

Non-paper in view of a possible EC decision on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Commission Implementing Decision 2013/652/EU - ANNEX -

REV1 draft dated 22 January 2020

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Part A

Sampling framework and analysis

1. Origin of bacterial isolates subject to antimicrobial susceptibility testing

Member States shall obtain bacterial isolates for AMR monitoring from at least each of the following combinations of bacterial isolates/food-producing animal populations/food:

- (a) *Salmonella* spp. isolates obtained from:
 - (i) samples of each population of laying hens, broilers and fattening turkeys taken in the framework of the national control programmes provided for in Article 5 of Regulation (EC) No 2160/2003;
 - (ii) samples of caecal content taken at slaughter from fattening pigs;
 - (iii) samples of caecal content taken at slaughter from bovine animals under one year of age where the production of meat of those bovine animals in the Member State is more than 10 000 tonnes slaughtered per year;
 - (iv) samples of fresh meat of broilers and turkeys taken at the border control posts.
- (b) *C. jejuni* and *C. coli* isolates obtained from
 - (i) samples of caecal content taken at slaughter from broilers;
 - (ii) samples of caecal content taken at slaughter from fattening turkeys where the production of turkey meat in the Member State is more than 10 000 tonnes slaughtered per year;
 - (iii) samples of caecal content taken at slaughter from fattening pigs;
 - (iv) samples of caecal content taken at slaughter from bovine animals under one year of age where the production of meat of those bovine animals in the Member State is more than 10 000 tonnes slaughtered per year.
- (c) Indicator commensal *E. coli* isolates obtained from:
 - (i) samples of caecal content taken at slaughter from broilers;
 - (ii) samples of caecal content taken at slaughter from fattening turkeys where the production of turkey meat in the Member State is more than 10 000 tonnes slaughtered per year;
 - (iii) samples of caecal content taken at slaughter from fattening pigs;
 - (iv) samples of caecal content taken at slaughter from bovine animals under one year of age where the production of meat of those bovine animals in the Member State is more than 10 000 tonnes slaughtered per year;
 - (v) samples of fresh meat of broilers, turkeys, pigs and bovine animals taken at the border control posts.
- (d) ESBL-, AmpC- and/or CP- *E. coli* isolates obtained from:
 - (i) samples of caecal content taken at slaughter from broilers;

- (ii) and samples of caecal content taken at slaughter from fattening turkeys where the production of turkey meat in the Member State is more than 10 000 tonnes slaughtered per year;
 - (iii) samples of caecal content taken at slaughter from fattening pigs;
 - (iv) samples of caecal content taken at slaughter from bovine animals under one year of age where the production of meat of those bovine animals in the Member State is more than 10 000 tonnes slaughtered per year;
 - (v) samples of fresh meat of broilers, turkeys, pigs and bovine animals taken at retail;
 - (vi) samples of fresh meat of broilers, turkeys, pigs and bovine animals taken at the border control posts.
- (e) *E. faecalis* and *E. faecium* isolates from:
- (i) samples of caecal content taken at slaughter from broilers;
 - (ii) samples of caecal content taken at slaughter from fattening turkeys where the production of turkey meat in the Member State is more than 10 000 tonnes slaughtered per year;
 - (iii) samples of caecal content taken at slaughter from fattening pigs;
 - (iv) samples of caecal content taken at slaughter from bovine animals under one year of age where the production of meat of those bovine animals in the Member State is more than 10 000 tonnes slaughtered per year;
 - (v) samples of fresh meat of broilers, turkeys, pigs and bovine animals taken at the border control posts;

2. Sampling frequency

Member States shall carry out the AMR monitoring of each combination of bacterial isolates/food-producing animal populations/food, as listed in point 1, in accordance with the following rotational system:

- (a) In the years 2021, 2023, 2025 and 2027: AMR monitoring shall be carried out in fattening pigs, bovine animals under one year of age, pig meat and bovine meat. However, the monitoring of AMR in *E. faecalis* and *E. faecium* and the monitoring of CP-producing *E. coli* are not compulsory in the years 2023 and 2027.
- (b) In the years 2022, 2024 and 2026: AMR monitoring shall be carried out in laying hens, broilers, fattening turkeys and fresh meat thereof. However, the monitoring of AMR in *E. faecalis* and *E. faecium* and the monitoring of CP-producing *E. coli* are not compulsory in the year 2024.

3. Sampling design and sample size

3.1. At slaughterhouse level

- a) Sampling design:

When designing their sampling plan at slaughterhouse level, Member States shall take into account the most recent version of the EFSA technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria¹.

Member States shall ensure a proportionate stratified sampling of samples of caecal content in slaughterhouses processing at least 60 % of the specific domestic animal population in the Member States with an even distribution over the monitoring year of the samples taken, and a randomisation of the sampling days of each month. The samples shall be taken from healthy animals sampled from randomly selected epidemiological units. The epidemiological unit for broilers and fattening turkeys is the flock. The epidemiological unit for fattening pigs and bovine animals under one year of age is the slaughter batch. Only one sample from the same epidemiological unit shall be taken per year. Each sample shall be taken from one carcass randomly selected from the same epidemiological unit. However, for broilers, each sample shall be taken from ten carcasses randomly selected from the same epidemiological unit.

The number of samples collected per slaughterhouse must be proportional to the annual throughput of each slaughterhouse covered by the sampling plan.

b) Sample size:

In order to test for antimicrobial susceptibility the required minimum number of bacterial isolates referred to in point 4.1, Member States shall take a sufficient number of samples by accounting for the prevalence of the bacterial species monitored in the animal population considered. However, in view to ensure the specific monitoring of ESBL-, AmpC- and/or CP-*E. coli* referred to in point 5, Member States shall collect at least 300 samples from each animal population referred to in points 1(d)(i) and (ii). By way of derogation, where Member States have an annual production of less than 100 000 tonnes of broiler and turkey meat slaughtered per year respectively, less than 100 000 tonnes of pig meat slaughtered per year and less than 50 000 tonnes bovine meat slaughtered per year, Member States may decide to collect a minimum of 150 samples instead of 300 samples.

3.2. *At retail level*

a) Sampling design:

When designing their sampling plan at retail level, Member States shall take into account the most recent version of the EFSA technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria².

Member States shall ensure a proportionate stratified sampling of samples of the fresh meat taken at retail, with a proportional allocation of the number of samples to the population of the geographical region (NUTS-3 area) accounting for at least 80 % of the national population. They shall also ensure an even distribution over the monitoring year of the samples of fresh meat and a randomisation of the sampling days of each month. The batches to be sampled on a given day shall be randomly selected.

b) Sample size:

Member States shall collect 300 samples from each fresh meat category referred to in point 1(d)(iii). By way of derogation, where Member States have an annual production of less than 100 000 tonnes of broiler and turkey meat slaughtered per year respectively, less than 100 000 tonnes of pig meat slaughtered per year and less than 50 000 tonnes bovine meat slaughtered per year, they may decide to collect 150 samples instead of 300 samples.

¹ <https://www.efsa.europa.eu/it/efsajournal/pub/3686>

² See footnote 1

3.3. At border control posts

a) Sampling design:

When designing their sampling plan at border control posts, Member States shall take into account the most recent version of the EFSA technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria³.

Member States shall ensure a proportionate stratified sampling of consignments and meat samples per border control post and country of origin with an even distribution over the monitoring year of the consignments of imported fresh meat sampled at border control posts level, and a randomisation of the sampling days of each month. All border control posts shall be included in the sampling plan. The consignments to be sampled on a given day shall be randomly selected and when sampling a consignment, samples must be randomly taken. If a consignment is composed of different batches, the samples shall be taken from different batches. Samples shall not be pooled.

b) Sample size:

The number of samples to be taken per year shall be calculated taking into account import data of previous years and the indicative frequencies set out in Table 1.

Table 1

Fresh meat subject to AMR testing at import: indicative frequencies for calculating the sample size

Type of fresh meat	CN code	Percentage of consignments to be sampled per year ⁽⁴⁾	Number of samples to be collected per consignments
Broiler meat	0207 11 10, 0207 11 30, 0207 11 90, 0207 12 10, 0207 12 90, 0207 13 10, 0207 13 20, 0207 13 30, 0207 13 40, 0207 13 50, 0207 13 60, 0207 13 70, 0207 13 91, 0207 13 99, 0207 14 10, 0207 14 20, 0207 14 30, 0207 14 40, 0207 14 50, 0207 14 60, 0207 14 70, 0207 14 91, 0207 14 99	3%	4

³ See footnote 1

⁴ If the calculation of the number of consignments to be sampled gives a value of less than one, the competent authority shall sample one consignment

Turkey meat	0207 24 10, 0207 24 90, 0207 25 10, 0207 25 90, 0207 26 10, 0207 26 20, 0207 26 30, 0207 26 40, 0207 26 50, 0207 26 60, 0207 26 70, 0207 26 80, 0207 26 91, 0207 26 99, 0207 27 10, 0207 27 20, 0207 27 30, 0207 27 40, 0207 27 50, 0207 27 60, 0207 27 70, 0207 27 80, 0207 27 91, 0207 27 99	21%	4
Pig meat	0203 11 10, 0203 11 90, 0203 12 11, 0203 12 19, 0203 12 90, 0203 19 11, 0203 19 13, 0203 19 15, 0203 19 55, 0203 21 10, 0203 21 90; 0203 22 11; 0203 22 19; 0203 22 90; 0203 29 11; 0203 29 13; 0203 29 15; 0203 29 55; 0203 29 59; 0203 29 90	27%	4
Bovine meat	0201 10 00; 0201 20 20; 0201 20 30; 0201 20 50; 0201 20 90; 0201 30 00; 0202 10 00; 0202 20 10; 0202 20 30; 0202 20 50; 0202 20 90; 0202 30 10; 0202 30 50; 0202 30 90	2%	4

4. Antimicrobial susceptibility testing

4.1. Number of isolates to be tested

Member States shall test for antimicrobial susceptibility the following number of isolates:

For *Salmonella* spp:

- at least 170 isolates obtained from samples referred to in point 1(a)(i). No more than one isolate per *Salmonella* serovar from the same epidemiological unit per year should be tested and the isolates shall be obtained from healthy animals. Where the number of isolates yearly available per animal population in a Member State is higher than 170, a random selection of those isolates must be performed in a way that ensures a geographical representativeness and an even distribution of the date of sampling over the year. When the number of isolates yearly available is lower than 170, all of them shall be tested;
- at least 170 isolates obtained from samples referred to in point 1(a)(ii). By way of derogation, where Member States have an annual production of less than 100 000 tonnes of pig meat slaughtered per year, they may decide to test a minimum of 85 isolates instead of 170 isolates;
- at least 170 isolates obtained from samples referred to in point 1(a)(iii)
- all isolates obtained from samples referred to in point 1(a)(iv).

For *C. coli* and *C. jejuni*:

- at least 170 isolates of the nationally most prevalent species of *Campylobacter* (among *C. coli* and *C. jejuni*) from samples referred to in point 1(b);
- all isolates, from the samples referred to in point 1(b), of the less prevalent *Campylobacter* species (among *C. coli* and *C. jejuni*) recovered from the isolation process performed in accordance with the most recent version of the protocol of the EURL for *Campylobacter*⁵ or with an alternative protocol validated against the protocol of the EURL;

For indicator commensal *E. coli*:

- at least 170 isolates obtained from samples referred to in points 1(c)(i) and (iv). By way of derogation, where Member States have an annual production of less than 100 000 tonnes of broiler and turkey meat slaughtered per year respectively and less than 100 000 tonnes of pig meat slaughtered per year, they may decide to test a minimum of 85 isolates instead of 170 isolates;
- all isolates obtained from samples referred to in point 1(c)(v).

For ESBL-, AmpC- and/or CP- *E. coli*:

- all isolates obtained from samples referred to in point 1(d).

For *E. faecalis* and *E. faecium*:

- at least 170 isolates of *E. faecalis* and 170 isolates of *E. faecium* obtained from samples referred to in points 1(e)(i) to (iv). By way of derogation, where Member States have an annual production of less than 100 000 tonnes of broiler and turkey meat slaughtered per year respectively and less than 100 000 tonnes of pig meat slaughtered per year, they may decide to test a minimum of 85 isolates instead of 170 isolates;
- all isolates obtained from samples referred to in point 1(e)(v).

4.2. *Methods for antimicrobial susceptibility testing*

Member States shall use the epidemiological cut-off values and the concentration ranges set out in Tables 1, 2 and 3 below to determine the antimicrobial susceptibility of *Salmonella* spp., *C. coli*, *C. jejuni*, indicator commensal *E. coli*, *E. faecalis* and *E. faecium*.

Any *E. coli* and *Salmonella* isolate tested in accordance with Table 1 showing resistance to cefotaxime or ceftazidime or meropenem shall be further tested with a second panel of antimicrobial substances in accordance with Table 4.

For the specific monitoring of ESBL-, AmpC- and/or CP- *E. coli*, Member States shall use the methods referred to in point 5.

⁵ Public reference to the protocol to be inserted when available

The antimicrobial susceptibility testing must be performed by the laboratories referred to in Article 3(2)(a). The testing must be performed by using the broth microdilution method according to the international reference method ISO 20776-1:2019.

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Table 1

Panel of antimicrobial substances to be included in AMR monitoring, EUCAST thresholds for resistance and concentration ranges to be tested in *Salmonella* spp. and indicator commensal *E. coli* (First panel)

Antimicrobial	Class of antimicrobial	Species	Interpretative thresholds of AMR (mg/L)		Range of concentrations (mg/L) (No of wells in brackets)
			ECOFF	Clinical breakpoint	
Amikacin	Aminoglycoside	<i>Salmonella</i>	NA	> 16	4-128 (6)
		<i>E. coli</i>	> 8	> 16	
Ampicillin	Penicillin	<i>Salmonella</i>	> 8	> 8	1-32 (6)
		<i>E. coli</i>	> 8	> 8	
Azithromycin	Macrolide	<i>Salmonella</i>	NA	NA	2-64 (6)
		<i>E. coli</i>	NA	NA	
Cefotaxime	Cephalosporin	<i>Salmonella</i>	> 0.5	> 2	0.25-4 (5)
		<i>E. coli</i>	> 0.25	> 2	
Ceftazidime	Cephalosporin	<i>Salmonella</i>	> 2	> 4	0.25-8 (6)
		<i>E. coli</i>	> 0.5	> 4	
Chloramphenicol	Phenicol	<i>Salmonella</i>	> 16	> 8	8-64 (4)
		<i>E. coli</i>	> 16	> 8	
Ciprofloxacin	Fluoroquinolone	<i>Salmonella</i>	> 0.06	> 0.06	0.015-8 (10)
		<i>E. coli</i>	> 0.06	> 0.5	
Colistin	Polymyxin	<i>Salmonella</i>	NA	> 2	1-16 (5)
		<i>E. coli</i>	> 2	> 2	
Gentamicin	Aminoglycoside	<i>Salmonella</i>	> 2	> 4	0.5-16 (6)
		<i>E. coli</i>	> 2	> 4	
Meropenem	Carbapenem	<i>Salmonella</i>	> 0.125	> 8	0.03-16 (10)
		<i>E. coli</i>	> 0.125	> 8	
Nalidixic acid	Quinolone	<i>Salmonella</i>	> 8	NA	4-64 (5)
		<i>E. coli</i>	> 8	NA	
Sulfamethoxazole	Folate pathway antagonist	<i>Salmonella</i>	NA	NA	8-512 (7)
		<i>E. coli</i>	> 64	NA	
Tetracycline	Tetracycline	<i>Salmonella</i>	> 8	NA	2-32 (5)
		<i>E. coli</i>	> 8	NA	
Tigecycline	Glycylcycline	<i>Salmonella</i>	NA	NA	0.25-8 (6)
		<i>E. coli</i>	> 0.5	> 0.5	
Trimethoprim	Folate pathway antagonist	<i>Salmonella</i>	> 2	> 4	0.25-16 (7)
		<i>E. coli</i>	> 2	> 4	

NA: not available.

Table 2

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	Class of antimicrobial	Species	Interpretative thresholds of AMR (mg/L)		Range of concentrations (mg/L) (No of wells in brackets)
			ECOFF	Clinical breakpoint	
Chloramphenicol	Phenicol	<i>C. jejuni</i>	> 16	NA	2-64 (6)
		<i>C. coli</i>	> 16	NA	
Ciprofloxacin	Fluoroquinolone	<i>C. jejuni</i>	> 0.5	> 0.5	0.12-32 (9)
		<i>C. coli</i>	> 0.5	> 0.5	
Ertapenem	Carbapenem	<i>C. jejuni</i>	NA	NA	0.125-4 (6)
		<i>C. coli</i>	NA	NA	
Erythromycin	Macrolide	<i>C. jejuni</i>	> 4	> 4	1-512 (10)
		<i>C. coli</i>	> 8	> 8	
Gentamicin	Aminoglycoside	<i>C. jejuni</i>	> 2	NA	0.25-16 (7)
		<i>C. coli</i>	> 2	NA	
Tetracycline	Tetracycline	<i>C. jejuni</i>	> 1	> 2	0.5-64 (8)
		<i>C. coli</i>	> 2	> 2	

NA: not available

Table 3

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

Antimicrobial	Class of antimicrobial	Species	Interpretative thresholds of AMR (mg/L)		Range of concentrations (mg/L) (No of wells in brackets)
			ECOFF	Clinical breakpoint	
Ampicillin	Penicillin	<i>E. faecalis</i>	> 4	> 8	0.5-64 (8)
		<i>E. faecium</i>	> 4	> 8	
Chloramphenicol	Phenicol	<i>E. faecalis</i>	> 32	NA	4-128 (6)
		<i>E. faecium</i>	> 32	NA	
Ciprofloxacin	Fluoroquinolone	<i>E. faecalis</i>	> 4	> 4	0.12-16 (8)
		<i>E. faecium</i>	> 4	> 4	
Daptomycin	Lipopeptide	<i>E. faecalis</i>	> 4	NA	0.25-32 (8)
		<i>E. faecium</i>	> 8	NA	
Erythromycin	Macrolide	<i>E. faecalis</i>	> 4	NA	1-128 (8)
		<i>E. faecium</i>	> 4	NA	
Gentamicin	Aminoglycoside	<i>E. faecalis</i>	> 32	NA	8-1024 (8)
		<i>E. faecium</i>	> 32	NA	
Linezolid	Oxazolidinone	<i>E. faecalis</i>	> 4	> 4	0.5-64 (8)
		<i>E. faecium</i>	> 4	> 4	
Quinupristin/Dalfopristin	Streptogramin	<i>E. faecalis</i>	NA	NA	0.5-64 (8)
		<i>E. faecium</i>	NA	> 4	
Teicoplanin	Glycopeptide	<i>E. faecalis</i>	> 2	> 2	0.5-64 (8)
		<i>E. faecium</i>	> 2	> 2	
Tetracycline	Tetracycline	<i>E. faecalis</i>	> 4	NA	1-128 (8)
		<i>E. faecium</i>	> 4	NA	
Tigecycline	Glycylcycline	<i>E. faecalis</i>	> 0.5	> 0.25	0.03-4 (8)
		<i>E. faecium</i>	> 0.25	> 0.25	
Vancomycin	Glycopeptide	<i>E. faecalis</i>	> 4	> 4	1-128 (8)
		<i>E. faecium</i>	> 4	> 4	

NA: not available

5. Specific monitoring of ESBL- or AmpC- or CP-producing *E. coli*

5.1. Method for detection of presumptive ESBL-, AmpC- and/or CP-producing *E. coli*

- For the purpose of estimating the proportion of samples containing presumptive ESBL- or AmpC- or CP-producing *E. coli* among the caecal and food samples collected in accordance with point 1(d), the laboratories referred to in Article 3(2)(b) must use detection methods starting by a pre-enrichment step, followed by plating on a suitable selective agar validated with regard to specificity and

sensitivity for detection of ESBL-, AmpC- and/or CP-producing *E. coli* according to the most recent versions of the protocols of the EURL for AMR⁶.

All presumptive ESBL-, AmpC- and/or CP-producing *E. coli* isolates identified through the methods referred to in above shall be tested with the first panel and the second panel of antimicrobial substances in accordance with Table 1 and Table 4 respectively.

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⁶ <https://www.eurl-ar.eu/protocols.aspx>

Table 4

Panel of antimicrobial substances, EUCAST epidemiological cut-off values (ECOFFs) and clinical resistance breakpoints and concentrations ranges to be used for testing only *Salmonella* spp. and *E. coli* isolates resistant to cefotaxime or ceftazidime or meropenem – (Second panel)

Antimicrobial	Class of antimicrobial	Species	Interpretative thresholds of AMR (mg/L)		Range of concentrations (mg/L) (No of wells in brackets)
			ECOFF	Clinical breakpoint	
Cefepime	Cephalosporin	<i>Salmonella</i>	NA	> 4	0.06-32 (10)
		<i>E. coli</i>	> 0.125	> 4	
Cefotaxime	Cephalosporin	<i>Salmonella</i>	> 0.5	> 2	0.25-64 (9)
		<i>E. coli</i>	> 0.25	> 2	
Cefotaxime + clavulanic acid	Cephalosporin/beta-lactamase inhibitor combination	<i>Salmonella</i>	NA	NA	0.06-64 (11)
		<i>E. coli</i>	> 0.25	NA	
Cefoxitin	Cephameycin	<i>Salmonella</i>	> 8	NA	0.5-64 (8)
		<i>E. coli</i>	> 8	NA	
Ceftazidime	Cephalosporin	<i>Salmonella</i>	> 2	> 4	0.25-128 (10)
		<i>E. coli</i>	> 0.5	> 4	
Ceftazidime + clavulanic acid	Cephalosporin/beta-lactamase inhibitor combination	<i>Salmonella</i>	NA	NA	0.125-128 (11)
		<i>E. coli</i>	> 0.5	NA	
Ertapenem	Carbapenem	<i>Salmonella</i>	NA	> 0.5	0.015-2 (8)
		<i>E. coli</i>	NA	> 0.5	
Imipenem	Carbapenem	<i>Salmonella</i>	> 1	> 4	0.12-16 (8)
		<i>E. coli</i>	> 0.5	> 4	
Meropenem	Carbapenem	<i>Salmonella</i>	> 0.125	> 8	0.03-16 (10)
		<i>E. coli</i>	> 0.125	> 8	
Temocillin	Penicillin	<i>Salmonella</i>	> 16	NA	0.5-128 (9)
		<i>E. coli</i>	> 16	NA	

NA: not available

5.2. Quantitative method to assess the proportion of ESBL- or AmpC-producing *E. coli*

Member States may decide to assess the proportion of ESBL- and/or AmpC-producing *E. coli* compared to the total *E. coli* isolates present in a sample, especially if they detect a high prevalence of ESBL- and/or AmpC-producing *E. coli* when implementing the detection methods set out in point 5.1. In this case they shall enumerate ESBL- or AmpC-producing *E. coli* and the total *E. coli* by using dilution methods and subsequent by plating onto selective media and non-selective media, according to the most recent versions of the protocols of the EURL for AMR⁷.

6. Alternative method

Member States may decide to authorise the use of Whole Genome Sequencing (WGS) as an alternative method to the testing panels of antimicrobial substances of Tables 1 and 4 when carrying out the specific monitoring of ESBL- or AmpC- or CP-producing *E. coli* as referred to in point 5. They may also authorise WGS as an alternative use to the testing panel of antimicrobial substances of Table 4 when further testing, in accordance with point 4.2, *E. coli* and *Salmonella* isolates showing resistance to cefotaxime or ceftazidime or meropenem.

Laboratories implementing WGS as an alternative method shall use the most recent versions of the WGS testing protocols of the EURL for AMR⁸.

7. Quality control, storage of the isolates and confirmatory testing

The Member States shall ensure participation of the laboratories referred to in Article 3 to a quality assurance system including proficiency test set up at either national or Union level, to target species identification, sub-typing and antimicrobial susceptibility testing of the bacteria collected for the harmonised monitoring of AMR.

Isolates must be stored by the national reference laboratories for AMR at a temperature of – 80 °C for a minimum period of five years. Other methods of storage may alternatively be used provided that they ensure viability and absence of changes in strain properties.

When deemed scientifically relevant by the EFSA and the EURL for AMR, the laboratories referred to in Article 3 shall sent for a confirmatory testing to the EURL for AMR any isolate tested in accordance with points 4, 5 and 6.

⁷ <https://www.eurl-ar.eu/protocols.aspx>

⁸ <https://www.eurl-ar.eu/protocols.aspx>

Part B

Reporting

1. General provisions for reporting of the data

Member States shall draft reports and include the information referred to in point 2 for each individual isolate, considering separately each bacterial species and animal population combination and bacterial species and food combination referred to in point 1 of Part A. Member States must submit the results of the harmonised AMR monitoring provided for in this Decision in the form of isolate-based data using the data dictionary and the electronic collection forms provided by EFSA. Member States shall describe sampling designs, stratification and randomisation procedures per animal populations and food categories.

Where AMR monitoring is performed by using antimicrobial susceptibility testing, Member States shall report the information referred to in point 2.1.

Where AMR monitoring is performed by using WGS, Member States shall report the information referred to in point 2.2.

Data obtained on a voluntary basis must be reported separately to EFSA.

2. Reporting dataset

2.1 Reporting antimicrobial susceptibility testing results

The following information shall be included for each individual isolate:

-
- Identifier or code of the isolate
- Bacterial species
- Serovar (for *Salmonella* spp.)
- Phage type of *Salmonella* Enteritidis and *Salmonella* Typhimurium (optional)
- Food-producing animal population or food category
- Stage of sampling
- Type of sample
- Border control post identification number (for testing of imported meat only)
- Consignment identification number (for testing of imported meat only)
- Country of origin of the consignment (for testing of imported meat only)
- CN code (for testing of imported meat only)
- Sampler
- The sampling strategy
- Date of sampling
- Date of start of analysis (isolation)
- Identifier or code of the isolate given by the laboratory performing the antimicrobial susceptibility testing of the isolate

- Date of susceptibility testing
- Antimicrobial substance
- Minimum Inhibitory Concentration (MIC) value (in mg/L)
- Synergy testing with clavulanic acid for ceftazidime
- Synergy testing with clavulanic acid for cefotaxime

2.2 *Reporting antimicrobial susceptibility testing results*

Member States shall submit the WGS data of the isolate referred to in point 6 of Part A to EFSA and shall provide the following information per isolate:

- Identifier or code of the isolate
- Bacterial species
- Food-producing animal population or food category
- Stage of sampling
- Type of sample
- Border control post identification number (for testing of imported meat only)
- Consignment identification number (for testing of imported meat only)
- Country of origin of the consignment (for testing of imported meat only)
- CN code (for testing of imported meat only)
- Sampler
- The sampling strategy
- Date of sampling
- Date of start of analysis (isolation)
- Identifier or code of the isolate given by the laboratory
- Date of sequencing
- Version of the predictive tool
- AMR-conferring genes data
- Whole sequence
- Sequencing technology used
- Library preparation used