Non-paper
in view of a possible EC decision on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Commission Implementing Decision 2013/652/EU

REV2 draft dated 27 January 2020

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Commission Implementing Decision 2013/652/EU

(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 the 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 provides that Member States are to assess the trends and sources 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 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 EU implementing legislation, namely Decision 2013/652/EU, on monitoring 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 in order to evaluate the implementation of Decision 2013/652/EU by competent authorities. A final overview report[4] summarising this series of audits highlighted some implementation issues faced by Member States that could be taken into account by the Commission when revising Decision 2013/652/EU.

(6) On 5 June 2019, the European Food Safety Authority (EFSA) published a scientific report on “Technical specifications on harmonised monitoring of antimicrobial

1 OJ L 325, 12.12.2003, p. 31.
2 OJ L 303, 14.11.2013, p. 26.
3 COM/2017/0339 final.
4 DG(SANTE) 2019-6789

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 Decision 2013/652/EU to respond effectively to the constantly evolving threat of AMR and ensure continuity in following-up further trends in AMR after 2020. These recommended adaptations concern mainly 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 into account recommendations of the EFSA scientific report of 5 June 2019 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 as from 2021. It is also appropriate to minimise as much as possible the burden for the competent authorities in Member States, notably by addressing known implementation issues and focussing AMR monitoring on biological samples or bacterial isolates collected in the framework of already existing national control programmes.

(8) Whole genome sequencing (WGS) is a promising technology to replace conventional phenotypical testing in microbiology and is increasingly used worldwide. However, only a limited number of Member States is 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 technics on a voluntary basis only but to impose technical conditions on the WGS technic to ensure comparability of data.

(9) AMR is a global threat that can easily spread across borders. Therefore, in order to improve coordination and gain knowledge to help reducing AMR impact globally, it important 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 Decision 2013/652/EU, this Decision should apply from 1 January 2021.

(11) For the sake of legal clarity, 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:

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

[5] EFSA Journal 2019;17(6):5709.

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. This monitoring and reporting shall cover the following bacteria:

   (a) *Salmonella* spp.;

   (b) Extended Spectrum β-Lactamases- (ESBL-), AmpC β-Lactamases- (AmpC) and/or carbapenemase-producing (CP) *Salmonella* spp;

   (c) *Campylobacter jejuni* (*C. jejuni*);

   (d) *Campylobacter coli* (*C. coli*);

   (e) Indicator commensal *Escherichia coli* (*E. coli*);

   (f) ESBL-, AmpC- and/or CP-producing *E. coli;*

   (g) *Enterococcus faecalis* (*E. faecalis*);

   (h) *Enterococcus faecium* (*E. faecium*);

3. This monitoring and reporting 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) broiler meat;

   (g) turkey meat;

   (h) pig meat;

   (i) bovine meat.

4. Member States shall monitor and report AMR in specific combinations of bacteria/antimicrobial substances/food-producing animal populations/food 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;

(b) the definitions laid down in Commission Regulation (EC) 2073/2005;

(c) the definitions laid down in Regulation (EC) No 853/2004;

(d) the definitions laid down in Regulation (EC) No 2160/2003;

(e) the definitions laid down in Directive 2003/99/EC;

(f) the definitions laid down in Regulation (EU) 2019/6;

(g) 'slaughter batch' means a group of animals originating from the same herd, raised together 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/food and test for antimicrobial susceptibility the bacterial isolates obtained thereof 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 test bacterial isolates already 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 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. coli1* 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.

3. In accordance with Article 37 of Regulation (EU) 2017/625, the competent authority may designate other laboratories than national reference laboratories to carry out the tasks referred to in paragraph 2.

Article 4

Annual AMR reporting and assessment

Member States shall report annually the results of their AMR monitoring 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 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 with Article 4.

Article 6

Repeal

Commission 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,

For the Commission