TECHNICAL REPORT

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Manual for reporting on antimicrobial resistance within the framework of Directive 2003/99/EC and Decision 2013/652/EU for information deriving from the year 2015

European Food Safety Authority

Abstract

This manual provides guidance for reporting antimicrobial resistance under the framework of Directive 2003/99/EC and Implementing Commission Decision 2013/652/EU in food-producing animals and foodstuffs derived thereof. The objective is to harmonise and streamline the reporting made by the Member States to ensure that the antimicrobial resistance data collected are relevant and easy to analyse at the European Union level. Detailed guidelines are provided for the reporting of data and text forms. This guidance typically applies to *Salmonella*, *Campylobacter coli* and *Campylobacter jejuni,* and the animal populations and food categories to be reported on. Guidance is also provided on indicator *Escherichia coli*, indicator *Enterococcus* and meticillin-resistant *Staphylococcus aureus*. The manual notably includes specific guidance for reporting mandatory data on *Salmonella* spp. and commensal *E. coli* producers of ESBLs/AmpCs/carbapenemases obtained from the harmonised routine monitoring, and ESBL-/AmpC-/Carbapenemase-producing *E. coli* derived from specific monitoring, as well as voluntary data on specific monitoring of carbapenemase-producers.This manual is specifically aimed at guiding the reporting of information deriving from the year 2015.

Key words: reporting, antimicrobial resistance, zoonotic bacteria, indicator bacteria, MRSA

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Summary

This manual provides guidance on reporting antimicrobial resistance (AMR) under the framework of Directive 2003/99/EC and Implementing Commission Decision 2013/652/EU in food-producing animals and foodstuffs derived thereof. The objective is to harmonise and streamline the reporting made by the Member States (MSs) to ensure that the data collected are relevant and easy to analyse at the European Union (EU) level. Detailed guidelines are provided for the reporting of data and text forms in eXtensible Markup Language (XML) files, through the Data Collection Framework (DCF) of the EFSA.

This manual typically applies to the bacterial agents, animal populations and food categories to be reported. Instructions are given on the description of the sampling and monitoring schemes, as well as on the analyses of the results in the national reports. This manual specifically covers *Salmonella*, *Campylobacter coli, C. jejuni*, indicator *Escherichia coli*, indicator *Enterococcus* and MRSA, as included in the current data collection. These instructions are applicable to reporting data on AMR and MRSA prevalence, as well as the relative text forms through the DCF. Specific guidance is included for reporting on the prevalence, genetic diversity and AMR of meticillin-resistant *Staphylococcus aureus* (MRSA) from food-producing animals and food derived thereof.

The manual notably incorporates specific guidance for the mandatory reporting of data on *Salmonella* spp. and commensal indicator *E. coli* producers of ESBLs/AmpC/carbapenemases obtained from the harmonised routine monitoring, and data on ESBL-/AmpC-/Carbapenemase-producing *E. coli* derived from the specific monitoring as well as the voluntary reporting of data on the specific monitoring of carbapenemase-producers.This manual is aimed specifically at Member States (MSs) data providers to guide the reporting of information deriving from the year 2015.

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1. Introduction

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

The Directive 2003/99/EC[2] 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 (AMR) and food-borne outbreaks. EFSA is assigned the tasks of examining the data collected and preparing the EU Summary Reports (SR), which is produced in collaboration with the European Centre for Disease Prevention and Control (ECDC).

In 2013, based on the proposals issued by EFSA, the European Commission (EC) put forward and discussed with the MSs a new legislation on the harmonised monitoring of AMR in *Salmonella*, *Campylobacter* and indicator bacteria in food-producing animals and food derived thereof. The Commission implementing Decision 2013/652/EU[3] of 12 November 2013 establishes a list of combinations of bacterial agents, food-producing animal populations and food products and sets up priorities for the monitoring of AMR from a public health perspective.

Based on the data reported each year, EFSA and ECDC jointly produce an annual EUSR on zoonoses, zoonotic agents and food-borne outbreaks. Similarly, the two agencies produce a EUSR on antimicrobial resistance. To support the Member States (MSs) in their reporting, the existing reporting manuals for zoonoses, antimicrobial resistance and food-borne outbreaks need to be updated to take into account the latest recommendations on reporting of antimicrobial resistance data and data on zoonoses and food-borne outbreaks.

The BIOCONTAM and DATA units are invited to:

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

This technical report specifically addresses the third term of reference above: revise the manual for reporting on AMR when appropriate, and publish it as an EFSA technical report.

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

The European Union (EU) system for monitoring and collecting information on antimicrobial resistance (AMR) in food-producing animals and food thereof is established by Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents. This Directive requires Member States (MSs) to collect, assess and report data on zoonoses, zoonotic agents, AMR and food-borne outbreaks to the European Commission (EC) each year. The MSs are required to send their national reports on AMR to the EC each year by 31 May. The EC shall submit information to the European Food Safety Authority (EFSA), which shall examine the data and publish the EU Summary Report from the results.

Commission Implementing Decision 2013/652/EU entered into force in 2014. In accordance with this Decision, sampling should be performed at the level of domestically produced animal populations,

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

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

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

accounting for different production types, and not at the animal species level, with the aim of collecting data that, in the future, could be combined with those on exposure to antimicrobials. The collection and reporting of data should be performed at the isolate level in order to enable more in-depth analyses to be conducted on. Monitoring of AMR in *E. coli* became mandatory, as it is for *Salmonella* and *C. jejuni* in the major food-producing animal populations and the meat derived thereof. It also became mandatory the reporting of data on *Salmonella* spp. and indicator *E. coli* producing ESBLs/AmpC/Carbapenemase obtained from the harmonised routine monitoring, as that of data on ESBL-/AmpC-/Carbapenemase-producing *E. coli* derived from the harmonised specific monitoring.[4] Conversely, the specific monitoring of carbapenemase-producers[5] is simply advised according to the legislation, and the corresponding reporting may be performed on a voluntary basis.

The collection of AMR data on *Salmonella* and *Campylobacter* isolates from human cases of salmonellosis and campylobacteriosis in MSs is conducted in accordance with Decision 1082/2013/EU[6] on serious cross-border threats to health which, in October 2013, replaced Decision 2119/98/EC[7] on setting up a network for the epidemiological surveillance and control of communicable diseases in the EU. The EU Summary Report is prepared in collaboration with the European Centre for Disease Prevention and Control (ECDC).

1.3. Reporting through the Data Collection Framework

Regarding 2015 AMR data reporting, quantitative isolate-based data should be submitted to the EFSA Data Collection Framework (DCF) using either XML or Excel files.

The narrative part of reports in text forms should be also submitted through the DCF.

Separate guidelines are also given on the technical details of the DCF reporting system elsewhere (EFSA, 2016). The present manual provides primarily scientific guidance on reporting 2015 AMR data through the DCF.

Reporting isolate-based antimicrobial resistance data

Information on multi-drug resistance (MDR) are accessible, as quantitative isolate-based data are reported by the MSs. AMR may occur in association, meaning that an isolate may be resistant to different classes of antimicrobials simultaneously. Many patterns of MDR may be encountered within the same bacterial sub-type (e.g. serovar/serotype/phagetype and biotype). The collection and reporting of quantitative AMR data at the isolate level enables more in-depth scientific analyses. In particular, it is beneficial for detecting new MDR patterns and performing analyses of known co-resistance patterns, evaluating geographical progression over time, conducting retrospective analyses and may assist in source attribution. It also enables to infer presumptive phenotypes of ESBL-/AmpC-/Carbapenemase-producing *Salmonella*/indicator *E. coli*. In addition, the evaluation of phenotypic resistance patterns can give insights into resistance selection, since use of one antimicrobial can select for resistance to other unrelated antimicrobials (co-selection). Therefore, the collection of data on MDR is of the utmost importance for investigating the relationship between antimicrobial use and resistance.

It is also expected that the submission of data at the isolate level will facilitate the reporting of detailed epidemiological information, such as the serovar of *Salmonella* strains, the geographical area and the animal population (production type)/food category of origin. This should also ensure consistency with the detailed recommendations issued by EFSA (EFSA, 2012) as regards the way in which data are presented in the EU Summary Report on AMR.

[4] Isolation of bacteria using selective media containing a third-generation cephalosporin.
[5] isolation of bacteria using selective media containing a carbapenem.
[6] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC. OJ L 293, 5.11.2013, p. 1–15.
[7] Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community. OJ L 268, 3.10.1998, p. 1–7.

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

The narrative part should include **a description of the monitoring and/or control programme** from which the AMR/MRSA/ESBL/AmpC/Carbapenemase data are derived. This information ensures that the results will be understood and interpreted within the correct framework. The description should be detailed enough to give an accurate picture of the monitoring and control activities in place and to facilitate, where possible, the comparison of the results between different reporting years.

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

The text forms titles provided in the **data model** listed below should be used to report corresponding information and draft the narrative part of the report.

2.1. Text forms titles for reporting on sampling strategy used in monitoring

a) Description of sampling designs[8]**—**sampling design should be reported under this title. For example, the definition of the targeted population and its elements (epidemiological units that make up the population under study from which information is sought) (EFSA, 2014).

b) Stratification procedures per animal population and food category[8]—the stratification procedures should be reported under this title.

c) Randomisation procedures per animal population and food category[8]—the randomisation procedures should be reported under this title.

d) Sampling strategy used in monitoring—this part should describe, in general, the sampling strategy chosen and the purpose of the sampling:

- It is useful to state if the sampling covered the whole MS or only parts of it.
- The target population should be identified. It should be explained, for example, whether the entire animal population was covered or only a subset of it and the reasons for choosing this subset for sampling. Similarly, the categories of foodstuffs and feedingstuffs that were sampled should be identified.
- If the sampling was stratified, for example, by geographical regions or other criteria, such as size of the holdings, this should be described.
- It is important to explain how the units to be sampled were chosen, regardless of whether objective, selective, suspected, convenience or census sampling was applied or if several sampling methods were applied.
- It should specify who was performing the sampling, e.g. samples taken by the competent authority as part of an official sampling, samples taken by owners of animals, food or feed businesses, or by other representatives of private enterprises in the context of the hazard analysis critical control point (HACCP)/own checks.
- It is also essential to explain where the samples were taken, e.g. farm, slaughterhouse, hatchery, at a food processing plant or at a retail outlet. Equally important is the stage of sampling, which can be any step in the animal rearing process or the food chain. For example, the sample may be taken at the animal rearing period, production period, before or after the chilling of a carcase in a slaughterhouse or before or after the expiration of the shelf-life of foodstuffs.
- The framework of the sampling is an important part of the strategy. It should be stated whether the sampling was part of a permanent or temporary monitoring programme, linked to surveillance or control programmes or if it was the result of a single survey.

[8] New titles for text forms added as required by Decision 2013/652/EU.

1. Frequency of the sampling—this part should be used to explain how often samples were taken. The standard terms (e.g. every week, once a month, x times a year) provided in the pick list in the text forms should be used where possible. A more general statement can also be used, such as 'detection of annual prevalence of xx by yy% confidence level and zz% accuracy'.

2. Type of specimen taken—under this title, the specimen taken from the units sampled should be described. For example, in the case of animals, the specimen tested could be faeces, caecum or cloacal swab.

3. Methods of sampling (description of sampling techniques)—the sampling techniques, meaning the procedures used to obtain the sample, should be described here. This should include information on the site of sampling (e.g. the part of a carcase, the part of the facilities for an environmental sample), the size of the sample taken (e.g. in g, cm^2 or mL), the use of swabs or other instruments in the sampling (where relevant), the number of (sub) samples/sample units taken, the pooling of samples if any (refer to the number of samples combined by pooling, if available), the possible storage of samples and the length of storage (where relevant).

4. Procedures for the selection of isolates for antimicrobial testing—in the case that only part of the isolates identified at the national level were tested for antimicrobial resistance, the procedure for the selection should be reported here.

5. Methods used for collecting data—under this title the methods used for collecting data should be described.

2.2. Text forms titles for reporting on laboratory methodology used for identification of the microbial isolates

a) Laboratory methodology used for identification of the microbial isolates—the analytical method used for identification of the microbial isolates. Under this title, **the isolation methods** used for the specific monitoring of ESBL-/AmpC-/carbapenemase-producers and for the specific monitoring of Carbapenemase-producers may be reported. According to the legislation, the protocols developed by the EURL-AR should be used and reported here. In the case of the voluntary specific monitoring on Carbapenemase-producers, the selective media used (commercial plates, 'in house' media) should be also reported here. In general, any variation with regard to the EURL-AR protocols should be stated here.

b) Laboratory methodology used for detection for resistance—the following information should be reported:

1. Antimicrobials included in monitoring

2. Cut-off values used in testing

2.3. Text forms titles for reporting on control programme/mechanisms

a) The control programme/strategies in place—under this title, the control programmes in place in the MS should be described. The control programmes may be national or regional, and they may be approved nationally or by the Commission and co-financed by the EU based on Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014[9] on expenditure in the veterinary field. Control programmes run by the industry/food business operators are also included. The nature of the control programmes should be described including whether the programme is, for example, voluntary or mandatory, national or regional, approved by the EU or at national level or co-financed. The main features of the programme should be given. It is advisable to report the information derived from official programmes separately from information obtained from programmes run by the industry. Other control mechanisms may include control measures prescribed

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

in EU or national legislation, such as the rejection of contaminated carcases during meat inspection. The relevant legislation should be mentioned.

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

c) Notification system in place—the notification system should be described, including its legal basis and the date on which the disease or infection was notified.

2.4. Text forms titles for analysing investigation results

a) Result of the investigation—under this data element, the results reported should be summarised and the important findings and relevant conclusions based on the results should be presented.

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

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

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

3. Guidelines for reporting meticillin-resistant *Staphylococcus aureus* data

3.1. General recommendations

The results of investigations (i.e. prevalence data) have to be reported in the prevalence data model through the DCF.

- Information requested to be reported

Data on **foodstuffs** (see definitions in Appendix D) and **animals** (see definitions in Appendix E) should be categorised using the classification system provided by the catalogue. Although there is variability in the degree of detail which can be provided, data providers are strongly encouraged to provide as much relevant information as possible provided by the ZOO_CAT_MATRIX catalogue, as information provided by the catalogues enables relevant epidemiological data analyses.

MSs are invited to report all relevant information on the type of animals or food sampled, including the **sampling stage** and the **sampling context** (see definitions in Appendix C), when appropriate. Such information may include the type of animal population sampled (e.g. wild/farmed/zoo/pet), for those populations that could fall under more than one typology (e.g. wild boar), and the stage along the food chain from which samples have been collected.

To facilitate data extraction, information that could be reported in the specific data elements (such as *spa*-types for zoonotic agent or information on the sampling strategy, sampling unit, sample type or sample origin) should not be reported in the 'Comment' data element.

3.2. Meticillin-resistant *Staphylococcus aureus* in animals

Recommendations on the food-producing animal populations and samples to collect for MRSA monitoring are summarised in Table 1. More detailed information is also available elsewhere (EFSA, 2012).

Table 1: Recommendations on the food-producing animal populations and samples to collect for MRSA monitoring (EFSA, 2012)

Animal populations	MRSA	
	Where to collect	Samples to collect
Monitoring recommended to be performed consistently on a regular basis (every third year)		
Broilers	Farm	Boot swab[(a)]
Fattening pigs	Slaughterhouse/Farm	Pool of nostril swabs[(b)]/boot swab[(c)]
Dairy cattle	Dairy farm	Bulk tank milk
Monitoring recommended to be performed consistently on a regular basis, if production exceeds 10 million tonnes slaughtered/year (every third year)		
Fattening veal calves (under 1 year of age)[(e)]	Slaughterhouse	Nostril swabs
Fattening turkeys	Farm	Boot swabs[(a)]
Monitoring recommended to be performed on a voluntary basis (every third year)		
Breeders of pigs	Farm	Nose swab
Breeders of *Gallus gallus*, meat sector	Farm	Boot swab/nose skin swab[(a),(d)]
Breeders turkeys	Farm	Boot swab/nose skin swab[(a),(d)]
Beef animals	Slaughterhouse	Nostril swabs
Horses	Slaughterhouse	Nostril swabs

(a): In the framework of the *Salmonella* National Control Programmes, an additional boot swab sample may be obtained for MRSA testing.
(b): Sampling on farm is preferred for the purpose of assessing the risk factors for MRSA infection. In this case, larger pools of nose swabs can be collected.
(c): Sampling at slaughter or on farm depending on the considerations developed in the 'Technical specifications for the harmonised monitoring and reporting of AMR in MRSA in food-producing animals and food' (EFSA, 2012).
(d): Nose skin swabs have been reported to be more sensitive than boot swabs in poultry.
(e): In certain MSs, the calf population to be monitored for MRSA may also comprise fattening veal calves older than 1 year.

Relevant agent species to be reported

Strains of *Staphylococcus aureus* resistant to virtually all available beta-lactam antimicrobials, including meticillin (MRSA), should be reported. Information on the MRSA *spa*-types should also be reported if available, as well as further information related to the characterisation of clonal complexes and multi-locus sequence typing (MLST) types.

Types of specimen taken

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

Case definition/definition of a positive sample

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

Diagnostic/analytical methods typically used

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

Reporting the results in the prevalence data model

Specific guidelines for the reporting of data

- **Matrix**—for the specification of the animal species, the name of the animal species should be provided first, then more detailed information should be given, such as the type of animals (wild, farmed, pet), the production category (breeding, fattening animals), the production period (during rearing period, adult), the production system and housing conditions (not raised under controlled housing conditions, raised under controlled housing conditions) and the age of the animals (e.g. piglets, gilts, sows). For example: 'Cattle (bovine animals), meat production animals, calves (under 1 year)'. Generally, it is recommended that information

about the farmed or wild status of animal species is reported in cases where the animal species could be either farmed or wild.

- **Sampling stage**—to allow for comparability, data on the place or stage of sampling should be reported by using a classification system provided in the catalogue. The catalogue provide a list of main 'places' or 'stages' where samples may be taken, e.g. farm, slaughterhouse.
- **Sample origin**—is used to report the country of origin of the animal.
- **Sample type**—the sample category (i.e. 'animal sample') and the sample type (e.g. 'faeces', nasal swab) should be characterised here.
- **Sampling context**—the information on the context of sampling (e.g. monitoring, surveillance) should be reported by using a classification system from the catalogue. A list of sampling programmes (e.g. monitoring) and a list of options for reporting the type of monitoring or survey (e.g. EFSA specifications, active or passive), under the option monitoring, are provided.
- **Sampler**—who performed the sampling (e.g. competent authority ('official sampling') or industry ('HACCP and own checks')) should be reported.
- **Sampling strategy**—the type of sampling (e.g. 'objective sampling', 'suspect sampling').
- **Sampling details**—there is a free text data element that can be used to give further information on the sampling stage or context or other brief information which is not covered by the specific data elements.
- **Sampling unit**—use 'herd', 'flock', 'holding', 'slaughter batch' or 'animal'.
- **Source of information**—the institute (or laboratory) that has provided the data should be reported. Abbreviations should be clarified in the comment data element.
- **Total units tested**—the number of sampling units that are analysed in total, and for which results are available.
- **Total units positive**— the total number of sampling units considered infected or colonised with MRSA, based on the results of the analyses, should be reported.
- **Number of units positive**—the total number of units tested positive for a specific MRSA spa-type (e.g. spa-type t002) and/or clonal complex (e.g. spa-type t034- CC398) and/or MLST type (e.g. spa-type t011-CC398- ST398). This data element should be left blank if no positive units were detected.

Sampling definitions are presented in Appendix B.

3.2.1. Meticillin-resistant *Staphylococcus aureus* in food

Recommendations on the food categories and samples to collect for MRSA monitoring are summarised in Table 2. More relevant information is available elsewhere (EFSA, 2012).

Table 2: Recommendations on the food categories and samples to collect for MRSA monitoring

Food	MRSA Where to collect
Monitoring recommended to be performed on a voluntary basis (every third year)	
Fresh broiler meat	Cutting plant or retail
Fresh turkey meat	Cutting plant or retail
Fresh pork	Cutting plant or retail
Fresh beef	Cutting plant or retail
Fresh veal	Cutting plant or retail
Raw milk and/or raw milk products	Dairy/processing plant or retail

Relevant agent species to be reported

Strains of *S. aureus* resistant to virtually all available beta-lactam antimicrobials, including MRSA, should be reported.

Information on the MRSA *spa*-types may also be reported if available, as well as further information related to the characterisation of clonal complexes and MLST types.

Case definition/definition of a positive sample

- **MRSA-positive sample/batch**—a sample/batch from which MRSA has been isolated.

Diagnostic/analytical methods typically used

Currently, there is no internationally recognised standard method for the detection of MRSA in food.

Details should be provided in the MRSA text form on the diagnostic method used, including how verification of the presence of MRSA was carried out and, in particular, whether MRSA was detected by resistance testing of isolated *S. aureus* or by the use of selective media for MRSA.

Reporting the results in the prevalence data model

Specific guidelines for the reporting of data

- **Matrix**—for the specification of the food, a high level categorisation of foodstuffs should first be provided; thereafter, the reporting of more detailed information is allowed. For example: 'Milk, cows', raw milk for manufacture, intended for manufacturing of raw or low heat-treated products'. Where specific information is unavailable, one may use the unspecified option, e.g. 'Milk from other animal species' or 'unspecified'. This 'unspecified' option should be used only when there is a specific need and no other option is available.
- **Sampling stage**—to allow for comparability, data on the place or stage of sampling should be reported by using a classification system provided in the catalogue. The catalogue provide a list of main 'places' or 'stages' where samples may be taken, e.g. farm, slaughterhouse or at a retail.
- **Sample origin**—is used to report the country of origin of the animal.
- **Sample type**—the sample category (e.g. 'food sample') and the sample type (e.g. 'meat') should be characterised here.
- **Sampling context**—the information on the context of sampling (e.g. monitoring, surveillance) should be reported by using a classification system in the catalogue. A list of sampling programmes (e.g. monitoring) and a list of options for reporting on the type of monitoring or survey (e.g. EFSA specifications, active or passive), under the option monitoring, are provided.
- **Sampler**—who performed the sampling (e.g. 'official sampling' or 'HACCP and own checks') should be reported here.
- **Sampling strategy**—the type of sampling (i.e. 'census', 'convenient', 'objective', 'selective', 'suspect', or 'unspecified' sampling) should be reported.
- **Sampling details**—there is a free text data element that can be used to give further information on the sampling stage or context or other further brief information which is not covered by the specific data elements.
- **Sampling unit** –'single' or 'batch' should be used as the terms to be reported for food.
- **Sample weight**—the weight or volume of the specimen used in the laboratory for analysis, e.g. 10, etc.; for carcase swabs the area sampled could be reported (e.g. 100).
- **Sample weight unit**—the unit of the indicated sample weight e.g. gram, millilitre, square centimetre.
- **Source of information**—the institute (or laboratory) that has provided the data should be reported. Abbreviations should be clarified in the comment data element.

- **Total units tested**—the number of sampling units that are analysed in total, and for which results are available, should be reported here.
- **Total units positive**—the total number of sampling units considered contaminated with MRSA, based on the analyses results, should be reported.
- **Number of units positive**—the total number of units tested positive for a specific MRSA *spa*-type (e.g. *spa*-type t002) and/or clonal complex (e.g. *spa*-type t034-CC398) and/or MLST type (e.g. *spa*-type t011-CC398-ST398). This data element should be left blank if no positive units were detected.

4. Reporting on antimicrobial resistance

4.1. General recommendations

Decision 2013/652/EU lays down detailed rules for the harmonised monitoring and reporting of AMR to be carried out by the MSs. The present manual has been drafted taking these rules into account.

Detailed recommendations on the reporting of AMR have been issued by EFSA in the 'Technical specifications on the harmonised monitoring and reporting of AMR in MRSA in food-producing animals and food' (EFSA, 2012).

When reporting data on AMR from animal populations, it is advisable to differentiate between different production sectors and production stages, which may differ substantially in terms of occurrence of AMR because of important variations in management practices.

In accordance with Decision 2013/652/EU, MSs should report on AMR in (a) *Salmonella* spp., (b) *C. jejuni,* (c) indicator commensal *E. coli*, and (d) on extended-spectrum beta-lactamase (ESBL)-, AmpC- or carbapenemase-producing *Salmonella* spp. and *E. coli*,[10] derived from the routine monitoring and the specific monitoring.

Based on the requirements from Decision 2013/652/EU, it is mandatory that AMR data are reported for the animal populations/food categories listed in Table 3.

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
	Carcases of broilers, fattening turkeys, fattening pigs and bovines under one year of age
Campylobacter	Broilers, fattening turkeys, fattening pigs(a)
Indicator *E. coli*	Broilers, fattening turkeys, fattening pigs, bovines under one year of age(b)
	Fresh broiler meat, pig meat and bovine meat(b)
Indicator enterococci	Broilers, fattening pigs, fattening turkeys, fattening pigs, bovines under one year of age(c)

Note: In the years 2014, 2016, 2018 and 2020 for laying hens, broilers and fresh meat thereof, and fattening turkeys.
In the years 2015, 2017 and 2019, for pigs, bovines under one year of age, pig meat and bovine meat.
(a): If a MS decides to test for AMR in *C. coli* on a voluntary basis.
(b): For the purpose of monitoring of ESBL- or AmpC- or carbapenemase-producing *E. coli.*
(c): If a MS decides to test for AMR in *E. faecalis* and *E. faecium* on a voluntary basis.

The requirements for monitoring AMR by MSs are laid down in Decision 2013/652/EC. In particular, as regards the information that must be collected by MSs, the following categories are listed in Annex, Part B of the Decision:

1) General information

- Identifier or code of the isolate
- Bacterial species

[10] In 2015, the specific monitoring of ESBL-/AmpC-/carbapenemase-producing indicator commensal *E. coli* is mandatory. Specific monitoring focusing only on carbapenemase-producing isolates is voluntary in 2015.

- Serovar (for *Salmonella* spp.)
- Phage type of *Salmonella* Enteriditis and *Salmonella* Typhimurium (optional)

2) Specific information with regard to sampling

- Food-producing animal population or food category
- Stage of sampling
- Type of sample
- Sampler
- The sampling strategy
- Date of sampling
- Date of isolation

Requirements on the sampling unit, sampling stage, sample type, sampling context sampler and sampling strategy are summarised in Table 4.

3) Specific information with regard to antimicrobial resistance testing

- Identifier or code of the isolate given by the laboratory performing antimicrobial susceptibility testing of the isolate
- Date of susceptibility testing
- Antimicrobial substance

4) Specific information with regard to dilution method results

- Minimum inhibitory concentration (MIC) value (in mg/L)

5) Synergy testing results

- Synergy testing with clavulanic acid for ceftazidime
- Synergy testing with clavulanic acid for cefotaxime

Table 4: Requirements for isolate-based antimicrobial resistance data reporting based on Decision 2013/652/EU

Bacteria	Origin of the isolates	Sampling unit type[(a)]	Sampling stage	Sample type	Sampling context	Sampler	Sampling strategy
***Salmonella* spp.**	each population of laying hens, broilers and fattening turkeys sampled in the framework of the national control programmes, established in accordance with Article 5(1) of Regulation (EC) No 2160/2003;	herd/flock	Farm	environmental sample (please use the level 2 of the sample type for e.g. environmental sample - boot swabs)	Control and eradication programmes	Official sampling or Official and industry sampling	Census
	carcases of both broilers and fattening turkeys sampled for testing and verification of compliance, in accordance with point 2.1.5 of Chapter 2 of Annex I to Regulation (EC) No 2073/2005;	slaughter batch	Slaughterhouse	food sample - neck skin	Monitoring	HACCP and own checks/ Official sampling	Objective sampling
	carcases of fattening pigs sampled for testing and verification of compliance, in accordance with point 2.1.4 of Chapter 2 of Annex I to Regulation (EC) No 2073/2005;	slaughter batch	Slaughterhouse	food sample - carcase swabs	Monitoring	HACCP and own checks/ Official sampling	Objective sampling
	carcases of bovines under one year of age where the production of meat of those bovines in the Member State is more than 10 000 tonnes slaughtered per year sampled for testing and verification of compliance, in accordance with point 2.1.3 of Chapter 2 of Annex I to Regulation (EC) No 2073/2005.	slaughter batch	Slaughterhouse	food sample - carcase swabs	Monitoring	HACCP and own checks/ Official sampling	Objective sampling
C. jejuni	caecal samples gathered at slaughter from broilers and from fattening turkeys[(b)]	slaughter batch	Slaughterhouse	animal sample - caecum	Monitoring	Official sampling	Objective sampling
Indicator commensal *E. coli*	caecal samples gathered at slaughter from broilers and from fattening turkeys[(b)]	slaughter batch	Slaughterhouse	animal sample - caecum	Monitoring	Official sampling	Objective sampling

Bacteria	Origin of the isolates	Sampling unit type[(a)]	Sampling stage	Sample type	Sampling context	Sampler	Sampling strategy
	caecal samples gathered at slaughter from fattening pigs and bovines under one year of age[(b)]	slaughter batch	Slaughterhouse	animal sample - caecum	Monitoring	Official sampling	Objective sampling
Specific monitoring of ESBL/AmpC/Carbapenemase-producing *E. coli*	caecal samples gathered at slaughter from broilers and from fattening turkeys[(b)]	slaughter batch	Slaughterhouse	animal sample - caecum	Monitoring	Official sampling	Objective sampling
Specific monitoring of carbapenemase-producing micro-organism (voluntary)	caecal samples gathered at slaughter from fattening pigs and bovines under one year of age[(b)]	slaughter batch	Slaughterhouse	animal sample - caecum	Monitoring	Official sampling	Objective sampling
	samples of fresh meat of broilers, pig meat and bovine meat gathered at retail.	batch	Retail	food sample - meat	Monitoring	Official sampling	Objective sampling
***C. coli*[(c)]**	caecal samples gathered at slaughter from broilers;	slaughter batch	Slaughterhouse	animal sample - caecum	Monitoring	Official sampling	Objective sampling
	caecal samples gathered at slaughter from fattening pigs.	slaughter batch	Slaughterhouse	animal sample - caecum	Monitoring	Official sampling	Objective sampling
***E. faecalis* and *E. faecium*[(d)]**	caecal samples gathered at slaughter from broilers and from fattening turkeys[(b)]	slaughter batch	Slaughterhouse	animal sample - caecum	Monitoring	Official sampling	Objective sampling
	caecal samples gathered at slaughter from fattening pigs and bovines under one year of age[(b)]	slaughter batch	Slaughterhouse	animal sample - caecum	Monitoring	Official sampling	Objective sampling

(a): The Competent Authority may decide based on the sampling method and the analytical method.
(b): Where the production of the specific meat category in the MS is more than 10 000 tonnes slaughtered per year.
(c): Where a MS decides to test *C. coli* in accordance with Article 2(3)(a) of Decision 2013/652/EU.
(d): Where a MS decides to test *E. faecalis* and *E. faecium* in accordance with Article 2(3)(b) of Decision 2013/652/EU.

4.2. Antimicrobial resistance monitoring in *Salmonella* spp.

Relevant animal species/food categories to be reported

- **Domestic fowl (*Gallus gallus*)**: it is mandatory to report resistance data from laying hen flocks and broiler flocks separately. When data are available, information on breeders of egg production lines and breeders of meat production lines should also be reported separately. **(not mandatory for the 2015 data)**.
- **Turkeys**: it is mandatory to report data from fattening turkey flocks **(not mandatory for the 2015 data)**.
- **Carcases**: it is mandatory to report resistance data from carcases of broilers **(not mandatory for the 2015 data)**, fattening turkeys (**(not mandatory for the 2015 data)**), fattening pigs **(mandatory for the 2015 data)** and bovines under one year of age **(mandatory for the 2015 data if the production of those bovines in the MS is more than 10,000 tonnes slaughtered per year)**.

Relevant *Salmonella* serovars to be reported

It is mandatory to report at the serovar level, but reporting the phagetypes of *Salmonella* Enteriditis and *Salmonella* Typhimurium is optional.

Mandatory antimicrobials to be reported (first panel)

- Ampicillin
- Azithromycin
- Cefotaxime
- Ceftazidime
- Chloramphenicol
- Ciprofloxacin
- Colistin
- Gentamicin
- Meropenem
- Nalidixic acid
- Sulfamethoxazole
- Tetracycline
- Tigecycline
- Trimethoprim

Mandatory antimicrobials to be reported (second panel)

- Cefepime
- Cefoxitin
- Ceftazidime
- Ceftazidime + clavulanic acid
- Cefotaxime
- Cefotaxime + clavulanic acid
- Ertapenem
- Imipenem
- Meropenem
- Temocillin

4.2.1. Monitoring of presumptive ESBL-, AmpC- or carbapenemase-producing *Salmonella* derived from the 'routine monitoring'

Extended susceptibility testing to the second panel

All *Salmonella* spp. isolates randomly selected after testing with the first panel of antimicrobials and found to be resistant to cefotaxime, ceftazidime or meropenem should be further tested with the second panel of antimicrobial substances. This panel includes cefoxitin, cefepime and clavulanate in combination with cefotaxime and ceftazidime for the detection of ESBL and AmpC production. In addition, the second panel also contains imipenem, meropenem and ertapenem to phenotypically verify presumptive carbapenemase-producers.

In the case of discrepant results affecting the categorization of an isolate as resistant or susceptible to cefotaxime/ceftazidime/meropenem which are tested in both the first and the second panel, re-testing of the isolate concerned using both panels in parallel is recommended before reporting data. Similarly, whenever carbapenem resistance is registered, re-testing of the isolate concerned using both panels and bacterial species confirmation are recommended before reporting data.

Inference of the presumptive ESBL-, AmpC- or carbapenemase-producing phenotypes

Depending on the results obtained from the susceptibility testing performed with the second panel, the isolates can be subsequently classified by EFSA as presumptiveve ESBL-, AmpC-, ESBL/AmpC- or carbapenemase-producers (ESBL, AmpC or Carbapenemase-phenotypes) according to the criteria proposed by EUCAST (EUCAST, 2013).

If any additional molecular results on the resistance mechanisms conferring resistance to third-generation cephalosporins and/or carbapenems are available, reporting of the corresponding data are recommended.

4.3. Antimicrobial resistance monitoring in *Campylobacter* spp.

Relevant animal species/animal populations/agent species to be reported

For *C. jejuni* isolates (mandatory)

- **Broilers of *Gallus gallus***: it is mandatory to report data from carcases of broilers (caecal samples gathered at slaughter) **(not mandatory for the 2015 data)**.
- **Turkeys**: it is mandatory to report data from carcases of fattening turkeys (caecal samples gathered at slaughter) where the production of turkey meat in the MS is more than 10,000 tonnes per year **(not mandatory for the 2015 data)**.

For *C. coli* isolates (optional)

- **Domestic fowl (*Gallus gallus*)**: data from broilers (caecal samples gathered at slaughter).
- **Pigs**: data from fattening pigs (caecal samples gathered at slaughter).

Recommended antimicrobials to be reported

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

- Ciprofloxacin
- Erythromycin
- Gentamicin
- Nalidixic acid
- Tetracycline
- Streptomycin*

* On a voluntary basis.

It is recommended to report the total number of epidemiological unit tested to enable assessment of the prevalence of *C. jejuni* and *C. coli* in the animal populations investigated.

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

Relevant animal species/animal populations to be reported

- **Domestic fowl (*Gallus gallus*)**: it is mandatory to report data from broilers (caecal samples gathered at slaughter) **(not mandatory for the 2015 data)**.
- **Turkeys**: it is mandatory to report data on fattening turkeys (caecal samples gathered at slaughter) **(not mandatory for the 2015 data)**.
- **Pigs**: it is mandatory to report data on fattening pigs (caecal samples gathered at slaughter) **(mandatory for the 2015 data)**.
- **Cattle**: it is mandatory to report data on bovines under one year of age when the production of meat from those bovines in the MS is more than 10,000 tonnes per year **(mandatory for the 2015 data)**.

Mandatory antimicrobials to be reported (first panel)

- Ampicillin
- Azithromycin
- Cefotaxime
- Ceftazidime
- Chloramphenicol
- Ciprofloxacin
- Colistin
- Gentamicin
- Meropenem
- Nalidixic acid
- Sulfamethoxazole
- Tetracycline
- Tigecycline
- Trimethoprim

Mandatory antimicrobials to be reported (second panel)

- Cefepime
- Cefoxitin
- Ceftazidime
- Ceftazidime + clavulanic acid
- Cefotaxime
- Cefotaxime + clavulanic acid
- Ertapenem
- Imipenem
- Meropenem
- Temocillin

4.4.1. Monitoring of ESBL-, AmpC- or carbapenemase-producing *E. coli* derived from either routine monitoring or specific monitoring

Relevant samples to be tested

(i) Caecal samples gathered at slaughter from broilers and from fattening turkeys where the production of turkey meat in the MS is more than 10,000 tonnes per year **(not mandatory for the 2015 data)**.

(ii) Caecal samples gathered at slaughter from fattening pigs and bovines of less than 12 months of age where the production of meat from those bovines in the MS is more than 10,000 tonnes per year **(mandatory for the 2015 data)**.

(iii) Samples of fresh[11] meat of broilers **(not mandatory for the 2015 data)**, pig meat **(mandatory for the 2015 data)** and bovine meat **(mandatory for the 2015 data)** gathered at retail.

[11] Within the framework of this sampling plan, fresh meat is understood as chilled meat (meaning that frozen meat is excluded), including meat that is wrapped, vacuum-wrapped or wrapped in a controlled atmosphere (EFSA, 2014).

Both, randomly selected isolates recovered from the routine monitoring and resistant to third generation cephalosporins and/or carbapenems, as well as those isolates recovered from the specific monitoring using selective media (cephalosporins or carbapenems, for convenience referred as specific monitoring of ESBL/AmpC/Carbapenemase-producers and specific monitoring of carbapenemase-producers) are to be further tested by using the second panel of antimicrobials. Depending on the results obtained, these isolates can be classified as presumptive producers of ESBLs, AmpC or carbapenemases (ESBL-, AmpC- or Carbapenemase-phenotypes) according to the criteria proposed by EUCAST (EUCAST, 2013).

Specific monitoring of ESBL-/AmpC-/Carbapenemase-producing *E. coli*

For the detection of ESBL- or AmpC-producing *E. coli*, the method should start with a pre-enrichment step, followed by inoculation on McConkey agar containing a third-generation cephalosporin in a selective concentration, in accordance with the most recent version of the detailed protocol for standardisation of the EU Reference Laboratory for Antimicrobial Resistance.[12] Using this protocol, also carbapenemase-producing isolates could be recovered. It is of note that, as the isolates are recovered from plates containing cefotaxime at 1 mg/L (ECOFF), resistance to at least this antimicrobial is expected, and the testing of the second panel for most of the isolates will be necessary. The microbial species *E. coli* should be identified using an appropriate method. This monitoring will be referred as the specific monitoring of ESBL-/AmpC-/Carbapenemase-producing *E. coli*.

To facilitate the specific detection of ESBL-producing *E. coli*, the MS may decide, based on the epidemiological circumstances, to test, in parallel, an additional selective plate that inhibits the growth of AmpC-producing *E. coli*. When using this method, the results from this additional selective plate, which inhibits the growth of AmpC-producing *E. coli*, should be reported separately.

Specific monitoring of Carbapenemase-producing micro-organism

MSs may decide to detect for carbapenemase-producing microorganisms by using pre-enrichment and subsequent selective plating on carbapenem-containing media, in accordance with the most recent version of the detailed protocol for standardisation of the EU Reference Laboratory for AMR. This monitoring will be referred as the specific monitoring of carbapenemase-producers and is voluntary

Within the framework of both specific monitoring, it is recommended to report the total number of epidemiological units tested to enable assessment of the prevalence of ESBL-/AmpC- producing *E. coli* and of carbapenemase-producing *E. coli* in the animal populations investigated.

Monitoring of ESBL-/AmpC-/Carbapenemase-producing *E. coli* derived from the 'routine monitoring'

One randomly selected *E. coli* isolate obtained from each positive caecal sample and meat sample should be tested for resistance to the first panel of antimicrobials and then submitted for extended susceptibility testing (second panel) if cefotaxime, ceftazidime or meropenem are resistant, based on the interpretative criteria (epidemiological cut-off values).

Extended susceptibility testing to the second panel

All presumptive ESBL-, AmpC- or carbapenemase-producing *E. coli* isolates, identified through selective plating (derived from specific monitoring), and *E. coli* that, after testing with the first panel of antimicrobials in the routine monitoring, are found to be resistant to cefotaxime, ceftazidime or meropenem, should be further tested with the second panel of antimicrobials. This panel includes cefoxitin, cefepime and clavulanate in combination with cefotaxime and ceftazidime for the detection of ESBL and AmpC production. In addition, the second panel also contains imipenem, meropenem and ertapenem to phenotypically verify presumptive carbapenemase-producers.

[12] Available online: www.crl-ar.eu

In the case of discrepant results affecting the categorization of a given isolate as resistant or susceptible to cefotaxime/ceftazidime/meropenem which are substances tested in both the first and the second panel, re-testing of the isolate concerned using both panels in parallel is recommended to resolve the discrepancy before reporting data. Similarly, whenever carbapenem resistance is registered, re-testing the isolate concerned by using both panels and confirming the bacterial species are both recommended before reporting data.

Inference of the presumptive ESBL-, AmpC- or carbapenemase-producing phenotypes

Depending on the results obtained from the susceptibility testing performed with the second panel, the isolates can be classified as presumptiveve ESBL-, AmpC-, ESBL/AmpC- or carbapenemase-producers (ESBL, AmpC or Carbapenemase-phenotypes) according to the criteria proposed by EUCAST (EUCAST, 2013).

If any additional molecular results on the resistance mechanisms conferring resistance to third-generation cephalosporins and/or carbapenems are available, reporting of the corresponding data are recommended.

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

Relevant animal species/food categories to be reported on a voluntary basis

- **Domestic fowl (*Gallus gallus*)**: it is advisable to report data from broilers (caecal samples gathered at slaughter).
- **Turkeys**: it is advisable to report data from fattening turkeys (caecal samples gathered at slaughter) where the production of turkey meat in the MS is more than 10,000 tonnes per year.
- **Pigs**: it is advisable to report data from fattening pigs (caecal samples gathered at slaughter).
- **Cattle**: it is advisable to report data from bovines under one year of age (caecal samples gathered at slaughter).

Relevant agent species to be reported

Enterococcus faecium and *E. faecalis* should be reported separately.

Mandatory antimicrobials to be reported*

- Ampicillin
- Ciprofloxacin
- Chloramphenicol
- Daptomycin
- Erythromycin
- Gentamicin
- Linezolid
- Quinopristin/dalfopristin
- Teicoplanin
- Tigecycline
- Tetracycline
- Vancomycin

*If a MS decides to test *E. faecalis* and *E. faecium*, then the antimicrobials listed should be tested.

4.6. Antimicrobial resistance monitoring in meticillin-resistant *Staphylococcus aureus*

Relevant animal species/food categories to be reported

Monitoring recommended to be performed consistently on a regular basis (every third year):

- **Broilers**: at farm, boot swabs.
- **Fattening pigs**: slaughterhouse**/farm, pool of** nostril swabs/boot swabs.
- **Turkeys**: it is advisable to report data from breeding flocks and fattening turkey flocks or turkeys at slaughter separately.
- **Pigs**: it is advisable to report data from breeding pigs and growing/fattening pigs separately.
- **Cattle: it is advisable to report data from calves (under 1 year), young bovines** (between 12 and 24 months old) and adult cattle (more than 24 months old) **separately**. Distinctions between veal calves/other calves, young bovines of dairy and meat sectors, dairy cattle and beef cattle are also encouraged where data are available. MSs monitoring AMR in fattening veal calve populations, that are more than 12 months of age and typically raised for the production of rosé veal, may report data under the new category 'veal calves' (at or above 1 year).
- **Meat**: it is advisable to report resistance data from broiler meat, turkey meat, pig meat and bovine meat.

Recommended antimicrobials to be reported

The proposed lists of antimicrobials to be included in AMR monitoring for MRSA (EFSA, 2012) 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

5. Diagnostic/analytical methods typically used

Microdilution methods for testing have been confirmed and these should be accompanied by the application of European Committee on Antimicrobial Susceptibility Testing epidemiological cut-off values (ECOFFs) for the interpretation of microbiological resistance.

For *Salmonella*, the dilution method used should be as described by the Clinical and Laboratory Standards Institute (CLSI), which is accepted as an international reference method (ISO standard 20776-1:2006 (ISO, 2006)), as stated in Commission Decision 2007/407/EC.[13]

For *Campylobacter*, the dilution methods used should be those described by the National Committee for Clinical Laboratory Standards, in M45-A (CLSI, 2006) or M100-S17 (CLSI, 2007), or the methods described in CLSI guidelines M31-A3 (CLSI, 2008).

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

The cut-off values should be reported.

In the present manual, the term 'cut-off value' is consistent with the EFSA reports on the technical specifications for harmonised monitoring and reporting, as well as with Commission Implementing Decision 2013/652/EU[14], which recommends the use of epidemiologic cut-off values for monitoring.

MSs should test antimicrobials and interpret the results using the epidemiological cut-off values and concentration ranges shown in Tables 5, 6 and 7 to determine the susceptibility of *Salmonella* spp., *C. coli*, *C. jejuni*, indicator commensal *E. coli*, *E. faecalis* and *E. faecium.*

All presumptive ESBL- AmpC- or carbapenemase-producing *E. coli* isolates identified through the selective plating, as well as all those randomly selected isolates of *Salmonella* spp. and *E. coli* that, after testing with the first panel of antimicrobials in accordance with Table 5, are found to be resistant to cefotaxime, ceftazidime or meropenem, should be further tested with a second panel of antimicrobial substances, in accordance with Table 8. This panel includes cefoxitin, cefepime and clavulanate in combination with cefotaxime and ceftazidime for the detection of ESBL and AmpC production. In addition, the second panel also contains imipenem, meropenem and ertapenem to phenotypically verify presumptive carbapenemase producers.

[13] Commission Decision 2007/407/EC of 12 June 2007 on a harmonised monitoring of antimicrobial resistance in *Salmonella* in poultry and pigs. OJ L 153, 14.6.2007, p. 26–29.

[14] 2013/652/EU: Commission Implementing Decision of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria. OJ L 303, 14/11/2013, p. 26–39.

Table 5: Panel of antimicrobial substances to be included in AMR monitoring, European Committee on Antimicrobial Susceptibility Testing (EUCAST) interpretative thresholds for resistance and concentration ranges to be tested in *Salmonella* spp. and indicator commensal *E. coli* (First panel)

Antimicrobial	*Salmonella* Interpretative thresholds of AMR ECOFF[(a)]	*E. coli* Interpretative thresholds of AMR ECOFF [(a)]	Concentration range, mg/L (no of wells)
Ampicillin	> 8	> 8	1–64 (7)
Cefotaxime	> 0.5	> 0.25	0.25–4 (5)
Ceftazidime	> 2	> 0.5	0.5–8 (5)
Meropenem	> 0.125	> 0.125	0.03–16 (10)
Nalidixic acid	> 16	> 16	4–128 (6)
Ciprofloxacin	> 0.064	> 0.064	0.015–8 (10)
Tetracycline	> 8	> 8	2–64 (6)
Colistin	> 2	> 2	1–16 (5)
Gentamicin	> 2	> 2	0.5–32 (7)
Trimethoprim	> 2	> 2	0.25–32 (8)
Sulfamethoxazole	NA	> 64	8–1 024 (8)
Chloramphenicol	> 16	> 16	8–128 (5)
Azithromycin	NA	NA	2–64 (6)
Tigecycline	> 1	> 1	0.25–8 (6)

NA: not available
(a): EUCAST epidemiological cut-off values.

Table 6: Panel of antimicrobial substances to be included in AMR monitoring, EUCAST interpretative thresholds for resistance and concentration ranges to be tested in *C. jejuni* and *C. coli*

Antimicrobial	*C. jejuni* Interpretative thresholds of AMR ECOFF[(a)]	*C. coli* Interpretative thresholds of AMR ECOFF[(a)]	Concentration range, mg/L (no of wells)
Erythromycin	> 4	> 8	1–128 (8)
Ciprofloxacin	> 0.5	> 0.5	0.12–16 (8)
Tetracycline	> 1	> 2	0.5–64 (8)
Gentamicin	> 2	> 2	0.12–16 (8)
Nalidixic acid	> 16	> 16	1–64 (7)
Streptomycin[(b)]	> 4	> 4	0.25–16 (7)

NA: not available
(a): EUCAST epidemiological cut-off values.
(b): On a voluntary basis.

Table 7: Panel of antimicrobial substances to be included in AMR monitoring, EUCAST interpretative thresholds for resistance and concentration ranges to be tested in *E. faecalis* and *E. faecium*

Antimicrobial	*E. faecalis* Interpretative thresholds of AMR ECOFF[(a)]	*E. faecium* Interpretative thresholds of AMR ECOFF[(a)]	Concentrations range, mg/L (no of wells)
Gentamicin	> 32	> 32	8–1 024 (8)
Chloramphenicol	> 32	> 32	4–128 (6)
Ampicillin	> 4	> 4	0.5–64 (8)
Vancomycin	> 4	> 4	1–128 (8)
Teicoplanin	> 2	> 2	0.5–64 (8)
Erythromycin	> 4	> 4	1–128 (8)
Quinupristin/Dalfopristin	NA	> 1	
Tetracycline	> 4	> 4	1–128 (8)
Tigecycline	> 0.25	> 0.25	0.03–4 (8)
Linezolid	> 4	> 4	0.5–64 (8)
Daptomycin	> 4	> 4	0.25–32 (8)
Ciprofloxacin	> 4	> 4	0.12–16 (8)

NA: not available
(a): EUCAST epidemiological cut-off values.

Table 8: Panel of antimicrobial substances, EUCAST epidemiological cut-off values and clinical resistance breakpoints and concentration ranges to be used for testing only *Salmonella* spp. and indicator commensal *E. coli* isolates resistant to cefotaxime, ceftazidime or meropenem (second panel)

Antimicrobial	*Salmonella* Interpretative thresholds of AMR ECOFF[(a)]	*E. coli* Interpretative thresholds of AMR ECOFF[(a)]	Concentration range, mg/L (no of wells)
Cefoxitin	> 8	> 8	0.5–64 (8)
Cefepime	NA	> 0.125	0.06–32 (10)
Cefotaxime + clavulanic acid	NA	NA	0.06–64 (11)
Ceftazidime + clavulanic acid	NA	NA	0.125–128 (11)
Meropenem	> 0.125	> 0.125	0.03–16 (10)
Temocillin	NA	NA	0.5–64 (8)
Imipenem	> 1	> 0.5	0.12–16 (8)
Ertapenem	> 0.06	> 0.06	0.015–2 (8)
Cefotaxime	> 0.5	> 0.25	0.25–64 (9)
Ceftazidime	> 2	> 0.5	0.25–128 (10)

NA: not available.
(a): EUCAST epidemiological cut-off values.

References

CLSI (Clinical and Laboratory Standards Institute), 2006. Methods for antimicrobial dilution and disk susceptibility testing of infrequently isolated or fastidious bacteria; approved guideline. CLSI document M45-A2. Clinical and Laboratory Standards Institute, Wayne, PA, USA.

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Abbreviations

AMR	antimicrobial resistance
CCP	critical control point
CLSI	Clinical and Laboratory Standards Institute
DCF	Data Collection Framework
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECOFF	European Committee on Antimicrobial Susceptibility Testing epidemiological cut-off value
EEC	European Economic Community
EFSA	European Food Safety Authority
EMA	European Medicine Agency
ESBL	extended-spectrum beta-lactamase
EU	European Union
EUCAST	European Committee on Antimicrobial Susceptibility Testing
HACCP	Hazard Analysis and Critical Control Point
ISO	International Organization for Standardization
MDR	multi-drug resistance
MIC	minimum inhibitory concentration
MLST	multi-locus sequence typing
MRSA	meticillin-resistant *Staphylococcus aureus*
MS	Member State of the European Union
spa	*Staphylococcus* protein A
XML	extensible markup language

Appendix A – General definitions

Antimicrobial—a drug which, at low concentrations, exerts an action against microbial pathogens and exhibits selective toxicity towards them.[15] Antimicrobials typically include antibiotics but also antivirals and other drugs effective against microorganisms.

Antibiotic—a substance produced by or derived from a microorganism, which destroys or inhibits the growth of other microorganisms.

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

Cut-off value—the threshold value selected for distinguishing between negative and positive results, which may include an indeterminate or suspicious zone.

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

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

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

[15] Opinion of the Scientific Steering Committee on Antimicrobial Resistance 28 May 1999. Available online: http://ec.europa.eu/food/fs/sc/ssc/out50_en.pdf

Appendix B – Sampling definitions

Batch—a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period (Regulation (EC) No 853/2004[16]).

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

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

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

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

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

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

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

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

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

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

Appendix C – Definitions regarding the sampling context

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

Eradication programme—a programme applying measures aimed at eliminating selected zoonotic agents from a defined area. In the context of Directive 77/391/EEC,[17] the eradication programmes are devised so that, on their completion, herds are classified as officially brucellosis/tuberculosis-free.

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

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

Monitoring, **active**—an active monitoring programme of zoonotic agents or AMR in food and animals is based on random sampling strategies of the population of interest, stratified according to the relevant sub-categories of the population. The sampling strategy should ensure the sample representativeness of the population of interest, and the robustness of the sampling method.

Monitoring, **passive**—a passive monitoring programme of zoonotic agents or AMR includes information from diagnostic testing, or a representative selection of this information. Data on the prevalence of zoonotic agents and on AMR provided by a passive monitoring programme typically derive from diseased animals.

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

Official control—any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules (Regulation (EC) No 882/2004[18]).

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

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

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

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

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

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

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

Census—a strategy where all units of a population are sampled.

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

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

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

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

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

Appendix D – Definitions of foodstuffs

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

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

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

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

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

Food (or foodstuff)—any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans (Regulation (EC) No 178/2002[19]).

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

Meat—the edible parts of the animals mentioned in Appendix E, including blood (Regulation (EC) No 853/2004).

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

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

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

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

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

Processed products—foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics (Regulation (EC) No 852/2004[20]).

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

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

[19] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

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

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

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

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

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

Appendix E – Definitions of animals

Animal—any animal of the species referred to in EU Directives (Directive 64/432/EEC[21], Directive 91/68/EEC[22] and Directive 92/102/EEC[23]).

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

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

Breeding poultry—poultry of more than 72 hours old, intended for the production of hatching eggs (Directive 2009/158/EC[24]).

Calves—domestic animals of bovine species not exceeding a live weight of 300 kg, which do not yet have their second teeth (Decision 94/433/EC[25]).

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

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

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

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

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

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

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

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

Flock—all poultry of the same health status kept on the same premises or in the same enclosure and constituting a single epidemiological unit; in the case of housed poultry, this includes all birds sharing the same airspace (Regulation (EC) No 2160/2003[26]).

Goats—domestic animals of the species *Capra*.

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

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

[23] Council Directive 92/102/EEC of 27 November 1992 on the identification and registration of animals. OJ L 355, 5.12.1992, p. 32–36.

[24] Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs. OJ L 343, 22.12.2009, p. 74–113

[25] Commission Decision 94/433/EC of 30 May 1994 laying down detailed rules for the application of Council Directive 93/24/EEC as regards the statistical surveys on cattle population and production, and amending the said Directive. OJ L 179, 13.7.1994, p. 27–32.

[26] Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of *Salmonella* and other specified food-borne zoonotic agents. OJ L 325, 12.12.2003, p. 1–15.

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

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

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

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

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

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

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

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

Pigs—domestic animals of the species *Suis*.

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

Sheep—domestic animals of the species *Ovis*.

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

Steers—male bovine animals castrated before sexual maturity.