COMMISSION IMPLEMENTING DECISION (EU) 2023/1017

of 23 May 2023

amending Implementing Decision (EU) 2020/1729 as regards the monitoring of methicillin-resistant *Staphylococcus aureus* (MRSA) in fattening pigs

(notified under document C(2023)3251)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC ([1]), and in particular Articles 4(5), 7(3) and Article 9(1), fourth subparagraph, thereof,

Whereas:

(1) Directive 2003/99/EC requires the Member States to ensure that monitoring provides comparable data on the occurrence of antimicrobial resistance (AMR) in zoonotic agents and, in so far as 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 a report every year covering data collected in accordance with that Directive.

(3) Commission Implementing Decision (EU) 2020/1729 ([2]) lays down detailed rules for the harmonised monitoring and reporting of AMR in zoonotic and commensal bacteria. The rules laid down in that Implementing Decision cover the period 2021 to 2027 and provide for a yearly rotational sampling system of animal species. In accordance with that rotational system, fattening pigs have to be sampled in 2025.

(4) Methicillin-resistant *Staphylococcus aureus* (MRSA) is a pathogen that causes many healthcare- and community-associated infections that are difficult to treat in humans as they are resistant to multiple antibiotics. In recent decades, the emergence and increasing prevalence of livestock-associated MRSA (LA-MRSA), particularly sequence type 398 belonging to clonal complex 398, in pigs have become a global concern as its spread can compromise the effective treatment of infectious diseases in humans. Rearing and slaughtering pigs infected with LA-MRSA are also potential risk factors for infection in certain human populations such as farmers and slaughterhouse workers. Monitoring the prevalence of LA-MRSA in fattening pigs would therefore be very valuable for obtaining comprehensive, comparable and reliable information on the development and spread of MRSA at Union level in view to develop, if deemed necessary, appropriate interventions to prevent and control MRSA infections.

(5) On 17 October 2022, the European Food Safety Authority (EFSA) published a scientific report on "Technical specifications for a baseline survey on the prevalence of methicillin resistant *Staphylococcus aureus* (MRSA) in pigs" ([3]) (the EFSA technical specifications). This report highlights the appropriateness to conduct a one-year EU-wide survey in batches of fattening pigs at slaughter to estimate the MRSA prevalence in the European population of fattening pigs, and defines a protocol for this survey including the target population, sample requirements, analytical methods and data reporting requirements.

(6) The EFSA technical specifications should be considered when laying down rules for harmonised monitoring and reporting of MRSA in fattening pigs in the Union.

([1]) OJ L 325, 12.12.2003, p. 31.

([2]) 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 (OJ L 387, 19.11.2020, p. 8)

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

(7) In order to take advantage of the sampling of fattening pigs scheduled in 2025 for other bacteria in accordance with the yearly rotational system already in place, the requirements for MRSA monitoring in fattening pigs should be laid down in Implementing Decision (EU) 2020/1729 and apply from 1 January 2025.

(8) Implementing Decision (EU) 2020/1729 should therefore be amended accordingly.

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

HAS ADOPTED THIS DECISION:

Article 1

Amendments to Implementing Decision (EU) 2020/1729

Implementing Decision (EU) 2020/1729 is amended as follows:

(1) in Article 1(2), the following point (f) is added:

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

(2) in Article 3, paragraph 2 is replaced by the following:

'(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.';

(3) The Annex is amended in accordance with the Annex to this Decision.

Article 2

Application

This Decision shall apply from 1 January 2025.

Article 3

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 23 May 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

In the Annex to Commission Implementing Decision (EU) 2020/1729, Part A is amended as follows:

1. in point 1, the following paragraph (f) is added:

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

2. in point 2, paragraph (a) is replaced by the following:

'(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.'

3. point 3.1 is replaced by the following:

'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

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]).';

4. in point 4.1, the following paragraph is added:

'For MRSA:

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

5. point 4.2 is amended as follows:

a) the first paragraph is replaced by the following:

'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.';

b) the following paragraph is inserted after the third paragraph:

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

c) the following Table 4a is inserted after Table 4:

'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)

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

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'

6. the following point 5a is inserted after point 5:

'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 ([4]) confirmatory methods as referred to in EFSA technical specifications for a baseline survey on the prevalence of methicillin resistant *Staphylococcus aureus* (MRSA) in pigs ([5]) and detailed in the protocols of the EURL for AMR ([6]).

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 ([7]).

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 ([8]). 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.'

([4]) Method based on Polymerase Chain Reaction (PCR) assays
([5]) https://www.efsa.europa.eu/en/efsajournal/pub/7620
([6]) https://www.eurl-ar.eu/protocols.aspx
([7]) https://www.eurl-ar.eu/protocols.aspx
([8]) https://www.eurl-ar.eu/protocols.aspx