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)

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)

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), 8(3) and the fourth subparagraph of Article 9(1) thereof,

Whereas:

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

(3) Commission Implementing Decision 2013/652/EU[(2)] lays down detailed rules for the harmonised monitoring and reporting of AMR in zoonotic and commensal bacteria. These rules are applicable until 31 December 2020.

(4) In its Communication of 29 June 2017 to the Council and the European Parliament 'A European One Health Action Plan against Antimicrobial Resistance'[(3)], the Commission committed to review Union implementing legislation, namely Implementing Decision 2013/652/EU, concerned with the monitoring of AMR in zoonotic and commensal bacteria in farm animals and food to take into account new scientific developments and data collection needs.

(5) From 2015 to 2018, the Commission carried out a series of audits in Member States for the purposes of evaluating the implementation of Implementing Decision 2013/652/EU

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2020/1729. (See end of Document for details)*

by competent authorities. A final overview report[4] summarising this series of audits highlighted certain implementation challenges faced by Member States that should be taken into account by the Commission when revising Implementing Decision 2013/652/EU.

(6) On 5 June 2019, the European Food Safety Authority ('EFSA') published a scientific report entitled 'Technical specifications on harmonised monitoring of antimicrobial resistance in zoonotic and indicator bacteria from food#producing animals and food'[5]. This report recommends specific adaptations to the current AMR monitoring and reporting system as laid down in Implementing Decision 2013/652/EU in order to respond effectively to the constantly evolving threat of AMR and to ensure continuity in assessing future trends in AMR from 2021. These recommended adaptations primarily concern adaptations as to the food-producing animal populations or food categories to be sampled, the sampling design to be followed, the bacterial species to be tested for AMR and the analytical methods to be used by laboratories in charge of testing for AMR.

(7) In order to continue to obtain comparable and reliable data on AMR, it is important to take recommendations of the EFSA scientific report of 5 June 2019 into account when defining the most relevant combinations of bacterial species, food producing animal species and food products to be included in the harmonised monitoring and reporting of AMR from 2021. It is also appropriate to minimise the burden on competent authorities of Member States to the extent possible, notably by addressing known implementation challenges and by focussing AMR monitoring on biological samples or bacterial isolates collected within the framework of existing national control programmes.

(8) Whole genome sequencing ('WGS') is a promising technique to replace conventional phenotypical testing in microbiology and is increasingly used worldwide. However, only a limited number of Member States are currently able to use WGS for AMR monitoring on a routine basis. It is therefore appropriate to authorise the use of WGS as an alternative to the conventional phenotypical techniques on a voluntary basis only, but to impose technical conditions on the WGS technique to ensure data comparability.

(9) AMR is a global threat that can easily spread across borders. Therefore, in order to improve coordination and gain a deeper understanding of how to help reduce the impact of AMR impact globally, it is essential that food products imported into the Union are also subjected to AMR monitoring requirements.

(10) In order to ensure continuity of the harmonised AMR monitoring and reporting by Member States after the period covered by Implementing Decision 2013/652/EU, this Decision should apply from 1 January 2021.

(11) For the sake of legal clarity, Implementing Decision 2013/652/EU should be repealed.

(12) 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:

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2020/1729. (See end of Document for details)*

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).

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;

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[6];

(b) the definitions laid down in Commission Regulation (EC) No 2073/2005[7];

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(c) the definitions laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council[8];

(d) the definitions laid down in Regulation (EC) No 2160/2003 of the European Parliament and of the Council[9];

(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[10];

(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.

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.

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

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

c the alternative method referred to in point 6 of Part A of the Annex.

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.

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.

Done at Brussels, 17 November 2020.

For the Commission

Stella KYRIAKIDES

Member of the Commission