

II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION

COMMISSION DECISION

of 12 June 2007

on a harmonised monitoring of antimicrobial resistance in *Salmonella* in poultry and pigs

(notified under document number C(2007) 2421)

(Text with EEA relevance)

(2007/407/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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) thereof,

Whereas:

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

(2) A FAO/OIE/WHO workshop on scientific assessment on non-human usage of antimicrobials and antimicrobial resistance in 2003 concluded that there is clear evidence of adverse human health consequences due to resistant organisms resulting from non-human usage of antimicrobials: increased frequency of infections, increased frequency of treatment failures (in some cases death) and increased severity of infections, as documented for instance by fluoroquinolone-resistant human *Salmonella* infections. Evidence shows that the amount and pattern of non-human usage of antimicrobials affect the occurrence of resistant bacteria in animals and food and thereby human exposure to these resistant bacteria (Joint FAO/OIE/WHO Expert Workshop, 2003). However, it should be noted that most of the resistance problems in human medicine are caused by human usage and over usage of antimicrobial agents for therapy and prophylaxis (European Parliament, October 2006).

(3) The European Food Safety Authority (EFSA) indicates in its 'Community Summary Report on Trends and Sources of Zoonoses, Zoonotic agents, Antimicrobial Resistance and Foodborne Outbreaks in the European Union in 2005' ⁽²⁾ that a relatively high proportion of *Campylobacter* and *Salmonella* isolates from animals and food were resistant to antimicrobials commonly used in treatment of human diseases. Food-borne infections caused by these resistant bacteria pose a particular risk to humans due to possible treatment failure.

⁽¹⁾ OJ L 325, 12.12.2003, p. 31. Directive amended by Council Directive 2006/104/EC (OJ L 363, 20.12.2006, p. 352).

⁽²⁾ *The EFSA Journal* (2006), 94.

- (4) The Scientific Panel on Biological Hazards and of the Scientific Panel on Animal Health and Welfare of the EFSA, adopted an Opinion on 'Review of the Community Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Antimicrobial Resistance in the European Union in 2004' ⁽¹⁾ during its meeting on respectively 7 and 8 September 2006. With regard to antimicrobial resistance testing, the Opinion indicates the importance to provide detailed information on the *Salmonella* serovar for each isolate and to harmonise the breakpoints applied for resistance assessment and reporting.
- (5) The Task Force on Zoonoses Data Collection of the EFSA adopted a 'Report including a proposal for a harmonised monitoring scheme of antimicrobial resistance in *Salmonella* in fowl (*Gallus gallus*), turkeys and pigs and *Campylobacter jejuni* and *C. coli* in broilers' ⁽²⁾ on 20 February 2007. The report makes recommendations on a harmonised monitoring scheme and harmonised methodology for susceptibility testing.
- (6) In view of the increasing public health risk posed by antimicrobial resistance and the evidence that use of antibiotics affects this risk, comparable information should be collected from all Member States on the antimicrobial resistance occurrence in zoonotic agents in animals by implementing Article 7 of Directive 2003/99/EC. This implementation should be based on the proposal of the EFSA Task Force but is without prejudice to further implementation rules in the future.
- (7) 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

This Decision lays down detailed rules for monitoring antimicrobial resistance in accordance with Article 7(3) and Annex II(B) of Directive 2003/99/EC to be carried out in the

Member States. It shall cover *Salmonella* spp. in fowl (*Gallus gallus*), turkeys, and slaughter pigs without prejudice to additional antimicrobial resistance monitoring in accordance with the requirements in Article 7(1) of Directive 2003/99/EC.

Article 2

Collection and analyses of isolates

The collection of isolates of *Salmonella* spp. referred to in Article 1 and the analysis thereof shall be performed by the competent authority or under its supervision in accordance with the technical specifications set out in the Annex.

Article 3

Confidentiality of the data

National aggregated data and results of the analyses shall be made available publicly in a form that ensures confidentiality.

Article 4

Application

This Decision shall apply from 1 January 2008.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 12 June 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

⁽¹⁾ The EFSA Journal (2006), 403, pp. 1 to 62.

⁽²⁾ The EFSA Journal (2007) 96, pp. 1 to 46.

ANNEX

TECHNICAL SPECIFICATIONS REFERRED TO IN ARTICLE 2

1. Origin of isolates

Salmonella isolates collected through control and monitoring programmes, set up in accordance with Article 5 of Regulation (EC) No 2160/2003 of the European Parliament and of the Council ⁽¹⁾ and/or Commission Decisions 2006/662/EC ⁽²⁾, 2006/668/EC ⁽³⁾, shall be collected for antimicrobial resistance monitoring in accordance with Table 1.

Table 1:

Years in which certain zoonotic agents isolated from the indicated animal populations shall be selected for antimicrobial resistance testing

Year	<i>All Salmonella serovars</i>			
	Laying hens	Broilers	Turkeys	Slaughter pigs
2007			X (*)	X (**)
2008	X			
2009	X	X		
2010	X	X	X	
2011	X	X	X	X
2012	X	X	X	X

(*) Isolates from samples collected in 2007 and stored in accordance with the provisions in Decision 2006/662/EC.

(**) Isolates from samples collected in 2007 and stored in accordance with the provisions in Decision 2006/668/EC.

Not more than one isolate per *Salmonella* serovar from the same epidemiological unit per year shall be included in the monitoring. The epidemiological unit for laying hens, broilers, and turkeys is the flock. For pigs, the epidemiological unit is the holding.

2. Number of isolates to be tested

The number of *Salmonella* isolates to be included in the antimicrobial resistance monitoring per Member State per year shall be 170 for each study population (i.e. laying hens, broilers, turkeys and slaughter pigs).

In those Member States where, in any given year, a lower number of isolates than the target sample size is available from the monitoring or control programmes, all these isolates shall be included in the antimicrobial resistance monitoring.

In those Member States where a higher number of isolates is available all isolates, or a representative random selection equal or larger than the target sample size, shall be included.

3. Antimicrobial susceptibility testing

Member States shall test at least the antimicrobials that are specified in Table 2, using the cut-off values given and an appropriate concentration range to determine the susceptibility of *Salmonella*.

⁽¹⁾ OJ L 325, 12.12.2003, p. 1.

⁽²⁾ OJ L 272, 3.10.2006, p. 22.

⁽³⁾ OJ L 275, 6.10.2006, p. 51.

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 international reference method (ISO standard 20776-1:2006). It is recommended that the selected isolates of *S. Enteritidis* and *S. Typhimurium* are phage typed.

4. Collection of the data and reporting

The results of the antimicrobial resistance monitoring shall be assessed and reported, in accordance with Article 9 of Directive 2003/99/EC, in the yearly report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance.

Without prejudice to the provisions of Annex IV of Directive 2003/99/EC the following information shall be reported for *Salmonella* in laying hens, broilers, turkeys and pigs:

- Origin of isolates i.e. baseline study, control programme, passive surveillance,
- number of isolates susceptibility tested,
- number of isolates found to be resistant per antimicrobial, and
- number of fully-susceptible isolates and number of isolates resistant to 1, 2, 3, 4 and > 4 antimicrobials listed in Table 2.

Table 2:

Antimicrobials to be at least included for *Salmonella* and the cut-off values to be used to determine susceptibility

	Antimicrobial	Cut-off value (mg/L) R >
<i>Salmonella</i>	Cefotaxime	0,5
	Nalidixic acid	16
	Ciprofloxacin	0,06
	Ampicillin	4
	Tetracycline	8
	Chloramphenicol	16
	Gentamicin	2
	Streptomycin	32
	Trimethoprim	2
	Sulphonamides	256