

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 I

INTRODUCTORY PROVISIONS

Article 1

Subject matter and scope

1 The purpose of this Directive is to ensure that zoonoses, zoonotic agents and related antimicrobial resistance are properly monitored, and that food-borne outbreaks receive proper epidemiological investigation, to enable the collection in the Community of the information necessary to evaluate relevant trends and sources.

2 This Directive covers:

- a the monitoring of zoonoses and zoonotic agents;
- b the monitoring of related antimicrobial resistance;
- c the epidemiological investigation of food-borne outbreaks; and
- d the exchange of information related to zoonoses and zoonotic agents.

3 This Directive shall apply without prejudice to more specific Community provisions on animal health, animal nutrition, food hygiene, communicable human diseases, health and safety in the workplace, gene technology and transmissible spongiform encephalopathies.

Article 2

Definitions

For the purposes of this Directive, the following definitions shall apply:

1. the definitions laid down in Regulation (EC) No 178/2002, and
2. the following definitions:
 - (a) ‘zoonosis’ means any disease and/or infection which is naturally transmissible directly or indirectly between animals and humans;
 - (b) ‘zoonotic agent’ means any virus, bacterium, fungus, parasite or other biological entity which is likely to cause a zoonosis;
 - (c) ‘antimicrobial resistance’ means the ability of micro-organisms of certain species to survive or even to grow in the presence of a given concentration of an antimicrobial agent, that is usually sufficient to inhibit or kill micro-organisms of the same species;
 - (d) ‘food-borne outbreak’ means an incidence, observed under given circumstances, of two or more human cases of the same disease and/or infection, or a situation in which the observed number of cases exceeds the

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expected number and where the cases are linked, or are probably linked, to the same food source;

- (e) 'monitoring' means a system of collecting, analysing and disseminating data on the occurrence of zoonoses, zoonotic agents and antimicrobial resistance related thereto.

Article 3

General obligations

1 Member States shall ensure that data on the occurrence of zoonoses and zoonotic agents and antimicrobial resistance related thereto are collected, analysed and published without delay in accordance with the requirements of this Directive and of any provisions adopted pursuant to it.

2 Each Member State shall designate a competent authority or competent authorities for the purposes of this Directive and notify the Commission thereof. If a Member State designates more than one competent authority, it shall:

- a notify the Commission of the competent authority that will act as a contact point for contacts with the Commission; and
- b ensure that the competent authorities cooperate so as to guarantee the proper implementation of the requirements of this Directive.

3 Each Member State shall ensure that effective and continuous cooperation based on free exchange of general information and, where necessary, of specific data, is established between the competent authority or authorities designated for the purposes of this Directive and:

- a the competent authorities for the purposes of Community legislation on animal health;
- b the competent authorities for the purposes of Community legislation on feed;
- c the competent authorities for the purposes of Community legislation on food hygiene;
- d the structures and/or authorities referred to in Article 1 of Decision No 2119/98/EC;
- e other authorities and organisations concerned.

4 Each Member State shall ensure that the relevant officials of the competent authority or competent authorities referred to in paragraph 2 undertake suitable initial and ongoing training in veterinary science, microbiology or epidemiology, as necessary.

CHAPTER II

MONITORING OF ZOOSES AND ZOO NOTIC 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 [^{F1}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.

[^{F2}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
- 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.

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Article 5

Coordinated monitoring programmes

[^{F1} 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).

CHAPTER III

ANTIMICROBIAL RESISTANCE

Article 7

Monitoring of antimicrobial resistance

- 1 Member States shall ensure, in accordance with the requirements set out in Annex II, 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 Such monitoring shall supplement the monitoring of human isolates conducted in accordance with Decision No 2119/98/EC.
- 3 Detailed rules for the implementation of this Article shall be laid down in accordance with the procedure referred to in Article 12(2).

CHAPTER IV

FOOD-BORNE OUTBREAKS

Article 8

Epidemiological investigation of food-borne outbreaks

- 1 Member States shall ensure that, when a food business operator provides information to the competent authority pursuant to Article 19(3) of Regulation (EC) No 178/2002, the foodstuff involved, or an appropriate sample of it, is preserved in order not to impede its investigation in a laboratory or the investigation of any food-borne outbreak.
- 2 The competent authority shall investigate food-borne outbreaks in cooperation with the authorities referred to in Article 1 of Decision No 2119/98/EC. The investigation shall provide data on the epidemiological profile, the foodstuffs potentially implicated and the potential causes of the outbreak. The investigation shall include, as far as possible, adequate epidemiological and microbiological studies. The competent authority shall transmit to the Commission (which shall send it to the European Food Safety Authority) a summary report of the results of the investigations carried out, containing the information referred to in Part E of Annex IV.
- 3 Detailed rules concerning the investigation of food-borne outbreaks may be laid down in accordance with the procedure referred to in Article 12(2).
- 4 Paragraphs 1 and 2 shall apply without prejudice to Community provisions on product safety, early warning and response systems for the prevention and control of communicable human diseases, food hygiene and the general requirements of food law, in particular those concerning emergency measures and procedures for withdrawing food and feed from the market.

CHAPTER V

EXCHANGE OF INFORMATION

Article 9

Assessment of trends and sources of zoonoses, zoonotic agents and antimicrobial resistance

1 Member States shall assess trends and sources of zoonoses, zoonotic agents and antimicrobial resistance in their territory.

[^{F3}Each Member State shall transmit to the Commission every year by the end of May, for Bulgaria and Romania, for the first time, by the end of May 2008, and for Croatia, for the first time, by the end of May 2014, a report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance, covering the data collected pursuant to Articles 4, 7, and 8 during the previous year. Reports, and any summaries of them, shall be made publicly available.]

Reports shall also contain the information referred to in Article 3(2)(b) of Regulation (EC) No 2160/2003.

Minimum requirements concerning the reports are laid down in Annex IV. Detailed rules concerning the assessment of those reports, including the formats and the minimum information that they must include, may be laid down in accordance with the procedure referred to in Article 12(2).

Where the circumstances warrant it, the Commission may request specific additional information and the Member States shall submit reports to the Commission upon such request, or on their own initiative.

2 The Commission shall send the reports referred to in paragraph 1 to the European Food Safety Authority, which shall examine them and publish by the end of November a summary report on the trends and sources of zoonoses, zoonotic agents and antimicrobial resistance in the Community.

When preparing the summary report, the European Food Safety Authority may take into consideration other data provided for in the framework of Community legislation, such as:

- Article 8 of Directive 64/432/EEC,
- Article 14(2) of Directive 89/397/EEC⁽¹⁾,
- Article 24 of Decision 90/424/EEC,
- Article 4 of Decision No 2119/98/EC.

3 Member States shall provide the Commission with the results of coordinated monitoring programmes established in accordance with Article 5. The Commission shall send the results to the European Food Safety Authority. The results, and any summaries of them, shall be made publicly available.

Textual Amendments

- F3** Substituted by [Council Directive 2013/20/EU of 13 May 2013 adapting certain directives in the field of food safety, veterinary and phytosanitary policy, by reason of the accession of the Republic of Croatia.](#)

CHAPTER VI

LABORATORIES*Article 10***Community and national reference laboratories**

1 One or more Community reference laboratories for the analysis and testing of zoonoses and zoonotic agents and antimicrobial resistance related thereto may be designated in accordance with the procedure referred to in Article 12(2).

2 Without prejudice to the relevant provisions of Decision 90/424/EEC, the responsibilities and tasks of the Community reference laboratories, in particular with regard to coordination of their activities and those of the national reference laboratories, shall be laid down in accordance with the procedure referred to in Article 12(2).

3 Member States shall designate national reference laboratories for each field where a Community reference laboratory has been established and inform the Commission thereof.

4 Certain responsibilities and tasks of the national reference laboratories, in particular with regard to coordination of their activities and those of relevant laboratories in the Member States, may be laid down in accordance with the procedure referred to in Article 12(2).

CHAPTER VII

IMPLEMENTATION*[^{F1}Article 11***Amendments to the Annexes and transitional or implementing measures**

Annexes II, III and IV may be amended by the Commission. 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).

Transitional measures of general scope designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it with new non-essential elements, in particular further specifications of the requirements laid down in this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

Other implementing or transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 12(2).]

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Textual Amendments

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Article 12

Committee procedure

1 The Commission shall be assisted by the Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002 or, where appropriate, by the Committee set up under Decision No 2119/98/EC.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

[^{F13} Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.]

[^{F24} Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.]

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 13

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter within the scope of this Directive that could have a significant impact on public health, in particular before proposing any amendment to Annexes I or II or before establishing any coordinated monitoring programme in accordance with Article 5.

Article 14

Transposition

1 Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by 12 April 2004. They shall forthwith inform the Commission thereof.

They shall apply those measures by 12 June 2004.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the provisions of national law that they adopt in the field covered by this Directive.

CHAPTER VIII

FINAL PROVISIONS

Article 15

Repeal

Directive 92/117/EEC shall be repealed with effect from 12 June 2004.

However, measures which Member States have adopted pursuant to Article 8(1) of Directive 92/117/EEC and those implemented in accordance with Article 10(1) thereof and plans approved in accordance with Article 8(3) thereof shall remain in force until corresponding control programmes have been approved in accordance with Article 5 of Regulation (EC) No 2160/2003.

^{F4}*Article 16*

[^{F4}Amendment of Decision 90/424/EEC]

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Textual Amendments

F4 Deleted by [Council Decision of 25 May 2009 on expenditure in the veterinary field \(Codified version\) \(2009/470/EC\)](#).

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Article 17

Entry into force

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 18

Addressees

This Directive is addressed to the Member States.

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- (1) Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs ([OJ L 186, 30.6.1989, p. 23](#)).