

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

CHAPTER II

**MONITORING OF ZOOSE AND ZOOOTIC AGENTS**

*Article 4*

**General rules on monitoring of zoonoses and zoonotic agents**

1 Member States shall collect relevant and comparable data in order to identify and characterise hazards, to assess exposures and to characterise risks related to zoonoses and zoonotic agents.

2 Monitoring shall take place at the stage or stages of the food chain most appropriate to the zoonosis or zoonotic agent concerned, that is:

- a at the level of primary production; and/or
- b at other stages of the food chain, including in food and feed.

3 Monitoring shall cover zoonoses and zoonotic agents listed in Annex I, Part A. Where the epidemiological situation in a Member State so warrants, zoonoses and zoonotic agents listed in Annex I, Part B shall also be monitored.

4 [<sup>F1</sup>Annex I may be amended by the Commission to add zoonoses or zoonotic agents to, or delete them from, the lists therein, taking account in particular of the following criteria:]

- a their occurrence in animal and human populations, feed and food;
- b the gravity of their effects for humans;
- c their economic consequences for animal and human health care and for feed and food businesses;
- d epidemiological trends in animal and human populations, feed and food.

[<sup>F2</sup>Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the urgency procedure referred to in Article 12(4).]

5 Monitoring shall be based on the systems in place in Member States. However, where necessary to make data easier to compile and compare, detailed rules for the monitoring of zoonoses and zoonotic agents listed in Annex I may be laid down in accordance with the procedure referred to in Article 12(2) and taking into consideration other Community rules laid down in the fields of animal health, food hygiene and communicable human diseases.

Such detailed rules shall lay down minimum requirements for the monitoring of certain zoonoses or zoonotic agents. They may, in particular, specify:

- a the animal population or subpopulations or stages in the food chain to be covered by monitoring;
- b the nature and type of data to be collected;
- c case definitions;
- d sampling schemes to be used;
- e laboratory methods to be used in testing; and

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- f the frequency of reporting, including guidelines for reporting between local, regional and central authorities.

6 When considering whether to propose detailed rules in accordance with paragraph 5 to harmonise the routine monitoring of zoonoses and zoonotic agents, the Commission shall give priority to zoonoses and zoonotic agents listed in Part A of Annex I.

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.
- F2** Inserted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.

### Article 5

#### Coordinated monitoring programmes

[<sup>F1</sup> If data collected through routine monitoring in accordance with Article 4 are not sufficient, coordinated monitoring programmes concerning one or more zoonoses and/or zoonotic agents may be established by the Commission, especially when specific needs are identified, to assess risks or to establish baseline values related to zoonoses or zoonotic agents at the level of Member States or at Community level. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).]

2 Where a coordinated monitoring programme is established, special reference shall be made to zoonoses and zoonotic agents in animal populations referred to in Annex I to Regulation (EC) No 2160/2003.

3 Minimum rules concerning the establishment of coordinated monitoring programmes are laid down in Annex III.

#### Textual Amendments

- F1** Substituted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.

### Article 6

#### Food business operators' duties

1 Member States shall ensure that, when food business operators carry out examinations for the presence of zoonoses and zoonotic agents subject to monitoring under Article 4(2), they:

- a keep the results and arrange for the preservation of any relevant isolate for a period to be specified by the competent authority; and
  - b communicate results or provide isolates to the competent authority on request.
- 2 Detailed rules for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 12(2).