COMMISSION IMPLEMENTING DECISION (EU) 2020/1729

of 17 November 2020

on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Implementing Decision 2013/652/EU

(notified under document C(2020) 7894)

(Only the English version is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Articles 4(5), 7(3), 8(3) and the fourth subparagraph of Article 9(1) thereof,

Whereas:

(1) Directive 2003/99/EC requires Member States to ensure that monitoring provides comparable data on the occurrence of antimicrobial resistance ('AMR') in zoonotic agents and, in so far they present a threat to public health, other agents.

(2) Directive 2003/99/EC also requires Member States to assess the trends and sources of AMR in their territory and to transmit a report every year covering data collected in accordance with that Directive to the Commission.

(3) Commission Implementing Decision 2013/652/EU ([2]) lays down detailed rules for the harmonised monitoring and reporting of AMR in zoonotic and commensal bacteria. These rules are applicable until 31 December 2020.

(4) In its Communication of 29 June 2017 to the Council and the European Parliament 'A European One Health Action Plan against Antimicrobial Resistance' ([3]), the Commission committed to review Union implementing legislation, namely Implementing Decision 2013/652/EU, concerned with the monitoring of AMR in zoonotic and commensal bacteria in farm animals and food to take into account new scientific developments and data collection needs.

(5) From 2015 to 2018, the Commission carried out a series of audits in Member States for the purposes of evaluating the implementation of Implementing Decision 2013/652/EU by competent authorities. A final overview report ([4]) summarising this series of audits highlighted certain implementation challenges faced by Member States that should be taken into account by the Commission when revising Implementing Decision 2013/652/EU.

(6) On 5 June 2019, the European Food Safety Authority ('EFSA') published a scientific report entitled 'Technical specifications on harmonised monitoring of antimicrobial resistance in zoonotic and indicator bacteria from food-producing animals and food' ([5]). This report recommends specific adaptations to the current AMR monitoring and reporting system as laid down in Implementing Decision 2013/652/EU in order to respond effectively to the constantly evolving threat of AMR and to ensure continuity in assessing future trends in AMR from 2021. These recommended adaptations primarily concern adaptations as to the food-producing animal populations or food categories to be sampled, the sampling design to be followed, the bacterial species to be tested for AMR and the analytical methods to be used by laboratories in charge of testing for AMR.

([1]) OJ L 325, 12.12.2003, p. 31.
([2]) 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).
([3]) COM/2017/0339 final.
([4]) DG(SANTE) 2019-6789.
([5]) *EFSA Journal* 2019;17(6):5709.

(7) In order to continue to obtain comparable and reliable data on AMR, it is important to take recommendations of the EFSA scientific report of 5 June 2019 into account when defining the most relevant combinations of bacterial species, food producing animal species and food products to be included in the harmonised monitoring and reporting of AMR from 2021. It is also appropriate to minimise the burden on competent authorities of Member States to the extent possible, notably by addressing known implementation challenges and by focussing AMR monitoring on biological samples or bacterial isolates collected within the framework of existing national control programmes.

(8) Whole genome sequencing ('WGS') is a promising technique to replace conventional phenotypical testing in microbiology and is increasingly used worldwide. However, only a limited number of Member States are currently able to use WGS for AMR monitoring on a routine basis. It is therefore appropriate to authorise the use of WGS as an alternative to the conventional phenotypical techniques on a voluntary basis only, but to impose technical conditions on the WGS technique to ensure data comparability.

(9) AMR is a global threat that can easily spread across borders. Therefore, in order to improve coordination and gain a deeper understanding of how to help reduce the impact of AMR impact globally, it is essential that food products imported into the Union are also subjected to AMR monitoring requirements.

(10) In order to ensure continuity of the harmonised AMR monitoring and reporting by Member States after the period covered by Implementing Decision 2013/652/EU, this Decision should apply from 1 January 2021.

(11) For the sake of legal clarity, Implementing Decision 2013/652/EU should be repealed.

(12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

1. This Decision lays down harmonised rules for the period 2021-2027 for the monitoring and reporting of antimicrobial resistance ('AMR') to be carried out by Member States in accordance with Article 7(3) and 9(1) of Directive 2003/99/EC and Annex II (B) and Annex IV thereto.

2. The monitoring and reporting of AMR shall cover the following bacteria:

(a) *Salmonella* spp.;

(b) *Campylobacter coli* (*C. coli*);

(c) *Campylobacter jejuni* (*C. jejuni*);

(d) Indicator commensal *Escherichia coli* (*E. coli*);

(e) *Salmonella* spp. and *E. coli* producing the following enzymes:

(i) Extended Spectrum β-Lactamases (ESBL);

(ii) AmpC β-Lactamases (AmpC);

(iii) Carbapenemases (CP).

3. The monitoring and reporting of AMR may cover indicator commensal *Enterococcus faecalis* (*E. faecalis*) and *Enterococcus faecium* (*E. faecium*).

4. The monitoring and reporting of AMR shall cover the following food-producing animal populations and food:

(a) broilers;

(b) laying hens;

(c) fattening turkeys;

(d) bovine animals under one year of age;

(e) fattening pigs;

(f) fresh meat from broilers;

(g) fresh meat from turkeys;

(h) fresh meat from pigs;

(i) fresh meat from bovine animals.

5. Member States shall monitor and report AMR in specific combinations of bacteria/antimicrobial substances/food-producing animal populations and fresh meat derived thereof in accordance with Articles 3 and 4.

Article 2

Definitions

For the purposes of this Decision, the following definitions shall apply:

(a) the definitions laid down in Regulation (EU) 2017/625 of the European Parliament and of the Council ([6]);

(b) the definitions laid down in Commission Regulation (EC) No 2073/2005 ([7]);

(c) the definitions laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council ([8]);

(d) the definitions laid down in Regulation (EC) No 2160/2003 of the European Parliament and of the Council ([9]);

(e) the definitions laid down in Directive 2003/99/EC;

(f) the definitions laid down in Regulation (EU) 2019/6 of the European Parliament and of the Council ([10]);

(g) 'slaughter batch' means a group of animals originating from the same herd, raised together under the same conditions and sent to the slaughterhouse on the same day.

Article 3

Sampling framework and analysis

1. Member States shall sample the different food-producing animal populations and fresh meat derived thereof, as referred to in Article 1(4), and test the bacterial isolates obtained therefrom for antimicrobial susceptibility in accordance with the technical requirements set out in Part A of the Annex.

However, for the monitoring of *Salmonella* spp. in populations of broilers, laying hens and fattening turkeys, Member States may use bacterial isolates already obtained within the sampling framework of the national control programmes provided for in Article 5 of Regulation (EC) No 2160/2003.

2. National reference laboratories for AMR, or other laboratories designated by the competent authority in accordance with Article 37 of Regulation (EU) 2017/625, shall be responsible for carrying-out:

(a) the antimicrobial susceptibility testing of bacterial isolates, referred to in paragraph 1, in accordance with the technical requirements set out in point 4 of Part A of the Annex;

(b) the specific monitoring of ESBL-, AmpC- or CP-producing *E. coli* in accordance with the technical requirements set out in point 5 of Part A of the Annex;

(c) the alternative method referred to in point 6 of Part A of the Annex.

([6]) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

([7]) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1)

([8]) 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).

([9]) 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).

([10]) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

Article 4

Annual AMR reporting and assessment

Member States shall report the results of their AMR monitoring to the Commission annually, in accordance with the requirements of Part B of the Annex.

Member States shall also assess the results of their annual AMR monitoring and include that assessment in the report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance provided for in Article 9(1) of Directive 2003/99/EC.

Article 5

Publication of the data

The European Food Safety Authority shall publish the national isolate-based quantitative antimicrobial resistance data and results of the analyses reported in accordance with Article 4.

Article 6

Repeal

Implementing Decision 2013/652/EU is hereby repealed.

Article 7

Application

This Decision shall apply from 1 January 2021.

Article 8

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 17 November 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

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 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, except for Member States implementing a national programme for the control of salmonella which has been approved at EU level;

(iii) samples of caecal content taken at slaughter from bovine animals under one year of age where the national production of meat of those bovine animals is more than 10 000 tonnes per year;

(iv) samples of fresh meat of broilers and turkeys taken at the border control posts.

(b) *C. coli* and *C. jejuni* 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 national production of turkey meat is more than 10 000 tonnes per year;

(iii) samples of caecal content taken at slaughter from bovine animals under one year of age where the national production of meat of those bovine animals is more than 10 000 tonnes per year;

(iv) samples of caecal content taken at slaughter from fattening pigs.

(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 national production of turkey meat is more than 10 000 tonnes 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 national production of meat of those bovine animals is more than 10 000 tonnes per year;

(v) samples of fresh meat of broilers, turkeys, pigs and bovine animals taken at the border control posts.

(d) ESBL- or AmpC- or CP-producing *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 national production of turkey meat is more than 10 000 tonnes 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 national production of meat of those bovine animals is more than 10 000 tonnes 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) Where a Member State decides to monitor indicator commensal *E. faecalis* and *E. faecium* in accordance with Article 1(3), isolates of these bacteria 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 national production of turkey meat is more than 10 000 tonnes 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 national production of meat of those bovine animals is more than 10 000 tonnes per year.

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.

(b) In the years 2022, 2024 and 2026: AMR monitoring shall be carried out in laying hens, broilers, fattening turkeys and fresh meat derived from broilers and turkeys.

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 EFSA technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria ([1]).

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 period of the samples taken, and, to the extent possible, 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 epidemiological unit. However, for broilers, each sample shall be taken from ten carcasses randomly selected from the epidemiological unit.

The number of samples collected per slaughterhouse shall 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 annually a sufficient number of samples referred to in points 1(a)(ii) and (iii), 1(b) and 1 (c)(i) to (iv) by accounting for the estimated prevalence of the bacterial species monitored in the animal population considered.

By way of derogation, when the prevalence of the bacterial species monitored is known to be inferior or equal to 30 % in the animal population considered or when this prevalence is unknown in the first year of the monitoring or when the number of epidemiological units available for sampling is insufficient to prevent the repeated sampling of the same units, Member States may decide to limit to 300 the annual number of samples to be taken. This annual number can be further reduced to 150 for each specific combination of bacterial isolates/animal populations where Member States have an annual national production of less than 100 000 tonnes of broiler meat, less than 100 000 tonnes of turkey meat, less than 100 000 tonnes of pig meat or less than 50 000 tonnes of bovine meat. Member States making use of the possibility of limitation of the annual number of samples shall base their decision on documented evidence, such as results of surveys, and shall submit this evidence to the Commission before implementing the reduced sampling for the first time.

([1]) https://www.efsa.europa.eu/it/efsajournal/pub/3686

Member States shall take annually at least 300 samples from each animal population referred to in points 1(d)(i) to (iv). By way of derogation, where Member States have an annual national production of less than 100 000 tonnes of broiler meat, less than 100 000 tonnes of turkey meat, less than 100 000 tonnes of pig meat or less than 50 000 tonnes of bovine meat, they may decide to take a minimum of 150 samples instead of 300 samples for each specific animal population considered.

3.2. *At retail level*

(a) Sampling design:

When designing their sampling plan at retail level, Member States shall take into account EFSA technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria ([2]).

Member States shall ensure a proportionate stratified sampling of samples of the fresh meat taken at retail without pre-selecting samples based on the origin of the food, with a proportional allocation of the number of samples to the population of the geographical region. They shall also ensure an even distribution over the monitoring year of the samples of fresh meat and, to the extent possible, 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 take 300 samples from each fresh meat category referred to in point 1(d)(v). By way of derogation, where Member States have an annual production of less than 100 000 tonnes of broiler meat, less than 100 000 tonnes of turkey meat, less than 100 000 tonnes of pig meat or less than 50 000 tonnes of bovine meat, they may decide to take 150 samples instead of 300 samples for each specific category of fresh meat considered.

3.3. *At border control posts*

(a) Sampling design:

When designing their sampling plan at border control posts, Member States shall take into account EFSA technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria ([3]).

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. All border control posts designated for fresh meat 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 shall 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:

Member States shall determine the appropriate number of samples they shall take per year from each fresh meat category referred to in points 1(a)(iv), 1(c)(v) and 1(d)(vi) based on the indicative sampling frequency rates set out in Table 1.

Table 1

Fresh meat subject to AMR testing at import: indicative sampling frequency rates

Type of fresh meat	Recommended annual sampling frequency rates of consignments arrived at the border control posts
Broiler meat	3 %
Turkey meat	15 %
Pig meat	10 %
Bovine meat	2 %

([2]) See footnote 1.
([3]) See footnote 1.

4. **Antimicrobial susceptibility testing**

4.1. *Number of isolates to be tested*

Member States shall test for antimicrobial susceptibility the following number of isolates annually and ensure that no more than one isolate per bacterial species/*Salmonella* serovar from the same epidemiological unit is tested per year:

For *Salmonella* spp:

— up to 170 isolates obtained from samples referred to in point 1(a)(i). Where Member States have a national annual production of less than 100 000 tonnes of broiler meat, they may decide to set an upper limit of 85 isolates instead of 170 isolates. 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 the upper limit, a random selection of those isolates shall be performed in a way that ensures a geographical representativeness and, where possible, an even distribution of the date of sampling over the year. When the number of isolates yearly available is lower than the upper limit, all of them shall be tested,

— at least 170 isolates obtained from samples referred to in point 1(a)(ii) or, for Member States making use of the derogation referred to in the second paragraph of point 3(1)(b), all isolates obtained from these samples. By way of derogation, where Member States have a national annual production of less than 100 000 tonnes of pig meat, 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) or, for Member States making use of the derogation referred to in the second paragraph of point 3(1)(b), all isolates obtained from these samples,

— 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*) obtained from samples referred to in point 1(b)(i) to (iii) or, for Member States making use of the derogation referred to in the second paragraph of point 3(1)(b), all isolates obtained from these samples. By way of derogation, where Member States have a national annual production of less than 100 000 tonnes of broiler meat, they may decide to test a minimum of 85 isolates instead of 170 isolates,

— up to 170 isolates of the nationally less prevalent species of *Campylobacter* (among *C. coli* and *C. jejuni*) identified while recovering the isolates of the most prevalent *Campylobacter* species obtained from samples referred to in point 1(b)(i) to (iii),

— at least 170 isolates of *C. coli* obtained from samples referred to in point 1(b)(iv) or, for Member States making use of the derogation referred to in the second paragraph of point 3(1)(b), all isolates obtained from these samples. By way of derogation, where Member States have a national annual production of less than 100 000 tonnes of pig meat, they may decide to test a minimum of 85 isolates instead of 170 isolates.

For indicator commensal *E. coli:*

— at least 170 isolates obtained from samples referred to in points 1(c)(i) to (iv). By way of derogation, where Member States have a national annual production of less than 100 000 tonnes of broiler meat, less than 100 000 tonnes of turkey meat or less than 100 000 tonnes of pig meat, they may decide to test a minimum of 85 isolates instead of 170 isolates for each specific animal population considered,

— all isolates obtained from samples referred to in point 1(c)(v).

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

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

4.2. *Analytical methods for detection and antimicrobial susceptibility testing*

Member States shall use the epidemiological cut-off values and the concentration ranges set out in Tables 2, 3 and 4 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 2 showing resistance to cefotaxime or ceftazidime or meropenem shall be further tested with a second panel of antimicrobial substances in accordance with Table 5.

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

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

Table 2

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	*Salmonella*	> 4 *	> 16	4-128 (6)
		E. coli	> 8	> 16	
Ampicillin	Penicillin	*Salmonella*	> 8	> 8	1-32 (6)
		E. coli	> 8	> 8	
Azithromycin	Macrolide	*Salmonella*	NA	NA	2-64 (6)
		E. coli	NA	NA	
Cefotaxime	Cephalosporin	*Salmonella*	> 0,5	> 2	0,25-4 (5)
		E, coli	> 0,25	> 2	
Ceftazidime	Cephalosporin	*Salmonella*	> 2	> 4	0,25-8 (6)
		E, coli	> 0,5	> 4	
Chloramphenicol	Phenicol	*Salmonella*	> 16	> 8	8-64 (4)
		E, coli	> 16	> 8	
Ciprofloxacin	Fluoroquinolone	*Salmonella*	> 0,06	> 0,06	0,015-8 (10)
		E, coli	> 0,06	> 0,5	
Colistin	Polymyxin	*Salmonella*	NA	> 2	1-16 (5)
		E, coli	> 2	> 2	
Gentamicin	Aminoglycoside	*Salmonella*	> 2	> 4	0,5-16 (6)
		E, coli	> 2	> 4	
Meropenem	Carbapenem	*Salmonella*	> 0,125	> 8	0,03-16 (10)
		E, coli	> 0,125	> 8	
Nalidixic acid	Quinolone	*Salmonella*	> 8	NA	4-64 (5)
		E, coli	> 8	NA	
Sulfamethoxazole	Folate pathway antagonist	*Salmonella*	NA	NA	8-512 (7)
		E, coli	> 64	NA	
Tetracycline	Tetracycline	*Salmonella*	> 8	NA	2-32 (5)
		E, coli	> 8	NA	
Tigecycline	Glycylcycline	*Salmonella*	NA	NA	0,25-8 (6)
		E, coli	> 0,5	> 0,5	
Trimethoprim	Folate pathway antagonist	*Salmonella*	> 2	> 4	0,25-16 (7)
		E, coli	> 2	> 4	

NA: not available.
* tentative EUCAST threshold

Table 3

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	*C. jejuni*	> 16	NA	2-64 (6)
		C. coli	> 16	NA	
Ciprofloxacin	Fluoroquinolone	*C. jejuni*	> 0,5	> 0,5	0,12-32 (9)
		C. coli	> 0,5	> 0,5	
Ertapenem	Carbapenem	*C. jejuni*	NA	NA	0,125-4 (6)
		C. coli	NA	NA	
Erythromycin	Macrolide	*C. jejuni*	> 4	> 4	1-512 (10)
		C. coli	> 8	> 8	
Gentamicin	Aminoglycoside	*C. jejuni*	> 2	NA	0,25-16 (7)
		C. coli	> 2	NA	
Tetracycline	Tetracycline	*C. jejuni*	> 1	> 2	0,5-64 (8)
		C. coli	> 2	> 2	

NA: not available

Table 4

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	*E. faecalis*	> 4	> 8	0,5-64 (8)
		E. faecium	> 4	> 8	
Chloramphenicol	Phenicol	*E. faecalis*	> 32	NA	4-128 (6)
		E. faecium	> 32	NA	
Ciprofloxacin	Fluoroquinolone	*E. faecalis*	> 4	> 4	0,12-16 (8)
		E. faecium	> 4	> 4	
Daptomycin	Lipopeptide	*E. faecalis*	> 4	NA	0,25-32 (8)
		E. faecium	> 8	NA	
Erythromycin	Macrolide	*E. faecalis*	> 4	NA	1-128 (8)
		E. faecium	> 4	NA	
Gentamicin	Aminoglycoside	*E. faecalis*	> 64	NA	8-1 024 (8)
		E. faecium	> 32	NA	
Linezolid	Oxazolidinone	*E. faecalis*	> 4	> 4	0,5-64 (8)
		E. faecium	> 4	> 4	

Antimicrobial	Class of antimicrobial	Species	Interpretative thresholds of AMR (mg/L)		Range of concentrations (mg/L) (No of wells in brackets)
			ECOFF	Clinical breakpoint	
Quinupristin/ Dalfopristin	Streptogramin	*E. faecalis*	NA	NA	0,5-64 (8)
		E. faecium	NA	> 4	
Teicoplanin	Glycopeptide	*E. faecalis*	> 2	> 2	0,5-64 (8)
		E. faecium	> 2	> 2	
Tetracycline	Tetracycline	*E. faecalis*	> 4	NA	1-128 (8)
		E. faecium	> 4	NA	
Tigecycline	Glycylcycline	*E. faecalis*	> 0,25	> 0,25	0,03-4 (8)
		E. faecium	> 0,25	> 0,25	
Vancomycin	Glycopeptide	*E. faecalis*	> 4	> 4	1-128 (8)
		E. faecium	> 4	> 4	

NA: not available

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

5.1. *Methods for detection of presumptive ESBL- or AmpC- 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 fresh meat samples collected in accordance with point 1(d), the laboratories referred to in Article 3(2) shall use detection methods detailed in the protocols of the EURL for AMR ([4]).

All presumptive ESBL- or AmpC- 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 2 and Table 5 respectively.

Table 5

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	*Salmonella*	NA	> 4	0,06-32 (10)
		E. coli	> 0,125	> 4	
Cefotaxime	Cephalosporin	*Salmonella*	> 0,5	> 2	0,25-64 (9)
		E. coli	> 0,25	> 2	
Cefotaxime + clavulanic acid	Cephalosporin/ beta-lactamase inhibitor combination	*Salmonella*	NA	NA	0,06-64 (11)
		E. coli	> 0,25	NA	
Cefoxitin	Cephamycin	*Salmonella*	> 8	NA	0,5-64 (8)
		E. coli	> 8	NA	

([4]) https://www.eurl-ar.eu/protocols.aspx

Antimicrobial	Class of antimicrobial	Species	Interpretative thresholds of AMR (mg/L)		Range of concentrations (mg/L) (No of wells in brackets)
			ECOFF	Clinical breakpoint	
Ceftazidime	Cephalosporin	*Salmonella*	> 2	> 4	0,25-128 (10)
		E. coli	> 0,5	> 4	
Ceftazidime + clavulanic acid	Cephalosporin// beta-lactamase inhibitor combination	*Salmonella*	NA	NA	0,125-128 (11)
		E. coli	> 0,5	NA	
Ertapenem	Carbapenem	*Salmonella*	NA	> 0,5	0,015-2 (8)
		E. coli	NA	> 0,5	
Imipenem	Carbapenem	*Salmonella*	> 1	> 4	0,12-16 (8)
		E. coli	> 0,5	> 4	
Meropenem	Carbapenem	*Salmonella*	> 0,125	> 8	0,03-16 (10)
		E. coli	> 0,125	> 8	
Temocillin	Penicillin	*Salmonella*	> NA	NA	0,5-128 (9)
		E. coli	> 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- or AmpC-producing *E. coli* compared to the total *E. coli* isolates present in a sample. 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 protocols of the EURL for AMR ([5]).

6. **Alternative method**

Member States may decide to authorise the use of Whole Genome Sequencing ('WGS') as an alternative method to broth micro dilution using the testing panels of antimicrobial substances of Tables 2 and 5 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 method to broth micro dilution using the testing panel of antimicrobial substances of Table 5 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 protocols of the EURL for AMR ([6]).

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

The Member States shall ensure participation of the laboratories referred to in Article 3(2) to a quality assurance system including proficiency testing set up at either national or Union level, to target species identification, subtyping and antimicrobial susceptibility testing of the bacteria collected for the harmonised monitoring of AMR.

Resistant isolates shall be stored by the laboratories at a temperature of – 80 °C for a minimum period of five years. Other temperatures of storage may be used provided that they ensure viability and absence of changes in strain properties.

When deemed scientifically relevant by EFSA and the EURL for AMR, the laboratories referred to in Article 3(2) shall send for a confirmatory testing to the EURL for AMR any isolate tested in accordance with points 4, 5 and 6.

([5]) https://www.eurl-ar.eu/protocols.aspx
([6]) 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 shall 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.

Where Member States decide to report to EFSA data collected on a voluntary basis, these data shall be reported separately from data whose collection is compulsory.

2. **Reporting dataset**

2.1. *Reporting antimicrobial susceptibility testing results*

The following information shall be included for each individual isolate:

— Unique identifier or code of the isolate

— Bacterial species

— Serovar (for *Salmonella* spp.)

— Food-producing animal population or food category

— Stage of sampling

— Type of sample

— Trade Control and Expert System (TRACES) code of the border control post (for testing of imported meat only)

— Common Health Entry Document (CHED) reference of the consignment (for testing of imported meat only)

— Country of origin of the consignment (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 WGS testing results*

The following information shall be included for each individual isolate:

— Unique identifier or code of the isolate

— Bacterial species

— Food-producing animal population or food category
— Stage of sampling
— Type of sample
— TRACES code of the border control post (for testing of imported meat only)
— CHED reference of the consignment (for testing of imported meat only)
— Country of origin of the consignment (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
— Sequencing technology used
— Library preparation used