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[1], 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[(2)] 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[3]. 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[(4)].

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[(5)].

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.

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

(**2**) See footnote 1.

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

(**4**) See footnote 3.

(**5**) See footnote 3.

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. 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)

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)