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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)

(OJ L 387, 19.11.2020, p. 8)

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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);

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(f) methicillin-resistant *Staphylococcus aureus* (MRSA).

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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;

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(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 ([1]);

(b) the definitions laid down in Commission Regulation (EC) No 2073/2005 ([2]);

(c) the definitions laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council ([3]);

(d) the definitions laid down in Regulation (EC) No 2160/2003 of the European Parliament and of the Council ([4]);

(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 ([5]);

(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.

([1]) 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).

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

([3]) 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).

([4]) 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).

([5]) 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).

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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.

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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 of this Article, in accordance with the technical requirements set out in Part A, point 4, of the Annex;

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

(c) the specific monitoring of MRSA in accordance with the technical requirements set out in Part A, point 5a, of the Annex;

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

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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.

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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.

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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;

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(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.

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(f) MRSA isolates obtained from nasal samples taken at slaughter from fattening pigs.

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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:

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(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 except for the monitoring of MRSA in fattening pigs which shall not be carried out in the years 2023 and 2027.

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(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**

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3.1. *At slaughterhouse level*

(a) Sampling design:

When designing their sampling plan at slaughterhouse level for caecal content, Member States shall take into account EFSA technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria ([1]).

When designing their sampling plan at slaughterhouse level for nasal samples in fattening pigs, Member States shall take into account EFSA technical specifications for a baseline survey on the prevalence of methicillin resistant *Staphylococcus aureus* (MRSA) in pigs ([2]).

Member States shall ensure a proportionate stratified sampling of samples 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 shall be the flock. The epidemiological unit for fattening pigs and bovine animals under one year of age shall be the slaughter batch.

Only one caecal sample from the same epidemiological unit shall be taken per year. Each caecal sample shall be taken from one carcass randomly selected from the epidemiological unit. However, for broilers, each caecal sample shall be derived from ten carcasses randomly selected from the epidemiological unit.

Twenty nasal samples from twenty different pigs randomly selected from the same epidemiological unit shall be taken per year. These samples shall be pooled into four composite groups of five samples. If the epidemiological unit comprises less than twenty pigs, all the pigs of this epidemiological unit shall be sampled, and the resulting samples shall be pooled as evenly as possible to form the four composite groups of samples. The samples shall be taken after stunning of the pigs but before scalding of the carcasses.

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

(b) *Sampling 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 point 1(a)(ii) and (iii), point 1(b), and point 1(c)(i) to (iv) by accounting for the estimated prevalence of the bacterial species monitored in the animal population considered.

([1]) https://www.efsa.europa.eu/en/efsajournal/pub/6364
([2]) https://www.efsa.europa.eu/en/efsajournal/pub/7620

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By way of derogation from the first paragraph of this point, 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.

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 from that requirement, 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.

Member States shall sample annually enough epidemiological units from the animal population referred to in point 1(f) to achieve an accurate estimation of the prevalence of MRSA in their domestic population of fattening pigs. To this end, they shall use the calculation formulae for the number of slaughter batches to be sampled as referred to in EFSA technical specifications for a baseline survey on the prevalence of methicillin resistant *Staphylococcus aureus* (MRSA) in pigs ([3]).

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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 ([4]).

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]) https://www.efsa.europa.eu/en/efsajournal/pub/7620
([4]) See footnote 1.

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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 ([5]).

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 %

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,

([5]) See footnote 1.

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— 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).

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For MRSA:

— Up to 208 isolates obtained from samples referred to in point 1(f) and confirmed in accordance with point 5a.

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

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Member States shall use the epidemiological cut-off values and the concentration ranges set out in Tables 2, 3, 4 and 4a to determine the antimicrobial susceptibility of *Salmonella* spp., *C. coli*, *C. jejuni,* indicator commensal *E. coli, E. faecalis, E. faecium* and MRSA.

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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.

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For the specific monitoring of MRSA, Member States shall use the methods referred to in point 5a.

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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 ([6])	> 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	

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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	0,25-8 (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.
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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	

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Antimicrobial	Class of antimicrobial	Species	Interpretative thresholds of AMR (mg/L)		Range of concentrations (mg/L) (No of wells in brackets)
			ECOFF	Clinical breakpoint	
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	
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

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Table 4a

Panel of antimicrobial substances to be included in AMR monitoring, EUCAST thresholds for resistance and concentration ranges to be tested in *Staphylococcus aureus*

Antimicrobial	Class of antimicrobial	Interpretative thresholds of AMR (mg/L)		Range of concentrations (mg/L) (No of wells in brackets)
		ECOFF 2022	Clinical breakpoint 2022	
Cefoxitin	Cephamycin	>4	>4*	0,5-16 (6)
Chloramphenicol	Phenicol	>16	>8	4-64 (5)

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Antimicrobial	Class of antimicrobial	Interpretative thresholds of AMR (mg/L)		Range of concentrations (mg/L) (No of wells in brackets)
		ECOFF 2022	Clinical breakpoint 2022	
Ciprofloxacin	Fluoroquinolone	>2	>1	0,25-8 (6)
Clindamycin	Lincosamide	>0,25	>0,25	0,125-4 (6)
Erythromycin	Macrolide	>1	>1	0,25-8 (6)
Gentamicin	Aminoglycoside	>2	>2	0,5-16 (6)
Linezolid	Oxazolidinone	>4	>4	1-8 (4)
Mupirocin	Carboxylic acid	>1	NA	0,5-2 + 256 (4)
Quinupristin/Dalfopristin	Streptogramin	>1	>2	0,5-4 (4)
Sulfamethoxazole	Folate pathway antagonist	>128	NA	64-512 (4)
Tetracycline	Tetracycline	>1	>2	0,5-16 (6)
Tiamulin	Pleuromutilin	>2	NA	0,5-4 (4)
Trimethoprim	Folate pathway antagonist	>2	>4	1-16 (5)
Vancomycin	Glycopeptide	>2	>2	1-8 (4)

NA : not available, *: Not given as a clinical breakpoint by EUCAST

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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 ([7]).

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.

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

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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	
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

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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 ([8]).

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5a. **Specific monitoring of MRSA**

In order to detect MRSA in nasal samples collected in accordance with point 1(f), the laboratories referred to in Article 3(2) shall use isolation and PCR-based ([9]) confirmatory methods as referred to in EFSA technical specifications for a baseline survey on the prevalence of methicillin resistant *Staphylococcus aureus* (MRSA) in pigs ([10]) and detailed in the protocols of the EURL for AMR ([11]).

For confirming presumptive MRSA isolates, the laboratories may decide to replace the PCR-based confirmatory method by a WGS method implemented in accordance with the protocols of the EURL for AMR ([12]).

All confirmed MRSA isolates, with a maximum of 208 isolates, identified through the PCR-based or WGS methods shall be tested with the panel of antimicrobial substances in accordance with Table 4a. No more than one isolate per epidemiological unit shall be tested. MRSA isolates which have been confirmed by the PCR-based method and do not belong to the clonal complex 398 shall be tested by the WGS method implemented in accordance with the protocols of the EURL for AMR ([13]). Twenty percent of MRSA isolates confirmed by the PCR-based method and belonging to the clonal complex 398 shall be tested by the WGS method, with a maximum of twenty isolates tested.

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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 ([14]).

([8]) https://www.eurl-ar.eu/protocols.aspx
([9]) Method based on Polymerase Chain Reaction (PCR) assays
([10]) https://www.efsa.europa.eu/en/efsajournal/pub/7620
([11]) https://www.eurl-ar.eu/protocols.aspx
([12]) https://www.eurl-ar.eu/protocols.aspx
([13]) https://www.eurl-ar.eu/protocols.aspx
([14]) https://www.eurl-ar.eu/protocols.aspx

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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, sub-typing 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.

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

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— 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