Commission Implementing Decision of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria (notified under document C(2013) 7145) (Text with EEA relevance) (2013/652/EU)

COMMISSION IMPLEMENTING DECISION

of 12 November 2013

on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria

(notified under document C(2013) 7145)

(Text with EEA relevance)

(2013/652/EU)

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 Article 7(3) and the fourth subparagraph of Article 9(1) thereof,

Whereas:

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

(3) In the Communication of 15 November 2011 from the Commission to the European Parliament and the Council — Action Plan against the rising threats from Antimicrobial Resistance[(2)], the Commission proposes to put in place a five-year action plan to fight against AMR based on 12 key actions, including strengthened surveillance systems on AMR.

(4) In the Council Conclusions of 22 June 2012 on the impact of antimicrobial resistance in the human health sector and in the veterinary sector — a One Health Perspective[(3)], that Institution calls upon the Commission to follow up on its Communication of 15 November 2011 through concrete initiatives to implement the 12 actions set out in that Communication, and to collaborate closely with the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA) in strengthening the assessment and evaluation of the occurrence of AMR in humans, in animals and in food in the Union.

(5) During its plenary sitting of 11 December 2012, the Parliament adopted a Report on the Microbial Challenge — Rising threats from Antimicrobial Resistance[4]. In that Report, the Parliament welcomes the Commission's five-year action plan on tackling AMR and considers that the measures recommended in it need to be implemented as soon as possible. The Parliament, in particular, calls on the Commission and the Member States to seek greater cooperation and coordination on the early detection, alert and coordinated response procedures regarding pathogenic antimicrobial resistant bacteria in humans, animals, fish and foodstuffs in order to continuously monitor the extent and growth of AMR.

(6) Under its Joint FAO/WHO Food Standards Programme, the Codex Alimentarius Commission adopted, during its 34th session in Geneva, the Guidelines for the Risk Analysis of Foodborne Antimicrobial Resistance[5] which highlight AMR as a major global public health concern and a food safety issue. The use of antimicrobial agents in food-producing animals and crops is a potentially important risk factor for the selection and dissemination of AMR microorganisms and determinants from animals and food crops to humans via the consumption of food.

(7) Those Codex Guidelines conclude, inter alia, that surveillance programmes on the prevalence of foodborne AMR provide information that is useful for all parts of the AMR risk analysis process. The methodology of surveillance programmes should be internationally harmonised as far as possible. The use of standardised and validated antimicrobial susceptibility testing methods and harmonised interpretive criteria are essential to ensure that data are comparable.

(8) The Terrestrial Animal Health Code of the World Animal Health Organisation (OIE)[6] in its Chapter 6.7 on 'Harmonisation of National AMR Surveillance and Monitoring programmes', underlines the need for the surveillance and monitoring of AMR in order to assess and determine the trends and sources of AMR in bacteria, to detect the emergence of new AMR mechanisms, to provide the data necessary for conducting risk analyses that are relevant to animal and human health, to provide a basis for policy recommendations for animal and human health and to provide information for evaluating antimicrobial prescribing practices and for prudent use recommendations.

(9) On 9 July 2008, the EFSA adopted a Scientific Opinion on Foodborne antimicrobial resistance as a biological hazard[7]. On 28 October 2009, the ECDC, the EFSA, the EMA and the Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published a joint scientific opinion on antimicrobial resistance focused on infections transmitted to humans from animals and food (zoonoses)[8]. On 5 March 2009, the EFSA adopted a scientific opinion on the assessment of the public health significance of meticillin resistant *Staphylococcus aureus* (MRSA)[9]. On 7 July 2011, the EFSA adopted a scientific opinion on the public health risks of bacterial strains producing extended-spectrum β-lactamases (ESBL) and/or AmpC β-lactamases (AmpC) in food and food-producing animals[10]. On 3 October 2011, the EFSA adopted a technical report on EFSA approaches to risk assessment in the area of antimicrobial resistance, with an emphasis on commensal microorganisms[11]. The main conclusion of all those opinions and reports is that, in view of the increasing public health concern

regarding AMR, the use of harmonised methods and epidemiological cut-off values is necessary to ensure the comparability of data over time at Member State level, and also to facilitate the comparison of the occurrence of AMR between Member States.

(10) On 14 June 2012, the EFSA published a scientific report on technical specifications on the harmonised monitoring and reporting of antimicrobial resistance in *Salmonella*, *Campylobacter* and indicator commensal *Escherichia coli* and *Enterococcus* spp. bacteria transmitted through food[(12)]. On 5 October 2012, the EFSA published a scientific report on technical specifications on the harmonised monitoring and reporting of antimicrobial resistance in methicillin-resistant *Staphylococcus aureus* (MRSA) in food-producing animals and food[(13)]. Those scientific reports recommend detailed rules for harmonised monitoring and reporting on the prevalence of resistant microorganisms in food-producing animals and food, in particular as regards the microorganisms to be included, the origin of the isolates of the microorganisms, the number of isolates to be tested, the antimicrobial susceptibility tests to be used, the specific monitoring of MRSA and ESBL- or AmpC-producing bacteria and the collection and reporting of the data. The involvement of the ECDC in this work will ensure the comparison between the data of the food-producing animals and food sector and the data of the human sector.

(11) In accordance with the findings of those reports and opinions, when defining the combinations of bacterial species, food-producing animal species and food products to be included in the harmonised monitoring and reporting of AMR, it is important to prioritise the most relevant from a public health perspective. In order to minimise the burden, the monitoring should be derived as much as possible from biological samples or isolates collected in the framework of national control programmes that have already been established.

(12) Regulation (EC) No 2160/2003 of the European Parliament and of the Council[(14)] provides that Member States are to establish national control programmes which are to include sampling for the testing of *Salmonella* spp. at different stages of the food chain. Commission Regulation (EC) No 2073/2005[(15)] lays down the microbiological criteria for certain microorganisms and the rules to be complied with by food business operators. In particular the competent authority is to ensure that food businesses operators comply with the rules and criteria laid down in that Regulation in accordance with Regulation (EC) No 882/2004 of the European Parliament and of the Council[(16)]. The monitoring of AMR in *Salmonella* spp. should be focused on isolates obtained from the national control programmes and from the testing and verification of compliance set up by the competent authority in accordance with Article 1 of Regulation (EC) No 2073/2005.

(13) Commission Decision 2007/407/EC[(17)] lays down detailed rules for monitoring AMR to be carried out by Member States, covering *Salmonella* spp. in fowl, turkeys and slaughter pigs for the period from 2007 to 2012. Such harmonised monitoring should be continued to follow the evolution of trends and be extended to AMR in other pathogens and commensals in line with the increasing public health concern on the role of these microorganisms in the overall risk of AMR referred to in scientific opinions. Monitoring and reporting in accordance to Article 7 and 9 of Directive 2003/99/EC should therefore be in compliance with provisions and technical requirements

on the harmonised monitoring and reporting of AMR which takes into account the recommendations set out in the EFSA reports.

(14) For the sake of clarity of Union legislation, Decision 2007/407/EC should be repealed.

(15) In order to allow Member States to organise themselves and to facilitate the planning of the monitoring and reporting provided for in this Decision, it should apply from 1 January 2014.

(16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

1 This Decision lays down detailed rules for the harmonised 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.

That monitoring and reporting shall cover the following bacteria obtained from samples from certain food-producing animal populations and certain food:

a *Salmonella* spp.;
b *Campylobacter jejuni* and *Campylobacter coli* (*C. jejuni* and *C. coli*);
c Indicator commensal *Escherichia coli* (*E. coli*);
d Indicator commensal *Enterococcus faecalis* and *Enterococcus faecium* (*E. faecalis* and *E. faecium*).

2 This Decision lays down specific requirements for the harmonised monitoring and reporting of the *Salmonella* spp., and *E. coli* producing the following enzymes in certain food-producing animal populations and in certain food:

a Extended-Spectrum β-Lactamases (ESBL);
b AmpC β-Lactamases (AmpC);
c Carbapenemases.

Article 2

Sampling framework and collection of isolates by Member States

1 Member States shall ensure the sampling for the monitoring of AMR in accordance with the technical requirements set out in Part A of the Annex.

2 Member States shall collect representative isolates of the following bacteria in accordance with the technical requirements set out in the part A of the Annex:

a *Salmonella* spp.;
b *C. jejuni*;
c Indicator commensal *E. coli*; and
d ESBL- or AmpC- or carbapenemase-producing *Salmonella* spp. and *E. coli*.

3 Member States may collect representative isolates of the following bacteria provided that they do so in accordance with the technical requirements set out in Part A of the Annex:

a *C. coli*;

b Indicator commensal *E. faecalis* and *E. faecium.*

Article 3

Isolates of *Salmonella* spp. obtained by food business operators

Where, due to a low bacterial prevalence or a low number of epidemiological units in a Member State the minimum number of *Salmonella* spp. isolates collected by the competent authority during official controls in accordance with point 1(a) of Part A of the Annex is not sufficient to achieve the minimal required number of isolates to be tested for antimicrobial susceptibility, the competent authority may use isolates obtained by food business operators provided that such isolates have been obtained by the food businesses operator in accordance with the following provisions:

(a) the national control programme provided for in Article 5 of Regulation (EC) No 2160/2003;

(b) the process hygiene criteria set out in points 2.1.3, 2.1.4 and 2.1.5 of Chapter 2 of Annex I to Regulation (EC) No 2073/2005.

Article 4

Analysis by national reference laboratories

1 National reference laboratories for AMR shall perform the following analysis:

a the antimicrobial susceptibility testing of the isolates set out in points 2 and 3 of Part A of the Annex;

b the specific monitoring of ESBL- or AmpC- or carbapenemase-producing *Salmonella* spp. and *E. coli* set out in point 4 of Part A of the Annex.

2 The competent authority may designate laboratories other than the national reference laboratory for AMR in accordance with Article 12 of Regulation (EC) No 882/2004 to perform the analysis provided for in paragraph 1.

Article 5

Assessment and reporting

Member States shall assess the results of the AMR monitoring provided for in Articles 2 and 3 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 6

Publication and confidentiality of the data

The European Food Safety Authority shall publish in accordance with Article 9(2) of Directive 2003/99/EC the national isolate-based quantitative antimicrobial resistance data and results of the analyses reported in accordance to Article 4.

Article 7

Repeal

Decision 2007/407/EC is hereby repealed.

Article 8

Application

This Decision shall apply from 1 January 2014.

Article 9

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 12 November 2013.

For the Commission

Tonio BORG

Member of the Commission

ANNEX

TECHNICAL REQUIREMENTS

PART A

SAMPLING FRAMEWORK AND ANALYSIS

1. Origin of isolates

Member States shall collect representative isolates for monitoring AMR from at least each of the following animal populations and food categories:

(a) *Salmonella* spp. isolates from:

- (i) each population of laying hens, broilers and fattening turkeys sampled in the framework of the national control programmes, established in accordance with Article 5(1) of Regulation (EC) No 2160/2003;
- (ii) carcases of both broilers and fattening turkeys sampled for testing and verification of compliance, in accordance with point 2.1.5 of Chapter 2 of Annex I to Regulation (EC) No 2073/2005;
- (iii) carcases of fattening pigs sampled for testing and verification of compliance, in accordance with point 2.1.4 of Chapter 2 of Annex I to Regulation (EC) No 2073/2005;
- (iv) carcases of bovines under one year of age where the production of meat of those bovines in the Member State is more than 10 000 tonnes slaughtered per year sampled for testing and verification of compliance, in accordance with point 2.1.3 of Chapter 2 of Annex I to Regulation (EC) No 2073/2005.

(b) *C. jejuni* isolates from caecal samples gathered at slaughter from broilers and from fattening turkeys where the production of turkey meat in the Member State is more than 10 000 tonnes slaughtered per year.

(c) Indicator commensal *E. coli* isolates from:

- (i) caecal samples gathered at slaughter from broilers and from fattening turkeys where the production of turkey meat in the Member State is more than 10 000 tonnes slaughtered per year;
- (ii) caecal samples gathered at slaughter from fattening pigs and bovines under one year of age where the production of meat of those bovines in the Member State is more than 10 000 tonnes slaughtered per year.

(d) ESBL- or AmpC- or carbapenemase-producing *E. coli* from:

- (i) caecal samples gathered at slaughter from broilers and from fattening turkeys where the production of turkey meat in the Member State is more than 10 000 tonnes slaughtered per year;
- (ii) caecal samples gathered at slaughter from fattening pigs and bovines under one year of age where the production of meat of those bovines in the Member State is more than 10 000 tonnes slaughtered per year;
- (iii) samples of fresh meat of broilers, pig meat and bovine meat gathered at retail.

(e) Where a Member State decides to test *C. coli* in accordance with Article 2(3)(a), isolates from:

(i) caecal samples gathered at slaughter from broilers;

(ii) caecal samples gathered at slaughter from fattening pigs.

(f) Where a Member State decides to test *E. faecalis* and *E. faecium* in accordance with Article 2(3)(b), isolates from:

(i) caecal samples gathered at slaughter from broilers and from fattening turkeys where the production of turkey meat in the Member State is more than 10 000 tonnes slaughtered per year;

(ii) caecal samples gathered at slaughter from fattening pigs and bovines under one year of age where the production of meat of those bovines in the Member State is more than 10 000 tonnes slaughtered per year.

Isolates obtained by the Member State from an origin other than those referred to in points (a) to (f), may be tested for AMR by the competent authority on a voluntary basis and kept separately when reported in accordance with point 2 of Part B of the Annex. However, when carrying out such testing for AMR, the specific technical requirements of points 3, 4 and 5 shall apply.

2. Sampling frequency, size and design

2.1. *Sampling frequency*

Member States shall carry out every two years the sampling, the collection and the antimicrobial susceptibility testing provided for in Article 2 to 4 of each combination of bacterial species and type of sample of animal populations or food categories listed in point 1 of this Part and the specific monitoring of ESBL- or AmpC- or carbapenemase-producing *Salmonella* spp. and *E. coli* in accordance with point 4 of this Part in accordance with the following rotation system:

(a) In the years 2014, 2016, 2018 and 2020 for laying hens, broilers and fresh meat thereof, and fattening turkeys. However, the specific monitoring of ESBL- or AmpC- or carbapenemase-producing indicator commensal *E. coli* in accordance with point 4.1 shall not be mandatory in the year 2014;

(b) In the years 2015, 2017 and 2019, for pigs, bovines under one year of age, pig meat and bovine meat.

2.2. *Sample size*

Member States shall test 170 isolates for antimicrobial susceptibility testing for each combination of bacterial species and type of sample of animal population or food category listed in point 1(a), (b), (c), (e) and (f). However, in Member States with a production of less than 100 000 tonnes of poultry meat slaughtered per year and less than 100 000 tonnes of pig meat slaughtered per year[18], they shall test 85 isolates instead of 170 isolates for each corresponding specific combination.

In those Member States where, in any given year, a higher number of isolates for some of the combinations of bacterial species and type of sample of animal population or food category listed in point 1(a), (b), (c), (e) and (f) is available, all isolates or a representative random selection equal to or greater than the number of isolates required in accordance with the first paragraph, shall be included in the antimicrobial susceptibility testing.

In those Member States where, due to a low bacterial prevalence or low number of epidemiological units, in any given year, the number of isolates required in accordance with

the first paragraph for some of the combinations of bacterial species and type of sample of animal population or food category listed in point 1(a), (b), (c), (e) and (f), cannot be achieved, all available isolates at the end of the monitoring period shall be included in the antimicrobial susceptibility testing.

For the specific monitoring of ESBL- or AmpC- or carbapenemase-producing indicator commensal *E. coli* set out in point 4.1, Member States shall analyse 300 samples of each of the animal population and food category, listed in point 1(d). However, in Member States with a production of less than 100 000 tonnes of poultry meat slaughtered per year, less than 100 000 tonnes of pig meat slaughtered per year and less than 50 000 tonnes bovine meat slaughtered per year[19] the Member States shall analyse 150 samples instead of 300 samples for each corresponding specific combination.

2.3. *Sampling design*

Isolates which are tested for antimicrobial susceptibility as provided for in Article 2 shall be obtained from monitoring programmes, based on randomised sampling design. The bacterial isolates referred to in Article 2 must originate from randomly selected epidemiological units or randomly selected within the slaughterhouses. Where diseased animals are sampled, the result of the antimicrobial susceptibility testing shall be kept separately when reported in accordance with point 2 of Part B.

The competent authority shall ensure the randomisation of the sampling scheme and its correct implementation.

In the case of sampling at slaughterhouses as provided for in point 1 of Part A, sampling shall be performed at slaughterhouses processing at least 60 % of the specific domestic animal population in the Member State, starting with the slaughterhouses of largest throughput.

Not more than one isolate per bacterial species from the same epidemiological unit per year shall be included in the monitoring provided for this Decision. The epidemiological unit for laying hens, broilers, and fattening turkeys shall be the flock. For fattening pigs and bovines under one year of age, the epidemiological unit shall be the holding.

2.3.1. *Representative sampling of samples at slaughter*

The random sampling plan shall be stratified per slaughterhouse by allocating the number of samples from domestically produced animals collected per slaughterhouse proportionally to the annual throughput of the slaughterhouse.

The collected samples at slaughter shall be evenly distributed over each month of the year to enable the different seasons to be covered.

Only one representative sample of caecal content per epidemiological unit, derived either from a unique carcass or from a number of carcasses, shall be gathered to account for clustering. The sampling shall otherwise be based on a random selection regarding sampling days each month and which batches are to be sampled on a selected sampling day.

The number of biological samples to be collected in accordance with point 1(a), (b), (c), (e) and (f) of Part A shall be determined in order to achieve the required number of isolates by accounting for the prevalence of the bacteria species monitored.

2.3.2. *Collection of representative Salmonella spp. isolates collected in the framework of the national control programmes for Salmonella spp. in relevant animal populations and in the framework of Regulation (EC) No 2073/2005*

Antimicrobial susceptibility testing shall be carried out for no more than one isolate per *Salmonella* serovar from the same epidemiological unit per year.

Where the number of *Salmonella* isolates yearly available per animal population in the Member State is higher than the number of isolates required in accordance with point 2.2, a random selection of at least 170 or 85 isolates shall be performed from the collection of yearly available isolates in the Member State, in a way that ensures geographical representativeness and an even distribution of the date of sampling over the year. Conversely, in the case of a low prevalence, all the *Salmonella* isolates available shall be tested for susceptibility.

2.3.3. *Collection of samples at retail*

Member States shall collect at retail random samples of fresh meat of broilers, pig meat and bovine meat without pre-selecting samples based on the origin of the food.

3. Antimicrobials for susceptibility testing, epidemiological cut-off values and concentration ranges to be used for antimicrobial susceptibility testing of the isolates

Member States shall test the antimicrobials and interpret the results using the epidemiological cut-off values and the concentration ranges that are set out in Tables 1, 2 and 3, to determine the susceptibility of *Salmonella* spp., *C. coli, C. jejuni*, indicator commensal *E. coli, E. faecalis* and *E. faecium.*

Dilution methods shall be performed according to the methods described by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) and the Clinical and Laboratory Standards Institute (CLSI), accepted as the international reference method (ISO standard 20776-1:2006).

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	Species	Interpretative thresholds of AMR(mg/L)		Range of concentrations (mg/L)(No of wells in brackets)
		ECOFF[a]	Clinical breakpoint[b]	
Ampicillin	*Salmonella*	> 8	> 8	1-64 (7)
	E. coli	> 8	> 8	
Cefotaxime	*Salmonella*	> 0,5	> 2	0,25-4 (5)
	E. coli	> 0,25	> 2	
Ceftazidime	*Salmonella*	> 2	> 4	0,5-8 (5)
	E. coli	> 0,5	> 4	
Meropenem	*Salmonella*	> 0,125	> 8	0,03-16 (10)

a EUCAST epidemiological cut-off values.

b EUCAST clinical resistance breakpoints.

c Data from EUCAST available for *Salmonella* Enteriditis, Typhimurium, Typhi and Paratyphi.

NA : not available.

	E. coli	> 0,125	> 8	
Nalidixic acid	*Salmonella*	> 16	NA	4-128 (6)
	E. coli	> 16	NA	
Ciprofloxacin	*Salmonella*	> 0,064	> 1	0,015-8 (10)
	E. coli	> 0,064	> 1	
Tetracycline	*Salmonella*	> 8	NA	2-64 (6)
	E. coli	> 8	NA	
Colistin	*Salmonella*	> 2	> 2	1-16 (5)
	E. coli	> 2	> 2	
Gentamicin	*Salmonella*	> 2	> 4	0,5-32 (7)
	E. coli	> 2	> 4	
Trimethoprim	*Salmonella*	> 2	> 4	0,25-32 (8)
	E. coli	> 2	> 4	
Sulfamethoxazole	*Salmonella*	NA	NA	8-1 024 (8)
	E. coli	> 64	NA	
Chloramphenicol	*Salmonella*	> 16	> 8	8-128 (5)
	E. coli	> 16	> 8	
Azithromycin	*Salmonella*	NA	NA	2-64 (6)
	E. coli	NA	NA	
Tigecycline	*Salmonella*	> 1[c]	> 2[c]	0,25-8 (6)
	E. coli	> 1	> 2	

a EUCAST epidemiological cut-off values.

b EUCAST clinical resistance breakpoints.

c Data from EUCAST available for *Salmonella* Enteriditis, Typhimurium, Typhi and Paratyphi.

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	**Species**	**Interpretative thresholds of AMR(mg/L)**		**Range of concentrations (mg/L)(No**
		ECOFF[a]	**Clinical breakpoint[b]**	

a EUCAST epidemiological cut-off values.

b EUCAST clinical resistance breakpoints.

c At a voluntary basis.

NA : not available.

				of wells in brackets)
Erythromycin	*C. jejuni*	> 4	> 4	1-128 (8)
	C. coli	> 8	> 8	
Ciprofloxacin	*C. jejuni*	> 0,5	> 0,5	0,12-16 (8)
	C. coli	> 0,5	> 0,5	
Tetracycline	*C. jejuni*	> 1	> 2	0,5-64 (8)
	C. coli	> 2	> 2	
Gentamicin	*C. jejuni*	> 2	NA	0,12-16 (8)
	C. coli	> 2	NA	
Nalidixic acid	*C. jejuni*	> 16	NA	1-64 (7)
	C. coli	> 16	NA	
Streptomycin[c]	*C. jejuni*	> 4	NA	0,25-16 (7)
	C. coli	> 4	NA	

a EUCAST epidemiological cut-off values.

b EUCAST clinical resistance breakpoints.

c At a voluntary basis.

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	**Species**	**Interpretative thresholds of AMR(mg/L)**		**Range of concentrations (mg/L)(No of wells in brackets)**
		ECOFF[a]	**Clinical breakpoint[b]**	
Gentamicin	*E. faecalis*	> 32	NA	8-1 024 (8)
	E. faecium	> 32	NA	
Chloramphenicol	*E. faecalis*	> 32	NA	4-128 (6)
	E. faecium	> 32	NA	
Ampicillin	*E. faecalis*	> 4	> 8	0,5-64 (8)
	E. faecium	> 4	> 8	
Vancomycin	*E. faecalis*	> 4	> 4	1-128 (8)
	E. faecium	> 4	> 4	

a EUCAST epidemiological cut-off values.

b EUCAST clinical resistance breakpoints.

NA : not available.

Teicoplanin	*E. faecalis*	> 2	> 2	0,5-64 (8)
	E. faecium	> 2	> 2	
Erythromycin	*E. faecalis*	> 4	NA	1-128 (8)
	E. faecium	> 4	NA	
Quinupristin/ Dalfopristin	*E. faecalis*	NA	NA	0,5-64 (8)
	E. faecium	> 1	> 4	
Tetracycline	*E. faecalis*	> 4	NA	1-128 (8)
	E. faecium	> 4	NA	
Tigecycline	*E. faecalis*	> 0,25	> 0,5	0,03-4 (8)
	E. faecium	> 0,25	> 0,5	
Linezolid	*E. faecalis*	> 4	> 4	0,5-64 (8)
	E. faecium	> 4	> 4	
Daptomycin	*E. faecalis*	> 4	NA	0,25-32 (8)
	E. faecium	> 4	NA	
Ciprofloxacin	*E. faecalis*	> 4	NA	0,12-16 (8)
	E. faecium	> 4	NA	

a EUCAST epidemiological cut-off values.

b EUCAST clinical resistance breakpoints.

NA : not available.

4. Specific monitoring of ESBL- or AmpC- or carbapenemase-producing *Salmonella* and *E. coli*

4.1. *Method for detection of ESBL- or AmpC- or carbapenemase-producing E. coli in broilers, fattening turkeys, fattening pigs, bovines under one year of age and fresh meat of broilers, pig meat and bovine meat*

For the purpose of estimating the proportion of samples containing ESBL- or AmpC- or carbapenemase-producing *E. coli* amongst the caecal samples collected from broilers, fattening turkeys, fattening pigs, bovines under one year of age, fresh meat of broilers, pig meat and bovine meat in accordance with point 1(d) of this Part, the following method shall apply.

For the detection of ESBL- or AmpC-producing *E. coli* the method shall start by a pre-enrichment step, followed by inoculation on McConkey agar containing a third generation cephalosporin in a selective concentration according to the most recent version of the detailed protocol for standardisation of the European Union Reference Laboratory for Antimicrobial Resistance[(20)]. The microbial species *E. coli* shall be identified using an appropriated method.

The Member State may decide, based on the epidemiological circumstances, to test in parallel an additional selective plate that inhibits for the growth of AmpC-producing *E. coli* to facilitate the specific detection of ESBL-producing *E. coli*. When using this possibility, the results of the additional selective plate that inhibits for growth of AmpC-producing *E. coli* shall be kept separately when reported in accordance with point 2 of Part B.

Member States may decide to detect for carbapenemase-producing micro-organisms by using selective pre-enrichment and subsequent selective plating on carbapenem-containing media, according to the most recent version of the detailed protocol for standardisation of the European Union Reference Laboratory for AMR[(21)].

One presumptive ESBL- or AmpC- or carbapenemase-producing *E. coli* isolate obtained from each positive caecal sample and meat sample shall be tested on the first panel of antimicrobials in accordance with Table 1 and further submitted to extended susceptibility testing as set out in point 4.2 if they are resistant to cefotaxime or ceftazidime or meropenem based on the interpretative criteria (epidemiological cut-off values) listed in Table 1.

4.2. *Method for further characterisation and classification of Salmonella* spp. *and E. coli isolates showing resistance to third-generation cephalosporins or meropenem*

All presumptive ESBL- or AmpC- or carbapenemase-producing *E. coli* isolates identified through the selective plating described in point 4.1 as well as all those randomly selected isolates of *Salmonella* spp. and *E. coli* that after testing with the first panel of antimicrobials in accordance with Table 1, are resistant to cefotaxime or ceftazidime or meropenem, shall be further tested with a second panel of antimicrobial substances in accordance with Table 4. This panel includes cefoxitin, cefepime and clavulanate synergy test in combination with cefotaxime and ceftazidime for detection of ESBL and AmpC production. In addition the second panel also contains imipenem, meropenem and ertapenem to phenotypically verify the presumptive carbapenemase-producers.

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 indicator commensal *E. coli* isolates resistant to cefotaxime or ceftazidime or meropenem — (Second panel)

Antimicrobial	Species	Interpretative thresholds of AMR(mg/L)		Range of concentrations (mg/L)(No of wells in brackets)
		ECOFF[a]	Clinical breakpoint[b]	
Cefoxitin	*Salmonella*	> 8	NA	0,5-64 (8)
	E. coli	> 8	NA	
Cefepime	*Salmonella*	NA	NA	0,06-32 (10)
	E. coli	> 0,125	> 4	
Cefotaxime + clavulanic acid[c]	*Salmonella*	NA[d]	NA[d]	0,06-64 (11)
	E. coli	NA[d]	NA[d]	

a EUCAST epidemiological cut-off values.

b EUCAST clinical resistance breakpoints.

c 4 mg/L clavulanic acid.

d The values shall be compared to the values of Cefotaxime and Ceftazidime and interpreted according to CLSI or EUCAST guidelines regarding synergy testing.

NA : not available.

Ceftazidime + clavulanic acid[c]	*Salmonella*	NA[d]	NA[d]	0,125-128 (11)
	E. coli	NA[d]	NA[d]	
Meropenem	*Salmonella*	> 0,125	> 8	0,03-16 (10)
	E. coli	> 0,125	> 8	
Temocillin	*Salmonella*	NA	NA	0,5-64 (8)
	E. coli	NA	NA	
Imipenem	*Salmonella*	> 1	> 8	0,12-16 (8)
	E. coli	> 0,5	> 8	
Ertapenem	*Salmonella*	> 0,06	> 1	0,015-2 (8)
	E. coli	> 0,06	> 1	
Cefotaxime	*Salmonella*	> 0.5	> 2	0,25-64 (9)
	E. coli	> 0,25	> 2	
Ceftazidime	*Salmonella*	> 2	> 4	0,25-128 (10)
	E. coli	> 0,5	> 4	

a EUCAST epidemiological cut-off values.

b EUCAST clinical resistance breakpoints.

c 4 mg/L clavulanic acid.

d The values shall be compared to the values of Cefotaxime and Ceftazidime and interpreted according to CLSI or EUCAST guidelines regarding synergy testing.

NA : not available.

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

Member States, especially the Member States which have detected a high prevalence of ESBL- or AmpC-producing *E. coli* by the detection method set out in point 4.1, may characterise the proportion of ESBL- or AmpC-producing *E. coli* within the whole *E. coli* population.

That shall be done by enumerating ESBL- or AmpC-producing *E. coli* and total *E. coli* present in a sample using dilution methods and subsequent plating onto selective media and non-selective media, according to the most recent version of the detailed protocol of the European Union Reference Laboratory for Antimicrobial Resistance[(22)].

5. **Quality control and storage of the isolates**

The laboratories designated by the competent authority to perform the antimicrobial susceptibility testing of the isolates included in the harmonised monitoring programme, shall be involved in a quality assurance system including proficiency test set up either at national or Union level, in identification, typing and susceptibility testing of the bacteria targeted by the harmonised monitoring of AMR.

Isolates shall 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.

PART B

REPORTING

1. General provisions for reporting of the data

Where AMR monitoring is performed by the competent authority from isolates obtained by a competent authority at other stages of the food chain than the ones referred to in point 1 of part A, but in accordance with the technical specifications referred to in points 3, 4 and 5 of part A, the results of this AMR monitoring shall be reported according to point 2 of this Part but they shall be kept separately reported and this will not change the number of isolates to be tested according to point 2 of Part A.

2. Information to be included for each individual sample

Reports shall be made including the information referred to in points 2.1 to 2.6 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 raw isolate-based data using the data dictionary and the electronic collection forms provided by EFSA[(23)].

2.1. *Overall description of the implementation of the AMR monitoring*

— Description of sampling designs, stratification and randomisation procedures per animal populations and food categories.

2.2. *General information*

— Identifier or code of the isolate
— Bacterial species
— Serovar (for *Salmonella* spp.)
— Phage type of *Salmonella* Enteriditis and *Salmonella* Typhimurium (optional)

2.3. *Specific information with regard to the sampling*

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

2.4. *Specific information with regard to antimicrobial resistance testing*

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

2.5. *Specific information with regard to dilution method results*

— Minimum Inhibitory Concentration (MIC) value (in mg/L)

2.6. *Synergy testing results*

— Synergy testing with clavulanic acid for ceftazidime

— Synergy testing with clavulanic acid for cefotaxime

(**1**) OJ L 325, 12.12.2003, p. 31.

(**2**) COM(2011) 748 final.

(**3**) OJ C 211, 18.7.2012, p. 2.

(**4**) OJ C 77 E, 15.3.2013, p. 20.

(**5**) CAC/GL 77-2011.

(**6**) http://www.oie.int

(**7**) *EFSA Journal* (2008) 765, 1-87.

(**8**) *EFSA Journal* 2009; 7(11):1372.

(**9**) *EFSA Journal* (2009) 993, 1-73.

(**10**) *EFSA Journal* 2011; 9(8):2322.

(**11**) *EFSA Journal* 2011; 9(10):196.

(**12**) *EFSA Journal* 2012; 10(6):2742.

(**13**) *EFSA Journal* 2012; 10(10):2897.

(**14**) Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).

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

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

(**17**) Commission Decision 2007/407/EC of 12 June 2007 on a harmonised monitoring of antimicrobial resistance in Salmonella in poultry and pigs (OJ L 153, 14.6.2007, p. 26).

(**18**) According to the most recent data available at Eurostat (http://epp.eurostat.ec.europa.eu).

(**19**) See footnote 1.

(**20**) www.crl-ar.eu

(**21**) See footnote 3.

(**22**) See footnote 3.

(**23**) www.efsa.europa.eu

Changes to legislation:
There are outstanding changes not yet made to Commission Implementing Decision of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria (notified under document C(2013) 7145) (Text with EEA relevance) (2013/652/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Annex Pt. A point 1(a)(i) word omitted by S.I. 2019/740 reg. 11(9)(a)(ii)(aa)
- Annex Pt. A point 2.3.2 heading word omitted by S.I. 2019/740 reg. 11(13)(a)
- Annex Pt. A point 5 word omitted by S.I. 2019/740 reg. 11(18)(a)
- Annex Pt. A point 1(a)(iv) word substituted by S.I. 2019/740 reg. 11(9)(a)(ii)(bb)
- Annex Pt. A point 1(b)-(d) word substituted by S.I. 2019/740 reg. 11(9)(a)(iii)
- Annex Pt. A point 2.2 word substituted by S.I. 2019/740 reg. 11(11)(a)(iv)
- Annex Pt. A point 2.2 word substituted by S.I. 2019/740 reg. 11(11)(b)
- Annex Pt. A point 2.2 words inserted by S.I. 2019/740 reg. 11(11)(a)(iii)
- Annex Pt. A point 2.2 words inserted by S.I. 2019/740 reg. 11(11)(c)(iii)
- Annex Pt. B point 2 words omitted by S.I. 2019/740 reg. 11(19)
- Annex Pt. A point 1 words substituted by S.I. 2019/740 reg. 11(9)(a)(i)
- Annex Pt. A point 1(e) words substituted by S.I. 2019/740 reg. 11(9)(a)(iv)
- Annex Pt. A point 1(f) words substituted by S.I. 2019/740 reg. 11(9)(a)(v)(aa)
- Annex Pt. A point 1(f)(i) words substituted by S.I. 2019/740 reg. 11(9)(a)(v)(bb)
- Annex Pt. A point 1(f)(ii) words substituted by S.I. 2019/740 reg. 11(9)(a)(v)(bb)
- Annex Pt. A point 1 words substituted by S.I. 2019/740 reg. 11(9)(b)
- Annex Pt. A point 2.1 words substituted by S.I. 2019/740 reg. 11(10)
- Annex Pt. A point 2.2 words substituted by S.I. 2019/740 reg. 11(11)(a)(i)
- Annex Pt. A point 2.2 words substituted by S.I. 2019/740 reg. 11(11)(a)(ii)
- Annex Pt. A point 2.2 words substituted by S.I. 2019/740 reg. 11(11)(c)(i)
- Annex Pt. A point 2.2 words substituted by S.I. 2019/740 reg. 11(11)(c)(ii)
- Annex Pt. A point 2.3 words substituted by S.I. 2019/740 reg. 11(12)
- Annex Pt. A point 2.3.2 words substituted by S.I. 2019/740 reg. 11(13)(b)
- Annex Pt. A point 2.3.3 words substituted by S.I. 2019/740 reg. 11(14)
- Annex Pt. A point 3 words substituted by S.I. 2019/740 reg. 11(15)
- Annex Pt. A point 4.1 words substituted by S.I. 2019/740 reg. 11(16)(a)
- Annex Pt. A point 4.1 words substituted by S.I. 2019/740 reg. 11(16)(b)
- Annex Pt. A point 4.3 words substituted by S.I. 2019/740 reg. 11(17)
- Annex Pt. A point 5 words substituted by S.I. 2019/740 reg. 11(18)(b)
- Art. 1 heading word inserted by S.I. 2019/740 reg. 11(2)(a)
- Art. 1(1) word omitted by S.I. 2019/740 reg. 11(2)(b)(i)
- Art. 1(1) words omitted by S.I. 2019/740 reg. 11(2)(b)(ii)
- Art. 1(2) word omitted by S.I. 2019/740 reg. 11(2)(c)
- Art. 2 heading words omitted by S.I. 2019/740 reg. 11(3)(a)
- Art. 2(1) words substituted by S.I. 2019/740 reg. 11(3)(b)
- Art. 2(2) words substituted by S.I. 2019/740 reg. 11(3)(b)
- Art. 2(3) words substituted by S.I. 2019/740 reg. 11(3)(c)
- Art. 3 words substituted by S.I. 2019/740 reg. 11(4)(a)
- Art. 5 words substituted by S.I. 2019/740 reg. 11(5)(a)
- Art. 5 words substituted by S.I. 2019/740 reg. 11(5)(b)
- Art. 6-9 omitted by S.I. 2019/740 reg. 11(6)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 1(3) inserted by S.I. 2019/740 reg. 11(2)(d)

– Art. 3(a) word omitted by S.I. 2019/740 reg. 11(4)(b)