsTested;*
AMR.50	totSampUnitsPositive	E	AMR41	If provided value of *totSampUnitsPositive* must be > 0;
AMR.50	totSampUnitsPositive	E	AMR43	Value of *totSampUnitsPositive* must be <= *value of totSampUnitsTested;*

B) AMR QUALITATIVE DATA MODEL 2013

13. Introduction

This data dictionary provides guidance for reporting on qualitative antimicrobial resistance (AMR) data from zoonotic and indicator bacteria in animals, food and feed under the framework of Directive 2003/99/EC.

The EFSA data model for qualitative AMR data is summarised in Table 11: and the complete set of business rules applied for data validation are presented in Table 12: .

14. Illustrative example of how to use the data model

An example of how to report results on six isolates tested for susceptibility to gentamicin and cefotaxime by using the AMR qualitative data model, is shown in Table 7: . It is intended to illustrate 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. It is noteworth that the terms still need to be coded before transmission to the DCF.

Data submitted to EFSA's DCF by using the AMR qualitative data model will be migrated automatically to a qualitative AMR table in the Zoonoses Web Application. Figure 4: presents the data shown in Table 7: after migration to the Zoonoses Web Application, while Figure 5: shows how the first row of Table 7: could look in an XML file according to the AMR qualitative data model.

Table 7: 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 qualitative data model – Excel file (some mandatory columns are not displayed here and terms have to be coded before transmission to DCF).

zoonosis	matrix	labTot Isol	substance	tested	resistant
Salmonella - S. Saintpaul	Turkeys - fattening flocks	42	Aminoglycosides - Gentamicin	6	5
Salmonella - S. Saintpaul	Turkeys - fattening flocks	42	Cephalosporins - Cefotaxime	6	3

Table Antimicrobial susceptibility testing of Salmonella in Turkeys - fattening flocks - at farm - Control and eradication programmes - Census - Official and industry sampling - animal sample - faeces

Salmonella	S. Saintpaul	
Isolates out of a monitoring program (yes/no)	yes	
Number of isolates available in the laboratory	42	
Antimicrobials:	N	n
Aminoglycosides - Gentamicin	6	5
Cephalosporins - Cefotaxime	6	3

Figure 4: Example data in a qualitative AMR table in the Zoonoses Web Application

```xml
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<dataset>
	<result>
		<repYear>2013</repYear>
		<repCountry>PN</repCountry>
		<lang>en</lang>
		<zoonosis>RF-00001234-MCG</zoonosis>
		<matrix>A041277A</matrix>
		<sampStage>E101A</sampStage>
		<sampType>S005A</sampType>
		<sampContext>K021A</sampContext>
		<sampler>CX03A</sampler>
		<progSampStrategy>ST50A</progSampStrategy>
		<labTotIsol>42</labTotIsol>
		<monitProgr>Y</monitProgr>
		<substance>RF-00000536-VET</substance>
		<tested>6</tested>
		<resistant>5</resistant>
	</result>
[…]
</dataset>
```


Figure 5: Example data of the first row of Table 7: in XML according to DCF's AMR qualitative data model

15. General information

15.1. Reporting year (*repYear AQL.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.

15.2. Reporting country (*repCountry AQL.02*)

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

15.3. Language (*lang AQL.03*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_LANG, domain: D_ALL_lang), however, **only the code 'en' for 'English' should be used**, since text in the free text data element (data element AQL.11 Sampling details) should be provided in English.

16. Information about type and source of samples and isolates

16.1. Zoonotic agent (*zoonosis AQL.04*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_PARAM_ZOO, domain: D_AMR_zoonosis). It enables reporting of the bacterial agents tested for antimicrobial resistance, specifying the genera, the species as well as the serovar/serotype/phagetype/*spa*-type of the bacteria in question, whenever relevant, and in particular for *Salmonella* and MRSA.

It is expected that AMR data are reported for *Salmonella*, preferentially at serovar level, for *Campylobacter jejuni*, *Campylobacter coli*, indicator *Escherichia coli*, indicator *Enterococcus faecium*, indicator *Enterococcus faecalis* and methicillin-resistant *Staphylococcus aureus* (MRSA).

For *Salmonella* the reporting of AMR data at the serovar level (level 2 term) is recommended to be performed consistently, as it is scientifically relevant to analyse resistance at this level, in particular for the serovars of public health significance, emerging serovars and serovars exhibiting particular combinations of resistance. Certain serovars of public health importance are listed in Table 8: . If desired, susceptibility data can be reported at an even greater level of detail than the recommended level 2 term, 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').

AMR data on '*Enterococcus*, pathogenic - *E. faecium'* (code 'RF-00004078-MCG') and '*Enterococcus*, pathogenic - *E. faecalis*' (code 'RF-00004076-MCG') should also be reported separately.

Note that indicator bacteria should be reported using level 2 of the pick list 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* as '*Enterococcus*, non-pathogenic - *E. faecium'* (code 'RF-00000114-MCG') and indicator *Enterococcus faecalis* as '*Enterococcus*, non-pathogenic - *E. faecalis*' (code 'RF-00000113-MCG').

Regarding MRSA the pick list 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.

Table 8: *Salmonella* serovars of public health importance and relative codes for DCF

Animal species/food	*Salmonella* serovar (Level 2 term)	Code for DCF
All animal species and derived meat	*S*. Typhimurium	RF-00002265-MCG
	S. Typhimurium, monophasic	RF-00003051-MCG
Gallus gallus (fowl): Breeders of egg production line, breeders of meat production line, laying hens, broilers and broiler meat	*S*. Enteritidis	RF-00002135-MCG
	S. Agona	RF-00001667-MCG
	S. Virchow	RF-00001152-MCG
	S. Hadar	RF-00001843-MCG
	S. Kentucky	RF-00000640-MCG
	S. Infantis	RF-00001894-MCG
Broilers and broiler meat	*S*. Java[(a)]	RF-00001325-MCG
Turkeys and turkey meat	*S*. Enteritidis	RF-00002135-MCG
	S. Agona	RF-00001667-MCG
	S. Kentucky	RF-00000640-MCG
	S. Newport	RF-00000960-MCG
	S. Saintpaul	RF-00001234-MCG
Pigs: breeding pigs, piglets, weaners to growers, fattening pigs, and swine meat	*S*. Derby	RF-00001592-MCG
	S. Agona	RF-00001667-MCG
Cattle: dairy cattle, beef cattle and bovine meat	*S*. Dublin	RF-00001517-MCG
	S. Infantis	RF-00001894-MCG

(a): Previously known as *S*. Paratyphi B var. Java

16.2. Matrix (*matrix AQL.05*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_MATRIX). It represents the food/feed category or the animal species from which the isolate tested for AMR derives from. Also 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).

As regards the reporting of food-producing animal species investigated, it is recommended that, where appropriate, the AMR data reported are stratified by animal age/production stage and/or production type, as levels of resistance may be quite distinct between these groups, reflecting the widely differing treatment regimes, management practices and hygienic conditions encountered. It is, therefore, recommended that AMR data are reported for the animal species/food categories listed in Table 9: .

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

It is recommended that relevant animal sub-populations (corresponding to the level 2, level 3 and level 4 terms) are selected, as far as the available information makes it possible and as enabled by the detailed pick list.

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 9: Recommended food and animal categories for AMR reporting

Bacteria	Animal species/Food categories
Salmonella	• Laying hens, broilers, fattening turkeys, fattening pigs, calves (under 1 year)[(a)], young bovines (1-2 years) and adult cattle (>2 years) • Broiler meat, turkey meat, pig meat and bovine meat
Campylobacter	• Broilers, fattening turkeys, fattening pigs, calves (under 1 year)[(a)], young bovines (1-2 years) and adult cattle (>2 years) • Broiler meat, turkey meat
Indicator *E. coli*	• Laying hens, broilers, fattening turkeys, fattening pigs, calves (under 1 year)[(a)], young bovines (1-2 years) and adult cattle (>2 years) • Broiler meat, turkey meat, pig meat and bovine meat
Indicator enterococci	• Laying hens, broilers, fattening pigs, fattening turkeys, calves (under 1 year)[(a)], young bovines (1-2 years) and adult cattle (>2 years) • Broiler meat, turkey meat, pig meat and bovine meat
Methicillin-resistant *Staphylococcus aureus* (MRSA)	• Broilers, breeders of *Gallus gallus*, meat sector, fattening turkeys, breeders turkeys, fattening pigs, breeders of pigs, dairy cattle, fattening veal calves (under 1 year of age), beef animals, horses • Fresh broiler meat, fresh turkey meat, fresh pig meat, fresh bovine meat, fresh veal, raw milk and/or raw milk products

(a): Those MSs monitoring AMR in fattening calve populations that are older than 12 months of age, and typically raised for the production of *rosé* veal, may report data under the category 'veal calves (at or above 1 year)' (code 'A0CHK').

17. Information about the sampling performed

17.1. Sampling stage (*sampStage AQL.06*)

This data element is **optional but recommended to be reported to EFSA**. It contains codes linked to a pick list (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. 'at farm' (code 'E101A'), 'at slaughterhouse' (code 'E311A') or 'at retail' (code 'E520A').

17.2. Sample type (*sampType AQL.07*)

This data element is **optional but recommended to be reported to EFSA**. It contains codes linked to a pick list (ZOO_CAT_SMPTYP). It describes the biological source of the sample, e.g. 'animal sample - nasal swab' (code 'S015A'); 'food sample - carcase swab' (code 'S021A').

17.3. Sampling context (*sampContext AQL.08*)

This data element is **optional but recommended to be reported to EFSA**. It contains codes linked to a pick list (ZOO_CAT_SRCTYP, domain: D_ALL_sampContext). It identifies the type of programme in the framework of which samples/isolates 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 case of clinical isolates the item 'clinical investigations' (code 'K020A') should be used. Reporting of the sampling context is recommended to enable evaluation of the representativeness of the AMR monitoring programmes.

17.4. Sampler (*sampler AQL.09*)

This data element is **optional but recommended to be reported to EFSA**. It contains codes linked to a pick list (ZOO_CAT_SMPLR). It indicates the type of the body who performed the sampling, e.g. 'Industry sampling' (code 'CX01A'); 'Official sampling' (code 'CX02A').

17.5. Sampling strategy (*progSampStrategy AQL.10*)

This data element is **optional but recommended to be reported to EFSA**. It contains codes linked to a pick list (ZOO_CAT_SAMPSTR). It is the sampling strategy performed in the programme or project identified by the Programme code, e.g. 'Objective sampling' (code 'ST10A'), 'Census' (code 'ST50A'). Reporting of the sampling strategy is recommended to enable evaluation of the representativeness of the AMR monitoring programmes.

17.6. Sampling details (*sampDetails AQL.11*)

This data element is **optional**. This is a free text of maximum 2 000 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 (see data element AQL.03 Language).

17.7. Monitoring programme (*monitProgr AQL.13*)

This data element is **optional**. It contains codes linked to a pick list (ZOO_CAT_YESNO) with values 'Yes' (code 'Y'), 'No' (code 'N') and 'Unknown' (code 'U'). It indicates whether the tested bacterial isolates originate from a monitoring programme or not.

17.8. Tested (*tested AQL.15*)

This data element is **mandatory.** This is a numerical data element (reported as '-1' if unknown). The number of tested (N) indicates the number of isolates of the specified context that have been tested for AMR.

17.9. Resistant (*resistant AQL.16*)

This data element is **mandatory**. This is a numerical data element (reported as '-1' if unknown). It indicates the number of isolates of the specified context regarded as resistant to the specific antimicrobial substance. Resistance against an antimicrobial is considered to be present in a bacterial isolate if the Minimum Inhibitory Concentration (MIC) exceeds the cut-off value.

18. Information about the laboratory

18.1. Total number of isolates in the laboratory (*labTotIsol AQL.12*)

This data element is **mandatory**. This is a numerical data element (reported as '-1' if unknown). It means the total number of isolates available in the laboratory testing for AMR for the specific bacterial species or serovars in relation with the given matrix. The reporting should be made at the bacterial species level for *C. jejuni*, *C. coli*, *E. coli* and *E. faecium* and *E. faecalis*. Regarding *Salmonella*, it is recommended to report at the serovar level if the isolates available have been serotyped. Regarding MRSA, it is recommended to report 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.

19. Information about the method and the antimicrobial

19.1. Antimicrobial substance (*substance AQL.14*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_PARAM_SUB, domain: D_AMR_substance). It indicates the antimicrobial substance against which the isolates were tested. Antimicrobial substances are listed within the pick list 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 10: (Please note that in the pick list you could find also other antimicrobial substance). It is noteworthy that the lists have been extended to include all substances recommended for susceptibility testing in the 'Technical specifications on the harmonised monitoring and reporting of antimicrobial resistance in *Salmonella*, *Campylobacter* and indicator *Escherichia coli* and *Enterococcus* spp. bacteria transmitted through food' (EFSA, 2012b) 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, 2012c).

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

Recommended set: cefoxitin, chloramphenicol, ciprofloxacin, clindamycin, erythromycin, gentamicin, linezolid, mupirocin, quinupristin/dalfopristin, sulfamethoxazole/trimethoprim, tetracycline, tiamulin, vancomycin.

Optional set: ceftobiprole, kanamycin, tigecycline, fusidic acid, daptomycin.

Table 10: Recommended antimicrobials for susceptibility testing and their codes for DCF

Salmonella	***C. jejuni/C. coli***	**Indicator *E. coli***	**Indicator enterococci**
Ampicillin RF-00000688-VET	Erythromycin RF-00000589-VET	Ampicillin RF-00000688-VET	Ampicillin RF-00000688-VET
Cefotaxime RF-00000717-VET	Ciprofloxacin RF-00000695-VET	Cefotaxime RF-00000717-VET	Chloramphenicol RF-00000525-VET
Chloramphenicol RF-00000525-VET	Tetracyclines[(a)]	Chloramphenicol RF-00000525-VET	Erythromycin RF-00000589-VET
Ciprofloxacin RF-00000695-VET	Streptomycin RF-0899-001-PPP	Ciprofloxacin RF-00000695-VET	Gentamicin RF-00000536-VET
Gentamicin RF-00000536-VET	Gentamicin RF-00000536-VET	Gentamicin RF-00000536-VET	Linezolid RF-00000758-VET
Nalidixic acid RF-00000547-VET	-	Nalidixic acid RF-00000547-VET	Quinopristin/dalfopristin RF-00000777-VET
Streptomycin RF-0899-001-PPP	-	Streptomycin RF-0899-001-PPP	Streptomycin RF-0899-001-PPP
Sulfonamides[(a)]	-	Sulfonamides[(a)]	Tetracyclines[(a)]
Tetracyclines[(a)]	-	Tetracyclines[(a)]	Vancomycin RF-00000569-VET
Trimethoprim RF-00000562-VET	-	Trimethoprim RF-00000562-VET	-

(a): In the case of sulphonamides and tetracyclines, these are classes of substances. Information can be reported at either the level of the class of substances, e.g. Sulfonamides (code 'RF-00000690-VET'), Tetracyclines (code 'RF-00000672-VET') or more in detail at the level of the actual substances tested, e.g. Sulfamethoxazole (code 'RF-00000612-VET') or Tetracycline (code 'RF-00000670-VET'). If known, it is recommended to report the substance for the sake of consistency.

Table 11: EFSA data model for qualitative antimicrobial resistance data reporting

Element Code	Element Name	Short Element name for XML/Excel transfer	Type	Constraint	Pick list	Domain
AQL.01	Reporting year	repYear	xs:integer(4)	Mandatory		
AQL.02	Reporting country	repCountry	xs:string(2)	Mandatory	ZOO_CAT_COUNTRY	D_ALL_repCountry
AQL.03	Language	lang	xs:string(2)	Mandatory	ZOO_CAT_LANG	D_ALL_lang
AQL.04	Zoonotic agent	zoonosis	xs:string(15)	Mandatory	ZOO_CAT_PARAM_ZOO	D_AMR_zoonosis
AQL.05	Matrix	matrix	xs:string(4000)	Mandatory	ZOO_CAT_MATRIX	
AQL.06	Sampling stage	sampStage	xs:string(5)	Optional	ZOO_CAT_SMPNT	D_PRV_sampStage
AQL.07	Sample type	sampType	xs:string(5)	Optional	ZOO_CAT_SMPTYP	
AQL.08	Sampling context	sampContext	xs:string(5)	Optional	ZOO_CAT_SRCTYP	D_ALL_sampContext
AQL.09	Sampler	sampler	xs:string(5)	Optional	ZOO_CAT_SMPLR	
AQL.10	Sampling strategy	progSampStrategy	xs:string(5)	Optional	ZOO_CAT_SAMPSTR	
AQL.11	Sampling details	sampDetails	xs:string(2000)	Optional		
AQL.12	Total number of isolates in the laboratory	labTotIsol	xs:integer(10)	Mandatory		
AQL.13	Monitoring programme	monitProgr	xs:string(1)	Optional	ZOO_CAT_YESNO	
AQL.14	Antimicrobial substance	substance	xs:string(15)	Mandatory	ZOO_CAT_PARAM_SUB	D_AMR_substance
AQL.15	Tested	tested	xs:integer(10)	Mandatory		
AQL.16	Resistant	resistant	xs:integer(10)	Mandatory		

Table 12: EFSA business rules for qualitative antimicrobial resistance data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
AQL.01	repYear	E	AQL01	Value of *repYear* must be = data collection reporting year;
AQL.03	lang	W	AQL07	WARNING. Value of *lang* should be = 'English' ('en');
AQL.04	zoonosis	E	AQL08	Value of *zoonosis* must be reported at least at level_2 of the pick list (domain D_AMR_zoonosis);
AQL.12	labTotIsol	E	AQL05	Value of *labTotIsol* must be >= -1;
AQL.15	tested	E	AQL02	Value of *tested* must be > 0;
AQL.15	tested	E	AQL03	Value of *tested* must be <= value of *labTotIsol;*
AQL.15	tested	E	AQL04	Value of *tested* must be >= value of *resistant;*
AQL.16	resistant	E	AQL06	Value of *resistant* must be >= 0;

C) AMR QUANTITATIVE DATA MODEL 2013

20. Introduction

This data dictionary provides guidance for reporting on quantitative antimicrobial resistance (AMR) data from zoonotic and indicator bacteria in animals, food and feed under the framework of Directive 2003/99/EC.

Quantitative AMR data are defined for the purpose of the reporting exercise as AMR data obtained using either diffusion or dilution methods and that are being reported in an aggregated manner (conversely to isolate-based AMR data).

The EFSA data model for quantitative AMR data is summarised in Table 17: and the complete set of business rules applied for data validation are presented in Table 18: .

21. Illustrative example of how to use the data model

An example of how to report results on six isolates tested by dilution method for susceptibility to gentamicin and cefotaxime by using the AMR quantitative data model, is shown in Table 13: . It is intended to point out 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. It is noteworth that the terms still need to be coded before transmission to DCF.

Data submitted to EFSA's DCF by using the quantitative data model will be migrated automatically to a quantitative AMR table in the Zoonoses Web Application. Figure 6: presents the data of the example shown in Table 13: after migration to the Zoonoses Web Application, while Figure 7: shows how the first row of Table 13: could look like in an XML file according to the AMR quantitative data model.

Table 13: 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 quantitative data model – Excel file (some mandatory columns are not displayed here and terms have to be coded before transmission to DCF).

zoonosis	matrix	totUnits Tested	totSamp UnitsTested	labTot Isol	substance	cutoffValue	lowest	highest	range	inhibited
Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	500	42	Aminoglycosides - Gentamicin	2	0.5	32	2	1
Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	500	42	Aminoglycosides - Gentamicin	2	0.5	32	32	3
Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	500	42	Aminoglycosides - Gentamicin	2	0.5	32	>32	2
Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	500	42	Cephalosporins - Cefotaxime	0.5	0.25	4	<=0.25	2
Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	500	42	Cephalosporins - Cefotaxime	0.5	0.25	4	0.5	1
Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	500	42	Cephalosporins - Cefotaxime	0.5	0.25	4	4	2
Salmonella - S. Saintpaul	Turkeys - fattening flocks	300	500	42	Cephalosporins - Cefotaxime	0.5	0.25	4	>4	1

S. Saintpaul	Turkeys - fattening flocks - before slaughter - at farm - Control and eradication programmes														
Isolates out of a monitoring program (yes/no)	yes														
Number of isolates available in the laboratory	42														
Antimicrobials:	Cut-off value	N	n	0.12	0.25	0.5	1	2	4	8	16	32	64	lowest	highest
Aminoglycosides - Gentamicin	2	6	5					1				3	2	0.5	32
Cephalosporins - Cefotaxime	0.5	6	3		2	1			2	1				0.25	4

Figure 6: Example data in a quantitative AMR table (Dilution method) in the Zoonoses Web Application


```xml
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<dataset>
	<result>
		<repYear>2013</repYear>
		<repCountry>PN</repCountry>
		<lang>en</lang>
		<zoonosis>RF-00001234-MCG</zoonosis>
		<matrix>A041277A</matrix>
		<sampStage>E101A</sampStage>
		<sampOrig>PN</sampOrig>
		<sampType>S005A</sampType>
		<totUnitsTested>300</totUnitsTested>
		<totSampUnitsTested>500</totSampUnitsTested>
		<sampUnitType>G202A</sampUnitType>
		<sampContext>K021A</sampContext>
		<sampler>CX03A</sampler>
		<progCode>SalmControl</progCode>
		<progSampStrategy>ST50A</progSampStrategy>
		<labTotIsol>42</labTotIsol>
		<anMethCode>F132A</anMethCode>
		<monitProgr>Y</monitProgr>
		<substance>RF-00000536-VET</substance>
		<cutoffValue>2</cutoffValue>
		<lowest>R016A</lowest>
		<highest>R052A</highest>
		<range>R020A</range>
		<inhibited>1</inhibited>
	</result>
[…]
</dataset>
```


Figure 7: Example data of the first row of Table 1: in XML according to DCF's AMR quantitative data model

21.1. How to report the Minimum Inhibitory Concentration (MIC)

The Figure 8: shows how MIC values relate to the data reported in the quantitative data model through DCF.

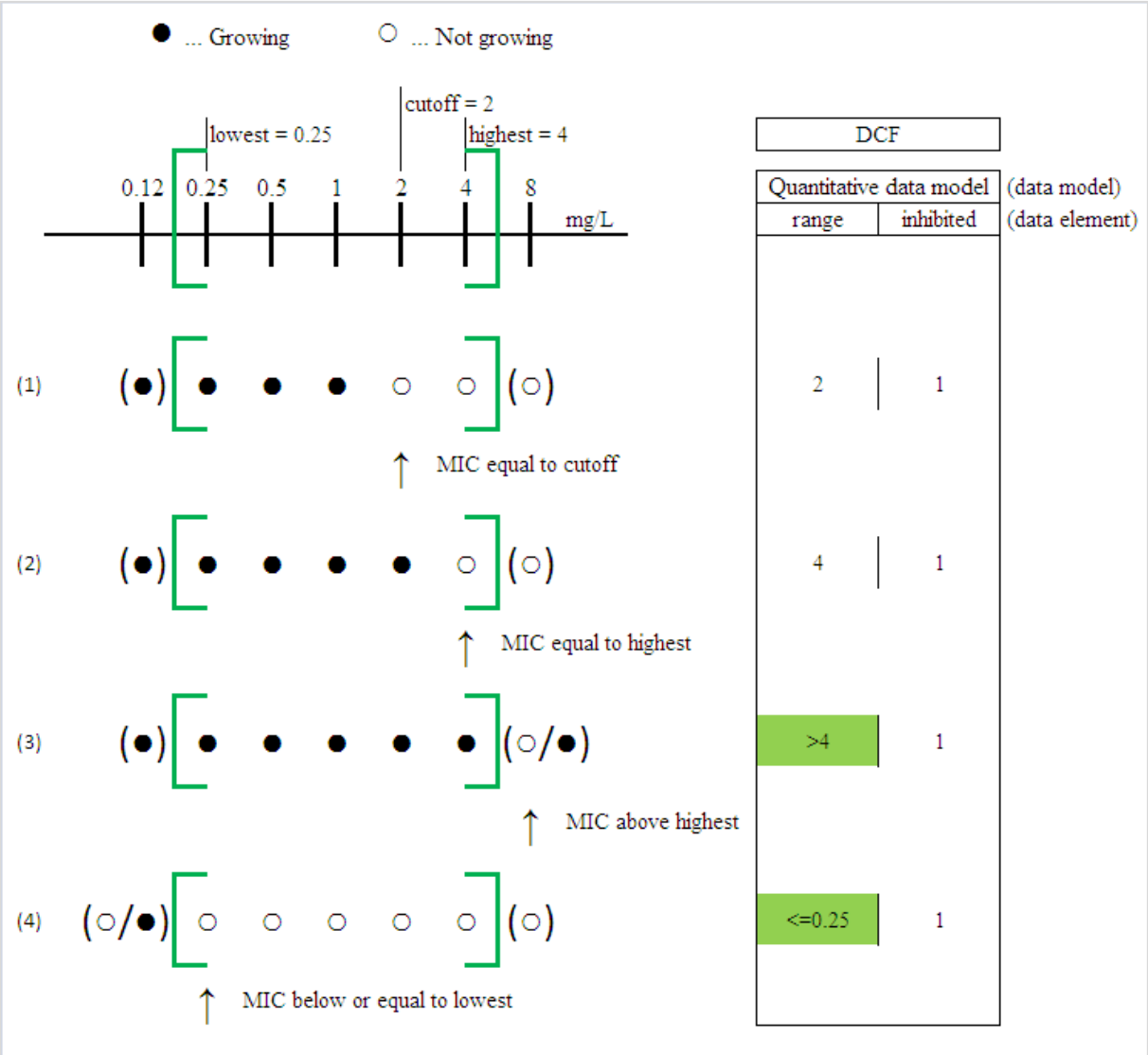

Figure 8: Minimum Inhibitory Concentration in the quantitative data model: The right hand column displays which values should be reported for the respective test results in the data element *range* (MIC values have to be coded before transmission to DCF)

22. General information

22.1. Reporting year (*repYear AQT.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.

22.2. Reporting country (*repCountry AQT.02*)

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

22.3. Language (*lang AQT.03*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_LANG, domain: D_ALL_lang), however, **only the code 'en' for 'English' should be used**, since text in the free text data element (data element AQT.11 Sampling details) should be provided in English.

23. Information about type and source of samples and isolates

23.1. Zoonotic agent (*zoonosis AQT.04*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_PARAM_ZOO, domain: D_AMR_zoonosis). It enables reporting, when relevant. of the bacterial agents tested for antimicrobial resistance, specifying the genera, the species as well as the serovar/serotype/phagetype/*spa*-type of the bacteria in question, particularly for *Salmonella* and MRSA.

It is expected that AMR data are reported for *Salmonella*; preferably at serovar level, for *Campylobacter jejuni*, *Campylobacter coli*, indicator *Escherichia coli*, indicator *Enterococcus faecium*, indicator *Enterococcus faecalis* and methicillin-resistant *Staphylococcus aureus* (MRSA).

For *Salmonella*, consistent reporting of AMR data at the serovar level (level 2 term) is recommended, as it is scientifically relevant to analyse resistance at this level, particularly for the serovars of public health significance and emerging serovars and serovars exhibiting particular combinations of resistance. Certain serovars of public health importance are listed in Table 14: . If desired, susceptibility data can be reported at an even greater level of detail than the recommended level 2 term, e.g. '*Salmonella* - *S*. Typhimurium - DT 137' (code 'RF-00002322-MCG').

Reporting of AMR data for '*Campylobacter* spp.' is discouraged 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').

AMR data on *'Enterococcus*, pathogenic - *E. faecium'* (code 'RF-00004078-MCG') and *'Enterococcus*, pathogenic - *E. faecalis*' (code 'RF-00004076-MCG') should also be reported separately.

Note that indicator bacteria should be reported using level 2 of the pick list 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* as *'Enterococcus*, non-pathogenic - *E. faecium'* (code 'RF-00000114-MCG') and indicator *Enterococcus faecalis* as *'Enterococcus*, non-pathogenic - *E. faecalis'* (code 'RF-00000113-MCG').

Regarding MRSA the pick list 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.

Table 14: Recommended *Salmonella* serovars of public health importance and codes for DCF

Animal species/food	*Salmonella* serovar (Level 2 term)	Code for DCF
All animal species and derived meat	*S*. Typhimurium	RF-00002265-MCG
	S. Typhimurium, monophasic	RF-00003051-MCG
Gallus gallus (fowl): Breeders of egg production line, breeders of meat production line, laying hens, broilers and broiler meat	*S*. Enteritidis	RF-00002135-MCG
	S. Agona	RF-00001667-MCG
	S. Virchow	RF-00001152-MCG
	S. Hadar	RF-00001843-MCG
	S. Kentucky	RF-00000640-MCG
	S. Infantis	RF-00001894-MCG
Broilers and broiler meat	*S*. Java[(a)]	RF-00001325-MCG
Turkeys and turkey meat	*S*. Enteritidis	RF-00002135-MCG
	S. Agona	RF-00001667-MCG
	S. Kentucky	RF-00000640-MCG
	S. Newport	RF-00000960-MCG
	S. Saintpaul	RF-00001234-MCG
Pigs: breeding pigs, piglets, weaners to growers, fattening pigs, and swine meat	*S*. Derby	RF-00001592-MCG
	S. Agona	RF-00001667-MCG
Cattle: dairy cattle, beef cattle and bovine meat	*S*. Dublin	RF-00001517-MCG
	S. Infantis	RF-00001894-MCG

(a): Previously known as *S*. Paratyphi B var. Java

23.2. Matrix (*matrix AQT.05*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_MATRIX). It represents the food/feed category or the animal species from which the isolate tested for AMR derives. Also 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).

As regards the reporting of food-producing animal species 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. It is therefore recommended that AMR data are reported for the animal species/food categories listed in Table 15: .

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

It is recommended that relevant animal sub-populations (corresponding to the level 2, level 3 and level 4 terms) are selected, as far as the available information make possible and as enabled by the detailed pick list.

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 15: Recommended food and animal categories for AMR reporting

Bacteria	Animal species/Food categories
Salmonella	• Laying hens, broilers, fattening turkeys, fattening pigs, calves (under 1 year)[(a)], young bovines (1-2 years) and adult cattle (>2 years) • Broiler meat, turkey meat, pig meat and bovine meat
Campylobacter	• Broilers, fattening turkeys, fattening pigs, calves (under 1 year)[(a)], young bovines (1-2 years) and adult cattle (>2 years) • Broiler meat, turkey meat
Indicator *E. coli*	• Laying hens, broilers, fattening turkeys, fattening pigs, calves (under 1 year)[(a)], young bovines (1-2 years) and adult cattle (>2 years) • Broiler meat, turkey meat, pig meat and bovine meat
Indicator enterococci	• Laying hens, broilers, fattening pigs, fattening turkeys, calves (under 1 year)[(a)], young bovines (1-2 years) and adult cattle (>2 years) • Broiler meat, turkey meat, pig meat and bovine meat
Methicillin-resistant *Staphylococcus aureus* (MRSA)	• Broilers, breeders of *Gallus gallus*, meat sector, fattening turkeys, breeders turkeys, fattening pigs, breeders of pigs, dairy cattle, fattening veal calves (under 1 year of age), beef animals, horses • Fresh broiler meat, fresh turkey meat, fresh pig meat, fresh bovine meat, fresh veal, raw milk and/or raw milk products

(a): MSs monitoring AMR in fattening calve populations that are older than 12 months of age, and typically raised for the production of *rosé* veal, may report data under the category 'veal calves (at or above 1 year)' (code 'A0CHK').

24. Information about the sampling

24.1. Sampling stage (*sampStage AQT.06*)

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (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. 'at farm' (code 'E101A'), 'at slaughterhouse' (code 'E311A') or 'at retail' (code 'E520A').

24.2. Sample origin (*sampOrig AQT.22*)

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (ZOO_CAT_COUNTRY). Sampling origin is used to indicate the country of origin for the animal, food or feed sampled (ISO 3166-1-alpha-2 country code). If the exact country of origin of the sampled item is not known, the following terms may be reported: 'European Union' (code 'EU'), 'Non EU' (code 'XE'), 'Non EEA' (code 'XC') or 'Unknown' (code 'XX').

24.3. Sample type (*sampType AQT.07*)

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (ZOO_CAT_SMPTYP). It describes the biological source of the sample, e.g. 'animal sample - nasal swab' (code 'S015A'); 'food sample - carcase swab' (code 'S021A').

24.4. Total units tested (*totUnitsTested AQT.23*)

This data element is **optional**. 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, strains or serovars (or other zoonotic agent) 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 for all isolates coming from the same monitoring context should be reported.

24.5. Total samples tested (*totSampUnitsTested AQT.24*)

This data element is **optional**. 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 monitoring context, -whether positive or negative, -in order to collect the bacterial isolates tested for antimicrobial susceptibility, from a specific reporting 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 (level2)) or a food category. These data may be used to assess the prevalence of resistant bacteria. Please note that the same number for all isolates coming from the same monitoring context should be reported, so that data deriving from clinical investigations, for example, are not mixed with data deriving from epidemiological monitoring of AMR.

24.6. Sampling unit type (*sampUnitType AQT.25*)

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (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’);

24.7. Sampling context (*sampContext AQT.08*)

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (ZOO_CAT_SRCTYP, domain: D_ALL_sampContext). It identifies the type of programme in the framework of which samples/isolates 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 case of clinical isolates the item ‘Clinical investigations’ (code ‘K020A’) should be used. Reporting of the sampling context is recommended to enable evaluation of the representativeness of the AMR monitoring programmes.

24.8. Sampler (*sampler AQT.09*)

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (ZOO_CAT_SMPLR). It indicates the type of body who performed the sampling, e.g. ‘Industry sampling’ (code ‘CX01A’); ‘Official sampling’ (code ‘CX02A’).

24.9. Programme code (*progCode AQT.26*)

This data element is **optional but is recommended to be reported at national level**. Its type is alphanumeric up to a maximum of 20 characters. This free text data element allows reporting of a unique identification code of the programme or project in the framework of which the sample analysed has been collected. It can refer to a specific piece of EU legislation or a national or regional control or monitoring plan.

24.10. Sampling strategy (*progSampStrategy AQT.10*)

This data element is **optional but is recommended to be reported to EFSA**. It contains codes linked to a pick list (ZOO_CAT_SAMPSTR). It is the sampling strategy performed in the programme or project identified by the Programme code, e.g. 'Objective sampling' (code 'ST10A'), 'Census' (code 'ST50A'). Reporting of the sampling strategy is recommended to enable evaluation of the representativeness of the AMR monitoring programmes.

24.11. Sampling details (*sampDetails AQT.11*)

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

24.12. Monitoring programme (*monitProgr AQT.14*)

This data element is **optional**. It contains codes linked to a pick list (ZOO_CAT_YESNO) with values 'Yes' (code 'Y'), 'No' (code 'N') and 'Unknown' (code 'U'). It indicates whether the tested bacterial isolates originate from a monitoring programme or not.

25. Information about the laboratory

25.1. Total number of isolates in the laboratory (*labTotIsol AQT.12*)

This data element is **mandatory**. This is a numerical data element (reported as '-1' if unknown). It means the total number of isolates available in the laboratory testing for AMR for the specific bacterial species or serovars in relation to the given matrix. The reporting should be made at the bacterial species level for *C. jejuni*, *C. coli*, *E. coli* and *E. faecium* and *E. faecalis*. Regarding *Salmonella*, it is recommended to report at the serovar level if the isolates available have been serotyped. Regarding MRSA, it is recommended to report 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.

26. Information about the method and the antimicrobials

26.1. Method (*anMethCode AQT.13*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_ANLYMD, domain: D_AMR_anMethCode). It describes the analytical method used in the 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');

26.2. Antimicrobial substance (*substance AQT.15*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_PARAM_SUB). It indicates the antimicrobial substance against which the isolates were tested. Antimicrobial substances are listed within the pick list 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 16: (Please note that in the pick list you could find also other antimicrobial substance). It is noteworthy that the lists have been extended to include all substances recommended for susceptibility testing in the 'Technical specifications on the harmonised monitoring and reporting of antimicrobial resistance in *Salmonella*, *Campylobacter* and indicator *Escherichia coli* and *Enterococcus* spp. bacteria transmitted through food'(EFSA, 2012b) 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, 2012c).

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

Recommended set: cefoxitin, chloramphenicol, ciprofloxacin, clindamycin, erythromycin, gentamicin, linezolid, mupirocin, quinupristin/dalfopristin, sulfamethoxazole/trimethoprim, tetracycline, tiamulin, vancomycin.

Optional set: ceftobiprole, kanamycin, tigecycline, fusidic acid, daptomycin.

Table 16: Recommended antimicrobials for susceptibility testing and their codes for DCF

Salmonella	***C. jejuni*/*C. coli***	**Indicator *E.coli***	**Indicator enterococci**
Ampicillin RF-00000688-VET	Erythromycin RF-00000589-VET	Ampicillin RF-00000688-VET	Ampicillin RF-00000688-VET
Cefotaxime RF-00000717-VET	Ciprofloxacin RF-00000695-VET	Cefotaxime RF-00000717-VET	Chloramphenicol RF-00000525-VET
Chloramphenicol RF-00000525-VET	Tetracyclines[(a)]	Chloramphenicol RF-00000525-VET	Erythromycin RF-00000589-VET
Ciprofloxacin RF-00000695-VET	Streptomycin RF-0899-001-PPP	Ciprofloxacin RF-00000695-VET	Gentamicin RF-00000536-VET
Gentamicin RF-00000536-VET	Gentamicin RF-00000536-VET	Gentamicin RF-00000536-VET	Linezolid RF-00000758-VET
Nalidixic acid RF-00000547-VET	-	Nalidixic acid RF-00000547-VET	Quinopristin/Dalfopristin RF-00000777-VET
Streptomycin RF-0899-001-PPP	-	Streptomycin RF-0899-001-PPP	Streptomycin RF-0899-001-PPP
Sulfonamides[(a)]	-	Sulfonamides[(a)]	Tetracyclines[(a)]
Tetracyclines[(a)]	-	Tetracyclines[(a)]	Vancomycin RF-00000569-VET
Trimethoprim RF-00000562-VET	-	Trimethoprim RF-00000562-VET	-

(a): In the case of sulfonamides and tetracyclines, these are classes of substances. Information can be reported at either the level of the class of substances, e.g. Sulfonamides (code 'RF-00000690-VET'), Tetracyclines (code 'RF-00000672-VET') or more in detail at the level of the actual substances tested, e.g. Sulfamethoxazole (code 'RF-00000612-VET') or Tetracycline (code 'RF-00000670-VET'). If known, it is recommended to report the substance for the sake of consistency.

26.3. Cut-off value (*cutoffValue AQT.16*)

This data element is **mandatory**. This data element allows numeric data values with decimal numbers and must be greater than zero. The data element indicates the cut-off value for the dilution or disc diffusion methods that should be used, according to the reporting Member States, 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. Nevertheless, Member States may prefer to use an *ad hoc* cut-off value for the interpretation of their national data.

Please avoid reporting duplicate AMR data using different ECOFFs for the same isolates (e.g. harmonised ECOFF and *ad hoc* ECOFF).

27. Information about MIC/IZD values

27.1. Lowest limit (*lowest AQT.17*)

This data element is **mandatory** for **dilution** method data. However, in the data model it is marked as optional because in case of diffusion data this data element must be left empty. It contains codes linked to a pick list (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 *Lowest limit* must be below *Highest limit*.

27.2. Highest limit (*highest AQT.18*)

This data element is **mandatory** for **dilution** method data. However, in the data model it is marked as optional because in case of diffusion data this data element must be left empty. It contains codes linked to a pick list (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 *Highest limit* must be above *Lowest limit*.

27.3. Range (MIC value or IZD value, considered) (*range AQT.19*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_FIXMEAS, domain: D_AQT_range). The list covers both the MIC values for the **dilution** method data and inhibition zone diameter values for the **diffusion** method data. It indicates the value of the minimum inhibition concentration or of the inhibition zone diameter, at which the number of isolates reported in the data element *'inhibited'* (*AQT.20)* were inhibited. For dilution, it is of note that the different concentrations tested (lying between the lowest and the highest limits reported) should be consistently and systematically considered in the reporting. In case no isolate was inhibited at the given range value, this row should not be reported.

27.4. Number of inhibited (*inhibited AQT.20*)

This data element is **mandatory**. It contains an integer value. It is the number of isolates that were inhibited at the reported value in the data element *Range (AQT.19)*. For example, for dilution method a number of inhibited isolates should be specified for a concentration lying between the lowest and the highest limits tested. In case no isolate was inhibited at the given range value, this row should not be reported, i.e. the value '0' should never be reported within this data element.

Table 17: EFSA data model for quantitative antimicrobial resistance data reporting

Element Code	Element Name	Short Element name for XML/Excel transfer	Constraint	Type	Pick list	Domain
AQT.01	Reporting year	repYear	Mandatory	xs:integer(4)		
AQT.02	Reporting country	repCountry	Mandatory	xs:string(2)	ZOO_CAT_COUNTRY	D_ALL_repCountry
AQT.03	Language	lang	Mandatory	xs:string(2)	ZOO_CAT_LANG	D_ALL_lang
AQT.04	Zoonotic agent	zoonosis	Mandatory	xs:string(15)	ZOO_CAT_PARAM_ZOO	D_AMR_zoonosis
AQT.05	Matrix	matrix	Mandatory	xs:string(4000)	ZOO_CAT_MATRIX	
AQT.06	Sampling stage	sampStage	Optional	xs:string(5)	ZOO_CAT_SMPNT	D_PRV_sampStage
AQT.22	Sample origin	sampOrig	Optional	xs:string(2)	ZOO_CAT_COUNTRY	
AQT.07	Sample type	sampType	Optional	xs:string(5)	ZOO_CAT_SMPTYP	
AQT.23	Total number of samples tested	totUnitsTested	Optional	xs:integer(10)		
AQT.24	Total number of sampling units tested	totSampUnitsTested	Optional	xs:integer(10)		
AQT.25	Sampling unit type	sampUnitType	Optional	xs:string(5)	ZOO_CAT_UNIT	D_AMR_sampUnitType
AQT.08	Sampling context	sampContext	Optional	xs:string(5)	ZOO_CAT_SRCTYP	D_ALL_sampContext
AQT.09	Sampler	sampler	Optional	xs:string(5)	ZOO_CAT_SMPLR	
AQT.26	Programme code	progCode	Optional	xs:string(20)		
AQT.10	Sampling strategy	progSampStrategy	Optional	xs:string(5)	ZOO_CAT_SAMPSTR	
AQT.11	Sampling details	sampDetails	Optional	xs:string(2000)		
AQT.12	Total number of isolates in the laboratory	labTotIsol	Mandatory	xs:integer(10)		
AQT.13	Method	anMethCode	Mandatory	xs:string(5)	ZOO_CAT_ANLYMD	D_AMR_anMethCode
AQT.14	Monitoring programme	monitProgr	Optional	xs:string(1)	ZOO_CAT_YESNO	
AQT.15	Antimicrobial substance	substance	Mandatory	xs:string(15)	ZOO_CAT_PARAM_SUB	
AQT.16	Cut-off value	cutoffValue	Mandatory	xs:double		
AQT.17	Lowest limit	lowest	Optional	xs:string(5)	ZOO_CAT_FIXMEAS	D_AMR_number
AQT.18	Highest limit	highest	Optional	xs:string(5)	ZOO_CAT_FIXMEAS	D_AMR_number
AQT.19	Range	range	Mandatory	xs:string(5)	ZOO_CAT_FIXMEAS	D_AQT_range
AQT.20	Number of inhibited	inhibited	Mandatory	xs:integer(10)		

Table 18: EFSA business rules for quantitative antimicrobial resistance data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
AQT.01	repYear	E	AQT01	Value of *repYear* must be = data collection reporting year;
AQT.03	lang	W	AQT06	WARNING. Value of *lang* should be = 'English' ('en');
AQT.04	zoonosis	E	AQT12	Value of *zoonosis* must be reported at least at level_2 of the pick list (domain D_AMR_zoonosis);
AQT.05	matrix	W	AQT20	WARNING. For data interpretation purposes, it is advised not to use general categories: value of *matrix* should NOT be IN ['Gallus gallus (fowl)' ('A006921A'), 'Gallus gallus (fowl) - unspecified' ('A031721A'), 'Compound feedingstuffs, not specified' ('A001421A')];
AQT.06	sampStage	W	AQT14	WARNING. For data interpretation purposes, value of *sampStage* should be <> NULL;
AQT.08	sampContext	W	AQT15	WARNING. For data interpretation purposes, value of *sampContext* should be <> NULL;
AQT.09	sampler	W	AQT16	WARNING. For data interpretation purposes, value of *sampler* should be <> NULL;
AQT.10	progSampStrategy	W	AQT17	WARNING. For data interpretation purposes, value of *progSampStrategy* should be <> NULL;
AQT.12	labTotIsol	E	AQT07	Value of *labTotIsol* must be >= -1;
AQT.16	cutoffValue	E	AQT02	Value of *cutoffValue* must be > 0 AND <= 5000;
AQT.16	cutoffValue	E	AQT13	Value of *cutoffValue* must be the same for each combination of values in *zoonosis* and *substance;*
AQT.16	cutoffValue	E	AQT19	Value of *cutoffValue* must be >= value of *lowest* AND < value of *highest;*
AQT.17	lowest	E	AQT03	If value of *anMethCode* is in level_2 = 'dilution' then value of *lowest* must be <> NULL;
AQT.17	lowest	E	AQT30	If value of *anMethCode* is in level_2 = 'diffusion' then value of *lowest* must be = NULL;
AQT.18	highest	E	AQT05	If value of *anMethCode* is in level_2 = 'dilution' then value of *highest* must be <> NULL;
AQT.18	highest	E	AQT31	If value of *anMethCode* is in level_2 = 'diffusion' then value of *highest* must be = NULL;
AQT.19	range	E	AQT24	If value of *anMethCode* level_2 = 'dilution' AND value of *range* (MIC) contains'<=' then the number in the value of *range* (MIC) must be = value of *lowest;*
AQT.19	range	E	AQT25	If value of *anMethCode* level_2 = 'dilution' AND value of *range* (MIC) contains'>' then the number in the value of *range* (MIC) must be = value of *highest;*
AQT.19	range	E	AQT27	If value of *anMethCode* level_2 = 'dilution' AND value of *range* (MIC) is numeric then value of *range* (MIC) must be > value of *lowest* AND <= value of *highest;*
AQT.19	range	E	AQT28	If value of *anMethCode* is in level_2 ='dilution' then value of *range* must be <> '<=6' ('R010A');
AQT.19	range	E	AQT29	If value of *anMethCode* is in level_2 ='dilution' then value of *range* must be <> '6' ('R024A');
AQT.20	inhibited	E	AQT08	Value of *inhibited* must be >= 0;
AQT.22	sampOrig	W	AQT11	WARNING. For data interpretation purposes, value of *sampOrig* should be <> NULL;
AQT.23	totUnitsTested	E	AQT18	Value of *totUnitsTested* must be > 0;

D) ANIMAL POPULATION DATA MODEL 2013

28. 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 19: and the complete set of business rules applied for data validation are presented in Table 20: .

29. General information and identification of the data

29.1. 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.

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

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

29.3. Language (*lang POP.03*)

This data element is **mandatory**. It contains codes linked to a pick list (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.

30. Information about type and source of data

30.1. Matrix (*matrix POP.04*)

This data element is **mandatory**. It contains codes linked to a pick list (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 presence of more detailed categories only where the 'in total' option is available, while in all other cases the parent level should only be used to report the population not reported at more detailed classification levels.

30.2. 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. In case the source year and the reporting year are the same, this data element must be left empty.

30.3. Unit (*unit POP.06*)

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

30.4. 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 the data element POP.06 (in order to say e.g. '100 slaughtered animal (heads) of sheep')

31. Additional information

31.1. Comment (*resComm POP.08)*

This data element is **optional**. This is a free text of maximum 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 19: EFSA data model for animal population data reporting

Element Code	Element Name	Short Element name for XML/Excel transfer	Type	Constraint	Pick list	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 20: EFSA business rules for animal population data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
POP.01	repYear	E	POP01	Value of repYear must be = data collection reporting year;
POP.03	lang	W	POP02	WARNING. Value of lang should be = 'English' ('en');
POP.05	sourceYear	E	POP03	Value of sourceYear must be < value of repYear;
POP.05	sourceYear	E	POP05	Value of sourceYear must be numeric;
POP.07	population	E	POP04	Value of population must be numeric;
POP.07	population	E	POP06	Sum of the values of population for the subcategories must be < value of population for the main category;
POP.07	population	E	POP07	Number of herds/flocks can not be > number of animals;
POP.07	population	E	POP08	Number of holdings can not be > number of herds/flocks;
POP.07	population	E	POP09	Number of holdings can not be > number of animals;

E) DISEASE STATUS DATA MODEL 2013

32. 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/CSV transmission of aggregated data on disease status data through the Data Collection Framework (DCF). The EFSA data model for disease status tables is summarised in Table 34: and the complete set of business rules applied for data validation are presented in Table 35: .

33. General information and identification of the sample

33.1. 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.

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

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

33.3. Region (*sampArea DST.03*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_NUTS). It indicates the area or region or province within the country (in accordance to 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.

33.4. Language (*lang DST.04*)

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

34. Information about type and source of data

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

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_PARAM_ZOO, domain: D_DST_zoonosis). It allows reporting on '*Mycobacterium'* (code 'RF-00000273-MCG') or '*Brucella'* (code 'RF-00000028-MCG').

34.2. Matrix (*matrix DST.06*)

This data element is **mandatory**. It contains codes linked to a pick list (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')

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

This data element is **mandatory**. It contains codes linked to a pick list (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 Table 21: to Table 33: to get the list of disease status units to be reported for each table (mandatory and optional).

34.4. 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 test should be reported while any additional information concerning the interval should be reported in the ‘Comment’ data element (*resComm DST.10*).

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

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_DSTABLE). It indicates the official EU reporting tables to which the data refer to. 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 Table 21: to Table 33: to get the list of Disease status units to be reported for each table (mandatory and optional).

35. Additional information

35.1. Comment (*resComm DST.10*)

This data element is **optional**. This is a free text of maximum 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 21: 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 22: 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 23: 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 24: 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
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 25: 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 26: 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 27: 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 28: 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 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 29: 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 30: 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 Brucella abortus	Investigations of suspect cases - Information about abortions - Number of abortions due to Brucella abortus
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 Brucella infections	Investigations of suspect cases - Information about abortions - Number of isolations of Brucella 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 31: 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 32: 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 33: 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 34: EFSA data model for disease status data reporting

Element Code	Element Name	Short Element name for XML/Excel transfer	Type	Constraint	Pick list	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 35: EFSA business rules for disease status data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
DST.01	repYear	E	DST01	Value of *repYear* must be = data collection reporting year;
DST.04	lang	W	DST02	WARNING. Value of *lang* should be = 'English' ('en');
DST.05	zoonosis	E	DST31	If value of *tableName* IN ['Bovine tuberculosis - data on animals - Community co-financed eradication programmes' ('ZT09A'), 'Bovine tuberculosis - data on herds - Community co-financed eradication programmes' ('ZT10A'), 'Bovine tuberculosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT11A'), 'Bovine tuberculosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT12A'), 'Tuberculosis in farmed deer' ('ZT13A')] then value of *zoonosis* must be = 'Mycobacterium' ('RF-00000273-MCG');
DST.05	zoonosis	E	DST32	If value of *tableName* IN ['Bovine brucellosis - data on animals - Community co-financed eradication programmes' ('ZT01A'), 'Bovine brucellosis - data on herds - Community co-financed eradication programmes' ('ZT02A'), 'Bovine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT03A'), 'Bovine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT04A'), 'Ovine or Caprine brucellosis - data on animals - Community co-financed eradication programmes' ('ZT05A'), 'Ovine or Caprine brucellosis - data on herds - Community co-financed eradication programmes' ('ZT06A'), 'Ovine or Caprine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT07A'), 'Ovine or Caprine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT08A')] then value of *zoonosis* must be = 'Brucella' ('RF-00000028-MCG');
DST.06	matrix	E	DST17	Value of *matrix* must be IN ['Cattle (bovine animals)' ('A006581A'), 'Sheep and goats' ('A002841A'), 'Deer - farmed' ('A006881A')] (domain D_DST_matrix);

Table 35 (continued): EFSA business rules for disease status data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
DST.06	matrix	E	DST33	If value of *tableName* IN ['Ovine or Caprine brucellosis - data on animals - Community co-financed eradication programmes' ('ZT05A'), 'Ovine or Caprine brucellosis - data on herds - Community co-financed eradication programmes' ('ZT06A'), 'Ovine or Caprine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT07A'), 'Ovine or Caprine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT08A')] then value of *matrix* must be = 'Sheep and goats' ('A002841A');
DST.06	matrix	E	DST34	If value of *tableName* = 'Tuberculosis in farmed deer' ('ZT13A') then value of *matrix* must be = 'Deer - farmed' ('A006881A');
DST.06	matrix	E	DST35	If value of *tableName* IN ['Bovine brucellosis - data on animals - Community co-financed eradication programmes' ('ZT01A'), 'Bovine brucellosis - data on herds - Community co-financed eradication programmes' ('ZT02A'), 'Bovine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT03A'), 'Bovine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT04A'), 'Bovine tuberculosis - data on animals - Community co-financed eradication programmes' ('ZT09A'), 'Bovine tuberculosis - data on herds - Community co-financed eradication programmes' ('ZT10A'), 'Bovine tuberculosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT11A'), 'Bovine tuberculosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT12A')] then value of *matrix* must be = 'Cattle (bovine animals)' ('A006581A');

Table 35 (continued): EFSA business rules for disease status data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
DST.07	unitDS	E	DST18	If value of *tableName* = 'Bovine tuberculosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT12A') then value of *unitDS* must be IN ['Number of herds with status officially free' ('DU54A'), 'Number of infected herds' ('DU56A'), 'Total number of herds' ('DU01A'), 'Interval between routine tuberculin tests' ('DU26A'), 'Number of animals detected positive in bacteriological examination' ('DU30A'), 'Number of animals tested with tuberculin routine testing' ('DU27A'), 'Number of animals with suspicious lesions of tuberculosis examined and submitted to histopathological and bacteriological examinations' ('DU29A'), 'Number of tuberculin tests carried out before the introduction into the herds' ('DU28A'), 'Total number of animals' ('DU07A')];
DST.07	unitDS	E	DST19	If value of *tableName* = 'Bovine tuberculosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT11A') then value of *unitDS* must be IN ['Number of animals with status officially free, at the end of the period' ('DU25A'), 'Number of herds with status officially free, at the end of the period' ('DU24A'), 'Total number of animals under the program, at the end of the period' ('DU53A'), 'Total number of herds under the program, at the end of the period' ('DU52A'), 'Number of animals with status free or officially free suspended, at the end of the period' ('DU21A'), 'Number of animals with status free, at the end of the period' ('DU23A'), 'Number of animals with status not free or not officially free and last check negative, at the end of the period' ('DU19A'), 'Number of animals with status not free or not officially free and last check positive, at the end of the period' ('DU17A'), 'Number of animals with unknown status, at the end of the period' ('DU15A'), 'Number of herds with status free or officially free suspended, at the end of the period' ('DU20A'), 'Number of herds with status free, at the end of the period' ('DU22A'), 'Number of herds with status not free or not officially free and last check negative, at the end of the period' ('DU18A'), 'Number of herds with status not free or not officially free and last check positive, at the end of the period' ('DU16A'), 'Number of herds with unknown status, at the end of the period' ('DU14A')];

Table 35 (continued): EFSA business rules for disease status data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
DST.07	unitDS	E	DST20	If value of *tableName* = 'Bovine tuberculosis - data on animals - Community co-financed eradication programmes' ('ZT09A') then value of *unitDS* must be IN ['Number of animals tested' ('DU09A'), 'Number of animals tested individually' ('DU10A'), 'Number of animals to be tested under the program' ('DU08A'), 'Number of positive animals' ('DU11A'), 'Total number of animals' ('DU07A'), 'Number of positive animals slaughtered' ('DU12A'), 'Total number of animals slaughtered' ('DU13A')];
DST.07	unitDS	E	DST21	If value of *tableName* = 'Bovine tuberculosis - data on herds - Community co-financed eradication programmes' ('ZT10A') then value of *unitDS* must be IN ['Number of herds under the program' ('DU02A'), 'Number of herds under the program tested/checked' ('DU03A'), 'Number of new positive herds' ('DU05A'), 'Number of positive herds' ('DU04A'), 'Total number of herds' ('DU01A'), 'Number of depopulated herds' ('DU06A')];

Table 35 (continued): EFSA business rules for disease status data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
DST.07	unitDS	E	DST22	If value of tableName = 'Ovine or Caprine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT08A') then value of unitDS must be IN ['Number of herds with status officially free' ('DU54A'), 'Number of infected herds' ('DU56A'), 'Total number of herds' ('DU01A'), 'Number of animals positive in microbiological testing under investigations of suspect cases' ('DU45A'), 'Number of animals serologically tested under investigations of suspect cases' ('DU40A'), 'Number of animals tested by microbiology under investigations of suspect cases' ('DU44A'), 'Number of animals tested under surveillance' ('DU32A'), 'Number of herds tested under surveillance' ('DU31A'), 'Number of infected herds tested under surveillance' ('DU33A'), 'Number of seropositive animals under investigations of suspect cases' ('DU42A'), 'Number of suspended herds under investigations of suspect cases' ('DU41A'), 'Total number of animals' ('DU07A')];

Table 35 (continued): EFSA business rules for disease status data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
DST.07	unitDS	E	DST23	If value of *tableName* = 'Ovine or Caprine brucellosis - data on status of herds at the end of the period - Community co-financed eradication programmes' ('ZT07A') then value of *unitDS* must be IN ['Number of animals with status officially free, at the end of the period' ('DU25A'), 'Number of herds with status officially free, at the end of the period' ('DU24A'), 'Total number of animals under the program, at the end of the period' ('DU53A'), 'Total number of herds under the program, at the end of the period' ('DU52A'), 'Number of animals with status free or officially free suspended, at the end of the period' ('DU21A'), 'Number of animals with status free, at the end of the period' ('DU23A'), 'Number of animals with status not free or not officially free and last check negative, at the end of the period' ('DU19A'), 'Number of animals with status not free or not officially free and last check positive, at the end of the period' ('DU17A'), 'Number of animals with unknown status, at the end of the period' ('DU15A'), 'Number of herds with status free or officially free suspended, at the end of the period' ('DU20A'), 'Number of herds with status free, at the end of the period' ('DU22A'), 'Number of herds with status not free or not officially free and last check negative, at the end of the period' ('DU18A'), 'Number of herds with status not free or not officially free and last check positive, at the end of the period' ('DU16A'), 'Number of herds with unknown status, at the end of the period' ('DU14A')];
DST.07	unitDS	E	DST24	If value of *tableName* = 'Ovine or Caprine brucellosis - data on animals - Community co-financed eradication programmes' ('ZT05A') then value of *unitDS* must be IN ['Number of animals tested' ('DU09A'), 'Number of animals tested individually' ('DU10A'), 'Number of animals to be tested under the program' ('DU08A'), 'Number of positive animals' ('DU11A'), 'Total number of animals' ('DU07A'), 'Number of positive animals slaughtered' ('DU12A'), 'Total number of animals slaughtered' ('DU13A')];

Table 35 (continued): EFSA business rules for disease status data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
DST.07	unitDS	E	DST25	If value of *tableName* = 'Ovine or Caprine brucellosis - data on herds - Community co-financed eradication programmes' ('ZT06A') then value of *unitDS* must be IN ['Number of herds under the program' ('DU02A'), 'Number of herds under the program tested/checked' ('DU03A'), 'Number of new positive herds' ('DU05A'), 'Number of positive herds' ('DU04A'), 'Total number of herds' ('DU01A'), 'Number of depopulated herds' ('DU06A')];
DST.07	unitDS	E	DST26	If value of tableName = 'Bovine brucellosis in countries and regions that do not receive Community co-financing for eradication programme' ('ZT04A') then value of unitDS must be IN ['Number of herds with status officially free' ('DU54A'), 'Number of infected herds' ('DU56A'), 'Total number of herds' ('DU01A'), 'Number of abortions due to Brucella abortus' ('DU39A'), 'Number of animals or pools tested under surveillance by bulk milk' ('DU35A'), 'Number of animals positive in microbiological testing under investigations of suspect cases' ('DU45A'), 'Number of animals positive to BST under investigations of suspect cases' ('DU43A'), 'Number of animals serologically tested under investigations of suspect cases' ('DU40A'), 'Number of animals tested by microbiology under investigations of suspect cases' ('DU44A'), 'Number of animals tested under surveillance' ('DU32A'), 'Number of herds tested under surveillance' ('DU31A'), 'Number of herds tested under surveillance by bulk milk' ('DU34A'), 'Number of infected herds tested under surveillance' ('DU33A'), 'Number of infected herds tested under surveillance by bulk milk' ('DU36A'), 'Number of isolations of Brucella infections' ('DU38A'), 'Number of notified abortions whatever cause' ('DU37A'), 'Number of seropositive animals under investigations of suspect cases' ('DU42A'), 'Number of suspended herds under investigations of suspect cases' ('DU41A'), 'Total number of animals' ('DU07A')];

Table 35 (continued): EFSA business rules for disease status data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
DST.07	unitDS	E	DST27	If value of *tableName* = 'Bovine brucellosis - data on status of herds at the end of the period - Community co-financed eradication' ('ZT03A') then value of *unitDS* must be IN ['Number of animals with status officially free, at the end of the period' ('DU25A'), 'Number of herds with status officially free, at the end of the period' ('DU24A'), 'Total number of animals under the program, at the end of the period' ('DU53A'), 'Total number of herds under the program, at the end of the period' ('DU52A'), 'Number of animals with status free or officially free suspended, at the end of the period' ('DU21A'), 'Number of animals with status free, at the end of the period' ('DU23A'), 'Number of animals with status not free or not officially free and last check negative, at the end of the period' ('DU19A'), 'Number of animals with status not free or not officially free and last check positive, at the end of the period' ('DU17A'), 'Number of animals with unknown status, at the end of the period' ('DU15A'), 'Number of herds with status free or officially free suspended, at the end of the period' ('DU20A'), 'Number of herds with status free, at the end of the period' ('DU22A'), 'Number of herds with status not free or not officially free and last check negative, at the end of the period' ('DU18A'), 'Number of herds with status not free or not officially free and last check positive, at the end of the period' ('DU16A'), 'Number of herds with unknown status, at the end of the period' ('DU14A')];
DST.07	unitDS	E	DST28	If value of *tableName* = 'Bovine brucellosis - data on animals - Community co-financed eradication programmes' ('ZT01A') then value of *unitDS* must be IN ['Number of animals tested' ('DU09A'), 'Number of animals tested individually' ('DU10A'), 'Number of animals to be tested under the program' ('DU08A'), 'Number of positive animals' ('DU11A'), 'Total number of animals' ('DU07A'), 'Number of positive animals slaughtered' ('DU12A'), 'Total number of animals slaughtered' ('DU13A')];

Table 35 (continued): EFSA business rules for disease status data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
DST.07	unitDS	E	DST29	If value of *tableName* = 'Bovine brucellosis - data on herds - Community co-financed eradication programmes' ('ZT02A') then value of *unitDS* must be IN ['Number of herds under the program' ('DU02A'), 'Number of herds under the program tested/checked' ('DU03A'), 'Number of new positive herds' ('DU05A'), 'Number of positive herds' ('DU04A'), 'Total number of herds' ('DU01A'), 'Number of depopulated herds' ('DU06A')];
DST.07	unitDS	E	DST30	If value of *tableName* = 'Tuberculosis in farmed deer' ('ZT13A') then value of *unitDS* must be IN ['Number of infected herds' ('DU56A'), 'Total number of herds' ('DU01A'), 'Interval between routine tuberculin tests' ('DU26A'), 'Number of animals detected positive in bacteriological examination' ('DU30A'), 'Number of animals tested with tuberculin routine testing' ('DU27A'), 'Number of animals with suspicious lesions of tuberculosis examined and submitted to histopathological and bacteriological examinations' ('DU29A'), 'Number of herds with status free' ('DU57A'), 'Number of tuberculin tests carried out before the introduction into the herds' ('DU28A'), 'Total number of animals' ('DU07A')];
DST.08	numUnits	E	DST03	In the Zoonoses Web Application, if *unitsDS* is <> 'Routine tuberculin testing - Interval between routine tuberculin tests' then the value of *numUnits* must be numeric;
DST.08	numUnits	E	DST06	Total Number of Herds DU01A must be greater than or equal to the Number of Herds under the Program DU02A
DST.08	numUnits	E	DST07	Number of Herds under the Program DU02A must be greater than or equal to the Number of herds under the program tested/checked DU03A
DST.08	numUnits	E	DST08	Number of herds under the program tested/checked DU03A must be greater than or equal to the Number of Positive Herds DU04A
DST.08	numUnits	E	DST09	Number of Positive Herds DU04A must be greater than or equal to the Number of New Positive Herds DU05A
DST.08	numUnits	E	DST10	Number of Herds under the Program DU02A must be greater than or equal to Number of Depopulated Herds DU06A
DST.08	numUnits	E	DST11	Total Number of Animals DU07A must be greater than or equal to the Number of animals to be tested under the program DU08A

Table 35 (continued): EFSA business rules for disease status data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
DST.08	numUnits	E	DST12	Number of Animals under the Program DU08A must be greater than or equal to the Number of Tested Animals DU09A
DST.08	numUnits	E	DST13	Number of Tested Animals DU016A must be greater than or equal to the Number of Positive Animals DU018A
DST.08	numUnits	E	DST14	Number of Animals under the Program must be equal to the Sum of Number of Animals on Status Unknown + Number of Animals not free or not officially free last check positive + Number of Animals not free or not officially free last check negative + Number of Animals free or officially free suspended + Number of Free Animals + Number of Officially Free Animals DU53A = DU15A + DU16A + DU17A + DU18A + DU19A + DU20A + DU21A + DU22A + DU23A + DU24A + DU25A
DST.08	numUnits	E	DST15	Total Number of Herds under the Program must be equal to the Sum of Number of Herds on Status Unknown + Number of Herds not free or not officially free last check positive + Number of Herds not free or not officially free last check negative + Number of Herds free or officially free suspended + Number of Free Herds + Number of Officially Free Herds DU52A = DU14A + DU16A + DU18A + DU20A + DU22A + DU24A
Context	Context	E	DST04	Value of numUnits must be the same for each combination of values in sampArea/zoonosis/matrix/unitDS/tableName;
General rule	General rule	E	DST05	MSs have to fill in the relevant tables depending on their official status and according to whether they receive EU cofinancing systemor not for their control and eradication programmes

F) FOOD-BORNE OUTBREAKS DATA MODEL 2013

36. Introduction

This data dictionary provides guidance for reporting on food-borne outbreak (FBO) data under the framework of Directive 2003/99/EC. The EFSA data model for FBO tables is summarised in Table 38: and the business rules applied for data validation are presented in Table 39: .

37. General constraints

37.1. Context and uniqueness of information for weak-evidence FBO reporting

The data elements Number of outbreaks, Number of human cases, Number of hospitalised, Number of deaths must be aggregated so that the information reported for the following set of data elements (context) is unique (Table 36:):

Table 36: Data elements defining the 'context' for weak-evidence FBO

Set of data elements
Reporting year
Reporting country
Outbreak strength = 'N'
Causative agent group

37.2. Context and uniqueness of information for strong-evidence FBO reporting

The data elements Number of outbreaks, Number of human cases, Number of hospitalised, Number of deaths must be aggregated so that the information reported for the following set of data elements (context) is unique (Table 37:):

Table 37: Data elements defining the 'context' for strong-evidence FBO

Set of data elements
Reporting year
Reporting country
Outbreak strength = 'Y'
Causative agent
FBO national code
Other agents
Outbreak type
Food vehicle
More food vehicle information
Nature of evidence
Setting
Place of origin of problem
Origin of food vehicle
Contributory factors

38. General information and identification of the isolate

38.1. 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.

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

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

38.3. Language (*lang FBO.03*)

This data element is **mandatory**. It contains codes linked to a pick list (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.

39. Information about type of food-borne outbreak

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

This data element is **mandatory**. It contains codes linked to a pick list (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).

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

This data element is **mandatory** when reporting weak-evidence FBO data (fboStrengthStrong = 'N'). It should be left **empty** when reporting strong-evidence FBO data (fboStrengthStrong = 'Y').
It contains codes linked to a pick list (ZOO_CAT_PARAM_ZOO, domain: D_FBO_fboCausativeAgentGroup). It indicates the groups of the causative agent according which the weak-evidence FBOs are categorised.

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

This data element is **mandatory** when reporting strong-evidence FBO data (fboStrengthStrong = 'Y'). It should be left **empty** when reporting weak-evidence FBO data (fboStrengthStrong = 'N'). It contains codes linked to a pick list (ZOO_CAT_PARAM_ZOO, domain: D_FBO_fboCausativeAgent) and indicates the causative agent. Causative agent is the agent considered being 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 pick list has 4 levels which will enable the reporting of different agent species, serovars and serotypes. It is recommended to report the causative agent using the most detailed description available.

40. Information about the outbreak

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

This data element is **optional** and can be reported only for strong-evidence FBO data (fboStrengthStrong = 'Y'). It should be left **empty** when reporting weak-evidence FBO data (fboStrengthStrong = 'N'). It is a free text data element for maximum 100 alphanumeric characters. It is used to include a national code / unique identifier for the FBO as a reference to a national database if such a code exists.

40.2. Other agents (*fboOtherAgents FBO.08*)

This data element is **optional** and can be reported only for strong-evidence FBO data (fboStrengthStrong = 'Y'). It should be left **empty** when reporting weak-evidence FBO data (fboStrengthStrong = 'N'). It contains codes linked to a pick list (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'

40.3. Outbreak type (*fboType FBO.09*)

This data element is **optional** and can be reported only for strong-evidence FBO data (fboStrengthStrong = 'Y'). It should be left **empty** when reporting weak-evidence FBO data (fboStrengthStrong = 'N'). It contains codes linked to a pick list (ZOO_CAT_OUTBRK). The pick list includes the terms 'General' (code 'TB01A') and 'Household / domestic kitchen' (code 'TB02A') in order to distinguish between these types of outbreaks. If this information is not available, the value 'Unknown' (code 'TB03A') can be chosen.

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

This data element is **mandatory** when reporting strong-evidence FBO data (fboStrengthStrong = 'Y'). It should be left **empty** when reporting weak-evidence FBO data (fboStrengthStrong = 'N'). It contains codes linked to a pick list (ZOO_CAT_FOODVH). This list covers the food vehicle categories, e.g. 'Eggs and egg products' (code 'B09647B').

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

This data element is **optional** and can be reported only for strong-evidence FBO data (fboStrengthStrong = 'Y'). It should be left **empty** when reporting weak-evidence FBO data (fboStrengthStrong = 'N'). It is a free text data element for maximum 2 000 alphanumeric characters and can be used to give more detailed information on the food vehicle (for example 'cheese made from raw goat milk'). It should be completed in English (see data element FBO.03 Language).

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

This data element is **mandatory** when reporting strong-evidence FBO data (fboStrengthStrong = 'Y'). It should be left **empty** when reporting weak-evidence FBO data (fboStrengthStrong = 'N'). It contains codes linked to a pick list (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).

40.7. Setting (*fboSetting FBO.13*)

This data element is **optional** and can be reported only for strong-evidence FBO data (fboStrengthStrong = 'Y'). It should be left **empty** when reporting weak-evidence FBO data (fboStrengthStrong = 'N'). It contains codes linked to a pick list (ZOO_CAT_SMPNT, domain: D_FBO_fboSetting). The setting is a 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').

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

This data element is **optional** and can be reported only for strong-evidence FBO data (fboStrengthStrong = 'Y'). It should be left **empty** when reporting weak-evidence FBO data (fboStrengthStrong = 'N'). It contains codes linked to a pick list (ZOO_CAT_SMPNT, domain: D_FBO_fboPlaceOrigin). The place of origin of the problem is the place, other than 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 pick list) can be chosen from the pick list and reported as a comma separated list of codes (without spacing).

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

This data element is **optional** and can be reported only for strong-evidence FBO data (fboStrengthStrong = 'Y'). It should be left **empty** when reporting weak-evidence FBO data (fboStrengthStrong = 'N'). It contains codes linked to a pick list (ZOO_CAT_COUNTRY, domain: D_FBO_fboVehicleOrigin). It indicates the country from which the food vehicle originated.

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

This data element is **optional** and can be reported only for strong-evidence FBO data (fboStrengthStrong = 'Y'). It should be left **empty** when reporting weak-evidence FBO data (fboStrengthStrong = 'N'). It contains codes linked to a pick list (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 pick list) can be reported as a comma separated list of codes (without spacing).

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

This data element is **mandatory**. It is a numerical integer data element.
In case of strong-evidence FBOs, it is the number of outbreaks sharing the same set of context data elements (see paragraph 37.2). In case of weak-evidence FBOs, it is the number of FBOs having the same causative agent group (see paragraph 37.1).

40.12. 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.

40.13. 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.

40.14. 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 which has been identified as responsible for the outbreak(s) should be reported. If this number is unknown '-1' can be reported.

41. Additional information

41.1. Comment (*resComm FBO.21*)

This data element is **optional**. It is a free text of maximum 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 38: EFSA data model for food-borne outbreak data reporting

Element Code	Element Name	Short Element name for XML/Excel transfer	Type	Constraint	Pick list	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	xs:string(15)	Optional	ZOO_CAT_PARAM_ZOO	D_FBO_fboCausativeAgentGroup
FBO.06	Causative agent	fboAgent	xs:string(15)	Optional	ZOO_CAT_PARAM_ZOO	D_FBO_fboCausativeAgent
FBO.07	FBO national code	fboCode	xs:string(100)	Optional		
FBO.08	Other agents	fboOtherAgents	xs:string(250)	Optional	ZOO_CAT_PARAM_ZOO	D_FBO_fboCausativeAgent
FBO.09	Outbreak type	fboType	xs:string(5)	Optional	ZOO_CAT_OUTBRK	
FBO.10	Food vehicle	fboVehicle	xs:string(7)	Optional	ZOO_CAT_FOODVH	
FBO.11	More food vehicle information	fboVehicleInfo	xs:string(2000)	Optional		
FBO.12	Nature of evidence	fboEvidence	xs:string(250)	Optional	ZOO_CAT_EVDNC	
FBO.13	Setting	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 39: EFSA business rules for food-borne outbreak data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
FBO.01	repYear	E	FBO01	Value of *repYear* must be = data collection reporting year;
FBO.03	lang	W	FBO02	WARNING. Value of *lang* should be = 'English' ('en');
FBO.05	fboAgentGroup	E	FBO03	If value of *fboStrengthStrong* = 'No' ('N') then value of *fboAgentGroup* must be <> NULL;
FBO.05	fboAgentGroup	E	FBO14	If value of *fboStrengthStrong* = 'Yes' ('Y') then value of *fboAgentGroup* must be = NULL;
FBO.06	fboAgent	E	FBO04	If value of *fboStrengthStrong* = 'Yes' ('Y') then value of *fboAgent* must be <> NULL;
FBO.06	fboAgent	E	FBO15	If value of *fboStrengthStrong* = 'No' ('N') then value of *fboAgent* must be = NULL;
FBO.07	fboCode	E	FBO16	If value of *fboStrengthStrong* = 'No' ('N') then value of *fboCode* must be = NULL;
FBO.08	fboOtherAgents	E	FBO17	If value of *fboStrengthStrong* = 'No' ('N') then value of *fboOtherAgents* must be = NULL;
FBO.09	fboType	E	FBO18	If value of *fboStrengthStrong* = 'No' ('N') then value of *fboType* must be = NULL;
FBO.10	fboVehicle	E	FBO05	If value of *fboStrengthStrong* = 'Yes' ('Y') then value of *fboVehicle* must be <> NULL;
FBO.10	fboVehicle	E	FBO19	If value of *fboStrengthStrong* = 'No' ('N') then value of *fboVehicle* must be = NULL;
FBO.11	fboVehicleInfo	E	FBO20	If value of *fboStrengthStrong* = 'No' ('N') then value of *fboVehicleInfo* must be = NULL;
FBO.12	fboEvidence	E	FBO06	If value of fboStrengthStrong = 'Yes' ('Y') then value of *fboEvidence* must be <> NULL;
FBO.12	fboEvidence	E	FBO21	If value of *fboStrengthStrong* = 'No' ('N') then value of *fboEvidence* must be = NULL;
FBO.13	fboSetting	E	FBO22	If value of *fboStrengthStrong* = 'No' ('N') then value of *fboSetting* must be = NULL;
FBO.14	fboPlaceOrigin	E	FBO23	If value of *fboStrengthStrong* = 'No' ('N') then value of *fboPlaceOrigin* must be = NULL;
FBO.15	fboVehicleOrigin	E	FBO24	If value of *fboStrengthStrong* = 'No' ('N') then value of *fboVehicleOrigin* must be = NULL;

Table 39 (continued): EFSA business rules for food-borne outbreak data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
FBO.16	fboFactor	E	FBO25	If value of *fboStrengthStrong* = 'No' ('N') then value of *fboFactor* must be = NULL;
FBO.17	numOutbreaks	E	FBO07	Value of *numOutbreaks* must be > 0;
FBO.17 & FBO.18 & FBO.19 & FBO.20	numOutbreaks & numHumanCases & numHospitalised & numDeaths	E	FBO26	If value of *fboStrengthStrong* = 'No' ('N') then the combination of values in *repYear/repCountry/fboAgentGroup* must be unique (values in *numOutbreaks*, *numHumanCases*, *numHospitalised* and *numDeaths* must be aggregated accordingly);
FBO.17 & FBO.18 & FBO.19 & FBO.20	numOutbreaks & numHumanCases & numHospitalised & numDeaths	E	FBO27	If value of *fboStrengthStrong* = 'Yes' ('Y') then the combination of values in *repYear/repCountry/fboAgent/fboCode/fboOtherAgents/fboType/fboVehicle/fboVehicleInfo/fboEvidence/fboSetting/fboPlaceOrigin/fboVehicleOrigin/fboFactor* must be unique (values in *numOutbreaks*, *numHumanCases*, *numHospitalised* and *numDeaths* must be aggregated accordingly);
FBO.18	numHumanCases	E	FBO08	Value of *numHumanCases* must be >= -1;
FBO.19	numHospitalised	E	FBO09	Value of *numHospitalised* must be >= -1;
FBO.19	numHospitalised	E	FBO11	Value of *numHospitalised* must be <= value of *numHumanCases;*
FBO.20	numDeaths	E	FBO10	Value of *numDeaths* must be >= -1;
FBO.20	numDeaths	E	FBO12	Value of *numDeaths* must be <= value of *numHumanCases;*

G) PREVALENCE DATA MODEL 2013

42. 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 Data Collection Framework (DCF). The EFSA data model for prevalence tables is summarised in Table 42: and the business rules applied for data validation are presented in Table 43: . Refer to Table 44: and Table 45: for examples on how to report prevalence data using the provided data model described in these guidelines.

43. General constraints

43.1. Context for aggregated data elements

For prevalence data, the set of data elements shown in Table 40: defines the so called 'context', that is the set of information that represents an aggregated sample. Aggregate data elements refer to this set of information and need to be the same for each record sharing the same 'context'.

Table 40: List of data elements defining the 'context'

Element Name
Reporting year
Reporting country
Zoonotic agent Level 1
Matrix
Sampling stage
Sample origin
Sample type
Sampling context
Sampler
Sampling strategy
Sampling details
Area of sampling
Sampling unit
Sample weight
Sample weight unit
Source of information
Target verification
Vaccination status
Analytical method
Quantity

Table 41: Aggregate data elements that must have the same value for each record sharing the same 'context'

Element Name
Number of flocks under control programme
Number of clinically affected herds
Total units tested
Total units positive

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 44:). 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 44: example on *Gallus gallus* (fowl) - breeding flocks test results).

No duplicated records are allowed for the same 'context', this means that all sampling results need to be aggregated by the set of data elements listed in Table 40: .

There is an exception to this definition in the context appliedto *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
- Total units positive

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 Total Units Tested and Total Units Positive represent the total units tested and positive for *Listeria monocytogenes* and *Escherichia coli*, pathogenic - Verotoxigenic *E. coli* (VTEC) and *Staphylococcus* - *S aureus*, meticillin resistant (MRSA), respectively (Table 45:).

Additionally, for *Listeria monocytogenes* and for Histamine the analytical method is not part of the context thus the Total Units Tested and Total Units Positive represent the total units tested and positive for the two requested analytical methods combined (Detection and Enumeration). The Units tested (unitsTested) will express the number of units tested by each method and the Units Positive (unitsPositive) will be used to express then number of units positive found by the specific analytical method (Table 45:).

43.2. Reporting units positive at different level 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 units positive should not be reported also at the parent level.

The units positive for S. Enteritidis for *Gallus gallus* (fowl) - laying hens - adult in Table 44: will be calculated by summing the units positive for the zoonosis level 2 *Salmonella* - *S.* Enteritidis (1) and the zoonosis level 3 *Salmonella* - *S.* Enteritidis - PT 12 (2) thus the result will be equal to 3.

There is an exception that applies when reporting data for zoonosis level 3, 4 and 5 for *Escherichia coli*, pathogenic - Verotoxigenic *E. coli* (VTEC) and for *Staphylococcus* - *S. aureus*, meticillin resistant (MRSA).

For *Escherichia coli*, pathogenic - Verotoxigenic *E. coli* (VTEC) all the VTEC non-O157 positive units must also be reported under the column VTEC non-O157, and the positive units for level 4 and 5 of VTEC O157 must be reported again under the VTEC O157 column.

For *Staphylococcus* - *S. aureus*, meticillin resistant (MRSA) the units positive reported at the zoonosis level 3, 4 and 5 need to be reported also at the parent level 2 that is in this case *Staphylococcus* - *S. aureus*, meticillin resistant (MRSA).

43.3. Reporting data at various level 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 a parent level of the matrix (e.g. *Gallus gallus*) as this will result in the so called "double reporting".

However, when reporting regional data in the data element Area of sampling (sampArea) a row should be reported for each region plus 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 country level the sampArea data element shall be left empty.

43.4. Comparison with the manual web-based reporting application

The three figures below (Figure 9: , Figure 10: and Figure 11:) 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 capital letters) must be repeated in all rows sharing the same context in the DCF. For simplification the context is indicated only by the matrix data element in these examples (although it includes other data elements such as Sampling stage, Sampling context, Sampler etc. as described in the previous paragraph 43.1).

Samonella

ZooWebApp					DCF							
Matrix	Total units tested	Total units positive for *Salmonella* spp.	*S.* Enteritidis	*S.* Typhimurium	zoonosis	matrix	totUnitsTested	totUnitsPositive	anMethCode	unitsTested	quantity	unitsPositive
M	A	B	C	D	S. Enteritidis	M	A	B				C
					S. Typhimurium	M	A	B				D

Figure 9: 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 *L. monocytogenes*	Units tested with detection method	*L. monocytogenes* presence in x g	Units tested with enumeration method	*L. monocytogenes* >detection limit but <=100 cfu/g	*L. monocytogenes* >100 cfu/g	zoonosis	matrix	totUnitsTested	totUnitsPositive	anMethCode	unitsTested	quantity	unitsPositive
								L. monocytogenes	M	A	B	detection	C		D
M	A	B	C	D	E	F	G	L. monocytogenes	M	A	B	enumeration	E	<= 100	F
								L. monocytogenes	M	A	B	enumeration	E	> 100	G

Figure 10: 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
M	A	B	C	D	E	F	Histamine	M	A	B	enumeration		<=100	C
							Histamine	M	A	B	enumeration		>100 to <=200	D
							Histamine	M	A	B	enumeration		>200 to <=400	E
							Histamine	M	A	B	enumeration		>400	F

Figure 11: Comparison between the web-based reporting tables and the data model for prevalence data on Histamine in food

44. General information and identification of the sample

44.1. 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.

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

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

44.3. Language (*lang PRV.03*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_LANG, domain: D_ALL_lang), however, **only the code 'en' for 'English' should be used**, since 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.

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

This data element is **mandatory**. It contains codes linked to a pick list (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*, meticillin resistant (MRSA)
- Histamine
- *Cronobacter*

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

This pick list 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 the zoonoses level 1.

When reporting positive findings for a zoonotic agent (e.g. *Salmonella*), the level 2 or higher of the pick list need 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 paragraph 43 for a description on how to report different levels of speciation for the same zoonotic agent.

44.5. Matrix (*matrix PRV.05*)

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_MATRIX, domain: D_PRV_matrix). It represents specific detail on the food, animal species or feed category reported on. Also 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 the level 2, level 3 and level 4 terms) are selected, as far as the available information makes possible and as enabled by the detailed pick list.

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').

45. Information about the sampling

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

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_SMPNT, domain: PRV_sampStage). The sampling stage is the stage along the food chain where the sample has been collected, e.g. 'at farm' (code 'E101A'), 'at slaughterhouse' (code 'E311A') or 'at retail' (code 'E520A'), 'unknown', (code E980A).

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

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

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

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

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

This data element is **mandatory**. It contains codes linked to a pick list (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. Reporting of the sampling context is recommended to enable the right interpretation of the data reported. If not known the term 'unspecified' (code 'K029A') is available.

45.5. Sampler (*sampler PRV.10)*

This data element is **mandatory**. It contains codes linked to a pick list (ZOO_CAT_SMPLR). It indicates the type of the body who performed the sampling, e.g. 'Industry sampling' (code 'CX01A'), 'Official sampling' (code 'CX02A'), and also 'not applicable' (code 'CX99A').

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

This data element is **mandatory**. It contains codes linked to a pick list (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.

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

This data element is **optional**. This is a free text of maximum 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).

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

This data element is **optional**. It contains codes linked to a pick list (ZOO_CAT_NUTS). It indicates the area or region or province of the sampling in which the animal/food/feed sample has been collected (Nomenclature of territorial units for statistics – NUTS coding system). Area of sampling must be currently reported only for rabies, *Echinococcus* and West Nile virus. 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 or the data element could be left empty.

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

This data element is **mandatory**. It contains codes linked to a pick list (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').

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

This data element is **optional** but for data interpretation purposes, value of sample weight is **mandatory** if sampling unit is equal to 'single (food/feed)' or 'batch (food/feed)'). This data element allows for numeric data values with decimal numbers. 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 test portion).

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

This data element is **mandatory if** sample weight is provided under PRV.15. It contains codes linked to a pick list (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').

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

This data element is **optional**. This is a free text of maximum 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).

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

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

- *'Gallus gallus (fowl) - breeding flocks, unspecified - adult' (code 'A041021A')*
- *'Gallus gallus (fowl) - laying hens - adult' (code 'A041031A')*
- *'Gallus gallus (fowl) - broilers - before slaughter' (code 'A000041A ')*
- *'Turkeys - breeding flocks, unspecified - adult' (code 'A041033A')*
- *'Turkeys - fattening flocks - before slaughter' (code 'A041278A')*

For all other data than *Salmonella* in the matrix categories cited above the target verification data element should <u>not</u> be reported.

It contains codes linked to a pick list with values 'Yes' (code 'Y'), 'No' (code 'N') and 'Unknown' (code 'U') (ZOO_CAT_YESNO). Target verification is used to indicate which information is to be used for the purpose of verifying if the EU *Salmonella* reduction target set by Commission Regulation

(EC) No 200/2010[7] for breeding flocks, Commission Regulation (EC) No 517/2011[8] for laying hen flocks of *Gallus gallus*, Commission Regulation (EC) No 200/2012[9] for broiler flocks of *Gallus gallus* and Commission Regulation (EC) No 1190/2012[10] for turkey flocks have been met.

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

This data element is **mandatory if** data element 'Target verification (*target* PRV.18) is reported and to be left empty in 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 control programme data element should not be reported because the data cannot be migrated to the Zoonoses Web Application.

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

This data element is **mandatory when** reporting on '***Coxiella* (Q fever) in animals**' and to 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'[11]. For other zoonoses than Q fever the number of clinically affected herds data element should not be reported because the data cannot be migrated to the Zoonoses Web Application.

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

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

46. Information about the result

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

This data element is **mandatory**. This is a numerical data element. It is the total number of the units tested for the selected zoonotic agent. Refer to paragraph 43, General constraints, for a detailed description on how to report aggregated data elements. See to Table 44: and Table 45: for examples.

46.2. 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 (*Salmonella*, *Campylobacter*) out of the total units tested.

[7] 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.

[8] 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.

[9] 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.

[10] 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.

[11] Scientific report submitted to EFSA. Question No EFSA-Q-2009-00511. Available online http://www.efsa.europa.eu/en/supporting/doc/48e.pdf.

In case of *Listeria* this is the total number of units found positive to *L. monocytogenes*. Refer to paragraph 43, General constraints, for a detailed description on how to report aggregated data elements. See to Table 44: and Table 45: for examples.

46.3. Quantity (*quantity PRV.24*)

This data element is **mandatory when** reporting on **enumeration method results of *Listeria*** (cfu/g) and **Histamine** (mg/Kg) in food. It contains codes linked to a pick list (ZOO_CAT_FIXMEAS, domain: D_PVR_Quantity). It indicates the quantity measured by the test.
In the *Listeria* in food table the code 'R073A' (corresponding to the term '<= 100') is used to report results where *L. monocytogenes* was found in numbers over the quantification limit but less than or equal to 100 cfu/g. Whereas the code 'R077A' (corresponding to the term '>100') is used to report results where *L. monocytogenes* was found in numbers more than 100 cfu/g.

In the *Histamine* in food table the codes 'R073A' to 'R076A' are used to report the numbers of units where histamine was found in quantities of 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'),
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').

46.4. 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 it is not permitted to report multiple analytical results for the same sample in cases other than *Listeria* in food. This is a numerical data element. It indicates the numbers of units tested by detection method or by enumeration method, respectively. Refer to paragraph 43 and Table 45: for further information and examples on how to report on this data element for *Listeria* in food.

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

This data element is **mandatory when** reporting a positive result and must be left empty for negative results. This is a numerical data element. It indicates the number of units tested positive for the agent species, serovar or serotype (e.g. *Salmonella* Typhimurium, *Salmonella* Infantis, *Campylobacter jejuni*) reported under the zoonosis PRV.04 data element. In case of *Listeria* in food table this data element must be used to report the number of units found positive for *L. monocytogenes* by each analytical method (detection and enumeration). Refer to paragraph 43.1, Table 44: and Table 45: for further information and examples on how to report on this data element.

47. Information about the test method

47.1. Method (*anMethCode PRV.23*)

This data element is **mandatory when** reporting data on *Listeria* in food and data on Histamine, and it is highly **recommended when** reporting data on VTEC, *Toxoplasma*, Q-fever, West Nile Virus and *Mycobacterium*. It contains codes linked to a pick list (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. **Results from different methods <u>for the same samples</u> 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 paragraphs 43.1 and 43.4 and Table 45: for a description and examples on how to report enumeration and detection method results for *Listeria* in food.

48. Additional information

48.1. Comment (*resComm PRV.27*)

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

Table 42: EFSA data model for prevalence data reporting

Element Code	Element Name	Short Element name for XML/Excel transfer	Constraint	Type	Pick list	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 43: EFSA business rules for prevalence data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
Entire row	Entire row	E	PRV46	Reporting for a specific biological sample and zoonotic agent must be unique. Duplicated rows were detected
Entire row	Entire row	W	PRV47	WARNING. The main row category should not include results of the row subcategories. A potential double reporting was detected. Units reported under the row main category are equal to the sum of units of row subcategories
Entire row	Entire row	E	PRV48	Multiple results for the same sample, context and zoonotic agent can not be reported. If results were obtained from more than one method for the same sample, context and zoonotic agent (zoonosis) only the aggregated result should be reported with method 'Classification not possible' (F001A).
PRV.01	repYear	E	PRV01	Value of *repYear* must be = data collection reporting year;
PRV.03	lang	W	PRV04	WARNING. Value of *lang* should be = 'English' ('en');
PRV.05	matrix	W	PRV25	WARNING. For data interpretation purposes, it is advised not to use general categories: value of *matrix* should NOT be IN ['Gallus gallus (fowl) - unspecified' ('A031721A'), 'Compound feedingstuffs, not specified' ('A001421A')];
PRV.05	matrix	E	PRV37	If value of matrix is a wild species then more detail must be provided to specify whether it is wild, farmed, pet or zoo animals (matrix level_2);
PRV.06	sampStage	W	PRV21	WARNING. For data interpretation purposes, value of *sampStage* should not be 'unspecified' ('E098A');
PRV.09	sampContext	W	PRV22	WARNING. For data interpretation purposes, value of *sampContext* should not be 'Unspecified' ('K029A');
PRV.10	sampler	W	PRV23	WARNING. For data interpretation purposes, value of *sampler* should not be 'Not applicable' ('CX99A');
PRV.11	progSampStrategy	W	PRV24	WARNING. For data interpretation purposes, value of *progSampStrategy* 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 & PRV.27	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'

Table 43 (continued): EFSA business rules for prevalence data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
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.14	sampUnit	E	PRV20	If value of speciesType (i.e. *matrix* level_0) = 'animal' then value of *sampUnit* IN ['herd/flock' ('G202A'), 'animal' ('G199A'), 'holding' ('G198A'), 'slaughter batch' ('G200A')] AND if value of speciesType (i.e. *matrix* level_0) IN ['food', 'feed'] then value of *sampUnit* IN ['single (food/feed)' ('G203A'), 'batch (food/feed)' ('G204A')];
PRV.15	sampWeight	E	PRV08	Value of *sampWeight* must be > 0;
PRV.15	sampWeight	E	PRV09	If value of *sampUnit* IN ['single (food/feed)' ('G203A'), 'batch (food/feed)'('G204A')] then value of *sampWeight* must be <> NULL;
PRV.15 & PRV.16	sampWeight & sampWeightUnit	E	PRV17	In the Zoonoses Web Application sample weight and sample weight unit must meet these formatting requirements: a number followed by a sapce and the unit of measure among cm^2, g, mL, kg;
PRV.16	sampWeightUnit	E	PRV10	If value of *sampWeight* <> NULL then value of *sampWeightUnit* must be <> NULL;

Table 43 (continued): EFSA business rules for prevalence data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
PRV.18	target	E	PRV02	If value of *zoonosis* level_1 = 'Salmonella' ('RF-00000304-MCG') AND value of *matrix* is IN ['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) - 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) - 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')] then value of *target* must be <> NULL;

Table 43 (continued): EFSA business rules for prevalence data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
PRV.19	contrFlocks	E	PRV03	If value of zoonosis level_1 = 'Salmonella' ('RF-00000304-MCG') AND value of matrix is IN ['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) - 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) - 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')] then value of contrFlocks must be <> NULL;
PRV.19	contrFlocks	E	PRV15	Value of *contrFlocks* must be numeric;
PRV.20	affectHerds	E	PRV16	Value of *affectHerds* must be numeric;
PRV.20	affectHerds	E	PRV28	If *zoonosis* level_1 = 'Coxiella (Q-fever)' ('RF-00000083-MCG') then value of *affectHerds* must be <> NULL;
PRV.21	totUnitsTested	E	PRV05	Value of *totUnitsTested* must be > 0;
PRV.21	totUnitsTested	E	PRV06	Value of *totUnitsTested* must be >= value of *totUnitsPositive;*
PRV.21	totUnitsTested	E	PRV12	Value of *totUnitsTested* must be numeric;
PRV.21	totUnitsTested	E	PRV32	Value of *totUnitsTested* must be >= value of *unitsTested;*
PRV.21	totUnitsTested	E	PRV36	Value of *totUnitsTested* must be <= sum of *unitsTested* of the same context;
PRV.22	totUnitsPositive	E	PRV07	Value of *totUnitsPositive* must be >= 0;

Table 43 (continued): EFSA business rules for prevalence data reporting

Element Code	Short Element name	ERROR TYPE	ERROR CODE	RULE
PRV.22	totUnitsPositive	E	PRV13	Value of *totUnitsPositive* must be numeric;
PRV.22	totUnitsPositive	E	PRV35	Value of *totUnitsPositive* must be <= sum of *unitsPositive* of the same context;
PRV.23	anMethCode	W	PRV11	WARNING. For data interpretation purposes, value of *anMethCode* should be <> NULL if value of *zoonosis* level_1 is IN ['Coxiella (Q-fever)' ('RF-00000083-MCG'), 'Escherichia coli, pathogenic' ('RF-00003550-MCG'), 'Mycobacterium' ('RF-00000273-MCG'), 'Toxoplasma' ('RF-00002512-MCG'), 'West Nile virus' ('RF-00002664-MCG')];
PRV.23	anMethCode	E	PRV49	If value of *zoonosis* level_1 = 'Listeria' ('RF-00000245-MCG') AND if value of speciesType (i.e. *matrix* level_0) ='food' then value of *anMethCode* must be IN ['Enumeration/Quantitative method' ('F141A'), 'Detection method - presence in x g' ('F145A')];
PRV.23	anMethCode	E	PRV50	If value of *zoonosis* = 'Histamine' ('RF-00000003-BGA') then value of *anMethCode* must be = 'Enumeration/Quantitative method' ('F141A');
PRV.24	quantity	E	PRV29	If value of *anMethCode* = 'Enumeration/Quantitative method' ('F141A') then value of *quantity* must be <> NULL;
PRV.25	unitsTested	E	PRV18	Value of *unitsTested* must be numeric;
PRV.25	unitsTested	E	PRV30	If value of *anMethCode* = 'Enumeration/Quantitative method' ('F141A') then value of *unitsTested* must be <> NULL;
PRV.26	unitsPositive	E	PRV14	Value of *unitsPositive* must be numeric;
PRV.26	unitsPositive	E	PRV31	If value of *anMethCode* = 'Enumeration/Quantitative method' ('F141A') then value of *unitsPositive* must be <> NULL;
PRV.26	unitsPositive	E	PRV33	If value of *unitsTested* is <> NULL then value of *unitsPositive* must be <> NULL;
PRV.26	unitsPositive	W	PRV34	WARNING. If value of anMethCode = 'Enumeration/Quantitative method' ('F141A') AND value of unitsPositive = value of unitsTested then this suggests that you are reporting only positive results;
PRV.26	unitsPositive	E	PRV40	If value of *totUnitsPositive* > 0 then value of *unitsPositive* must be >= 0;

Table 44: Example on how to report data on prevalence for *Salmonella*

Context									
repYear	**repCountry**	**matrix**	**sampStage, sampType, ...**	**zoonosis_L1**	**zoonosis**	**totUnitsTested**	**totUnitsPositive**	**unitsPositive**	**resComm**
2013	Pitcairn Islands	Gallus gallus (fowl) - laying hens - adult	at farm	*Salmonella*	Salmonella - Salmonella spp., unspecified	10	8	1	
2013	Pitcairn Islands	Gallus gallus (fowl) - laying hens - adult	at farm	*Salmonella*	Salmonella - S. Enteritidis	10	8	1	
2013	Pitcairn Islands	Gallus gallus (fowl) - laying hens - adult	at farm	*Salmonella*	Salmonella - S. Enteritidis - PT 12	10	8	2	
2013	Pitcairn Islands	Gallus gallus (fowl) - laying hens - adult	at farm	*Salmonella*	Salmonella - S. Tennessee	10	8	3	
2013	Pitcairn Islands	Gallus gallus (fowl) - laying hens - adult	at farm	*Salmonella*	Salmonella - S. Typhimurium	10	8	1	
2013	Pitcairn Islands	Meat from pig - fresh	at cutting plant	*Salmonella*	Salmonella - Salmonella spp., unspecified	1529	0		
2013	Pitcairn Islands	Gallus gallus (fowl) - breeding flocks	at farm	*Salmonella*	Salmonella - S. Typhimurium	50	1	1	2 serovars found in the same sample
2013	Pitcairn Islands	Gallus gallus (fowl) - breeding flocks	at farm	*Salmonella*	Salmonella - S. Enteritidis	50	1	1	2 serovars found in the same sample

Table 45: Example on how to report data on Prevalence for *Listeria monocytogenes*

Context											
rep Year	**repCountry**	**matrix**	**sampStage, sampType, …**	**zoonosis_L2**	**zoonosis**	**tot Units Tested**	**tot Units Positive**	**anMethCode**	**quantity**	**units Tested**	**units Positive**
2013	Pitcairn Islands	Fishery products, unspecified	at retail	*Listeria - L. monocytogenes*	*Listeria - L. monocytogenes*	63	10	Detection method - presence in x g		63	10
2013	Pitcairn Islands	Fishery products, unspecified	at retail	*Listeria - L. monocytogenes*	*Listeria - L. monocytogenes*	63	10	Enumeration method	<=100	50	9
2013	Pitcairn Islands	Fishery products, unspecified	at retail	*Listeria - L. monocytogenes*	*Listeria - L. monocytogenes*	63	10	Enumeration method	>100	50	1
2013	Pitcairn Islands	Cheeses made from cows' milk	at retail	*Listeria - L. monocytogenes*	*Listeria - L. monocytogenes*	30	12	Detection method - presence in x g		25	11
2013	Pitcairn Islands	Cheeses made from cows' milk	at retail	*Listeria - L. monocytogenes*	*Listeria - L. monocytogenes*	30	12	Enumeration method	<=100	10	0
2013	Pitcairn Islands	Cheeses made from cows' milk	at retail	*Listeria - L. monocytogenes*	*Listeria - L. monocytogenes*	30	12	Enumeration method	>100	10	3

I) TEXT FORMS DATA MODEL 2013

49. 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 46: .

49.1. General information and identification of the data

49.2. 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.

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

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

49.4. Language (*lang TXF.03*)

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

50. Information about paragraph

50.1. Paragraph (*paragraph TXF.04*)

This data element is **mandatory**. It contains codes linked to a pick list listing the available titles of paragraphs to be reported on (ZOO_CAT_PARAGRAPH). For example 'Antimicrobial resistance in *Campylobacter jejuni* and *coli* in cattle - Sampling strategy used in monitoring - Frequency of the sampling' (code 'Z100B').

50.2. Value (*value TXF.05)*

This data element is **mandatory**. This is a free text of maximum 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 46: EFSA data model for text forms data reporting

Element Code	Element Name	Short Element name for XML/Excel transfer	Constraint	Type	Pick list	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	Paragraph	paragraph	Mandatory	xs:string(5)	ZOO_CAT_PARAGRAPH	
TXF.05	Value	value	Mandatory	xs:string(4000)		

REFERENCES

EFSA (European Food Safety Authority), 2012a. Technical specifications for the analysis and reporting of data on antimicrobial resistance (AMR) in the European Union Summary Report. EFSA Journal 2012;10(2):2587, 53 pp. doi:10.2903/j.efsa.2012.2587

EFSA (European Food Safety Authority), 2012b. Technical specifications on the harmonised monitoring and reporting of antimicrobial resistance in *Salmonella*, *Campylobacter* and indicator *Escherichia coli* and *Enterococcus* spp. bacteria transmitted through food. EFSA Journal 2012;10(6):2742, 64 pp. doi:10.2903/j.efsa.2012.2742

EFSA (European Food Safety Authority), 2012c 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. 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 2013. EFSA supporting publication 2014:EN-573. 106 pp.

EFSA (European Food Safety Authority), 2014b. Manual for reporting on antimicrobial resistance in the framework of Directive 2003/99/EC and indicator bacteria for information derived from the year 2013. EFSA supporting publication 2014:EN-574. 102 pp.

EFSA (European Food Safety Authority), 2014c. Manual for reporting on food-borne outbreaks in accordance with Directive 2003/99/EC for information derived from the year 2013. EFSA supporting publication 2014:EN-575. 102 pp.

ABBREVIATIONS

AMR	Antimicrobial Resistance
AMPC	AmpC β-lactamases
CSV	Comma Separated Values
DCF	Data Collection Framework
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 Medicine Agency
ESBL	Extended-spectrum B-lactamases
EU	European Union
IZD	Inhibition zone diameter
MIC	Minimum Inhibitory Concentration
MLST	Multi-Locus Sequence Typing
MRSA	Methicillin-resistant *Staphylococcus aureus*
MS	Member State of the European Union
Spa	*Staphylococcus* protein A
VTEC	Verotoxigenic *E. coli*
XML	Extensible Markup Language

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

AMR	AMR isolate-based data model
AQL	AMR qualitative data model
AQT	AMR quantitative 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