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

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission[(1)],

Having regard to the opinion of the European Economic and Social Committee[(2)],

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(3)],

Whereas:

(1) Live animals and food of animal origin appear on the list in Annex I to the Treaty. Livestock farming and the placing on the market of food of animal origin constitute an important source of income for farmers. The implementation of veterinary measures aimed at raising the level of public and animal health in the Community assists the rational development of the farming sector.

(2) The protection of human health against diseases and infections transmissible directly or indirectly between animals and humans (zoonoses) is of paramount importance.

(3) Zoonoses transmissible through food may cause human suffering, as well as economic losses to food production and the food industry.

(4) Zoonoses transmitted through sources other than food, especially from wild animal and pet animal populations, are also a matter of concern.

(5) Council Directive 92/117/EEC of 17 December 1992 concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications[(4)] provided for the establishment of a monitoring system for certain zoonoses both at the level of Member States and at Community level.

(6) With the assistance of the Community reference laboratory for the epidemiology of zoonoses, the Commission collects the results of monitoring yearly from Member States and compiles them. Publication of the results has taken place yearly since 1995. They provide a basis for the evaluation of the current situation concerning zoonoses and

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zoonotic agents. However, the data collection systems are not harmonised and therefore do not permit comparisons between Member States.

(7) Other Community legislation provides for the monitoring and control of certain zoonoses in animal populations. In particular, Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine[(5)] deals with bovine tuberculosis and bovine brucellosis. Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals[(6)] deals with ovine and caprine brucellosis. This Directive should not create any unnecessary duplication of those existing requirements.

(8) Moreover, a future regulation of the European Parliament and of the Council on the hygiene of foodstuffs should cover specific elements necessary for prevention, control and monitoring of zoonoses and zoonotic agents and include specific requirements for the microbiological quality of food.

(9) Directive 92/117/EEC provides for collection of data on human cases of zoonoses. The aim of Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community[(7)] is to reinforce the collection of such data and to contribute to improving the prevention and control, in the Community, of communicable diseases.

(10) The collection of data on the occurrence of zoonoses and zoonotic agents in animals, food, feed and humans is necessary to determine the trends and sources of zoonoses.

(11) In its opinion on zoonoses adopted on 12 April 2000, the Scientific Committee on Veterinary Measures relating to Public Health considered that the measures in place at that time to control food-borne zoonotic infections were insufficient. It further considered that the epidemiological data that Member States were collecting were incomplete and not fully comparable. As a consequence, the Committee recommended improved monitoring arrangements and identified risk-management options. In particular, the Committee identified *Salmonella* spp., *Campylobacter* spp., verotoxigenic *Escherichia coli* (VTEC), *Listeria monocytogenes*, *Cryptosporidium* spp., *Echinococcus granulosus/multilocularis* and *Trichinella spiralis* as public health priorities.

(12) It is therefore necessary to improve the existing monitoring and data collection systems established by Directive 92/117/EEC. Simultaneously, Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents[(8)] will replace the specific control measures established by Directive 92/117/EEC. Directive 92/117/EEC should therefore be repealed.

(13) The new framework for scientific advice and scientific support in matters of food safety set up by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[(9)] should be used to collect and analyse the relevant data.

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(14) Where necessary to make data easier to compile and compare, monitoring should take place on a harmonised basis. This would make it possible to evaluate trends and sources of zoonoses and zoonotic agents within the Community. The data collected, together with data from other sources, should form the basis for risk assessment of zoonotic organisms.

(15) Priority should be given to those zoonoses posing the greatest risk to human health. However, the monitoring systems should also facilitate the detection of emerging or newly emerging zoonotic diseases and new strains of zoonotic organisms.

(16) The alarming emergence of resistance to antimicrobial agents (such as antimicrobial medicinal products and antimicrobial feed additives) is a characteristic that should be monitored. Provision should be made for such monitoring to cover not only zoonotic agents but also, in so far as they present a threat to public health, other agents. In particular, the monitoring of indicator organisms might be appropriate. Such organisms constitute a reservoir of resistance genes, which they can transfer to pathogenic bacteria.

(17) In addition to general monitoring, specific needs may be recognised which may necessitate the establishment of coordinated monitoring programmes. Attention should be paid in particular to zoonoses listed in Annex I to Regulation (EC) No 2160/2003.

(18) If thoroughly investigated, food-borne outbreaks of zoonoses provide the opportunity to identify the pathogen, the food vehicle involved and the factors in the food preparation and handling that contributed to the outbreak. It is therefore appropriate to make provision for such investigations and for close cooperation between the various authorities.

(19) Transmissible spongiform encephalopathies are covered by Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies[(10)].

(20) To ensure that information collected on zoonoses and zoonotic agents can be used effectively, appropriate rules should be laid down concerning the exchange of all relevant information. That information should be collected in Member States and transmitted to the Commission in the form of reports, which should be forwarded to the European Food Safety Authority and made available to the public in an appropriate way without delay.

(21) The reports should be submitted on an annual basis. However, additional reports may be appropriate, when warranted by circumstances.

(22) It may be appropriate to designate national and Community reference laboratories for giving guidance and assistance for analysis and testing in relation to zoonoses and zoonotic agents falling within the scope of this Directive.

(23) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field[(11)] should be amended in so far as concerns the detailed rules governing the Community's financial contribution towards certain actions relating to the monitoring and control of zoonoses and zoonotic agents.

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(24) Appropriate procedures should be laid down for amending certain provisions of this Directive to take account of technical and scientific progress and for the adoption of implementing and transitional measures.

(25) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee set up by Regulation (EC) No 178/2002.

(26) Member States cannot, acting alone, collect comparable data to provide a basis for risk assessment of zoonotic organisms of significance at Community level. The collection of such data can better be achieved at Community level. The Community may therefore adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives. The responsibility for establishing and maintaining monitoring systems should lie with Member States.

(27) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[12],

HAVE ADOPTED THIS DIRECTIVE:

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.

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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 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;

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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 ZOONOSES AND ZOONOTIC 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;

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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.

Article 5

Coordinated monitoring programmes

[F1 1 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.

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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

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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, and for Bulgaria and Romania, for the first time, by the end of May 2008, 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[(13)],
— Article 24 of Decision 90/424/EEC,

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— 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 2006/104/EC of 20 November 2006 adapting certain Directives in the field of agriculture (veterinary and phytosanitary legislation), by reason of the accession of Bulgaria and Romania.

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

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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).**]**

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 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.

[[F1]3 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.**]**

[[F2]4 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.

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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.

Article 16

Amendment of Decision 90/424/EEC

Decision 90/424/EEC is hereby amended as follows:

1. Article 29 is replaced by the following:

Article 29

1 Member States may seek a Community financial contribution for the monitoring and control of the zoonoses specified in the Annex, Group 2, in the framework of the provisions referred to in Article 24(2) to (11).

2 As regards control of zoonoses, the Community financial contribution shall be introduced as part of a national control programme referred to in Article 5 of Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents[(14)]. The level of Community financial participation shall be fixed at a maximum of 50 % of costs incurred for the implementation of mandatory control measures.

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2. the following Article is inserted:

Article 29a

Member States may seek from the Community the financial contribution referred to in Article 29(2) for a national plan which was approved on the basis of Directive 92/117/EEC, until the date on which corresponding control programmes have been approved in accordance with Article 6 of Regulation (EC) No 2160/2003.

3. In the Annex, the following indents shall be added to the list under Group 2:
   - Campylobacteriosis and agents thereof
   - Listeriosis and agents thereof
   - Salmonellosis (zoonotic salmonella) and agents thereof
   - Trichinellosis and agents thereof
   - Verotoxigenic *Escherichia coli*.

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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ANNEX I

A.Zoonoses and zoonotic agents to be included in monitoring

— brucellosis and agents thereof
— campylobacteriosis and agents thereof
— echinococcosis and agents thereof
— listeriosis and agents thereof
— salmonellosis and agents thereof
— trichinellosis and agents thereof
— tuberculosis due to *Mycobacterium bovis*
— verotoxigenic *Escherichia coli*

B. List of zoonoses and zoonotic agents to be monitored according to the epidemiological situation

1. Viral zoonoses
— calicivirus
— hepatitis A virus
— influenza virus
— rabies
— viruses transmitted by arthropods

2. Bacterial zoonoses
— borreliosis and agents thereof
— botulism and agents thereof
— leptospirosis and agents thereof
— psittacosis and agents thereof
— tuberculosis other than in point A
— vibriosis and agents thereof
— yersiniosis and agents thereof

3. Parasitic zoonoses
— anisakiasis and agents thereof
— cryptosporidiosis and agents thereof
— cysticercosis and agents thereof
— toxoplasmosis and agents thereof

4. Other zoonoses and zoonotic agents

ANNEX II

Requirements for monitoring of antimicrobial resistance pursuant to Article 7

A.General requirements

Member States must ensure that the monitoring system for antimicrobial resistance provided for in Article 7 provides at least the following information:

1. animal species included in monitoring;

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2. bacterial species and/or strains included in monitoring;

3. sampling strategy used in monitoring;

4. antimicrobials included in monitoring;

5. laboratory methodology used for the detection of resistance;

6. laboratory methodology used for the identification of microbial isolates;

7. methods used for the collection of the data.

B. Specific requirements

Member States must ensure that the monitoring system provides relevant information at least with regard to a representative number of isolates of *Salmonella* spp., *Campylobacter jejuni* and *Campylobacter coli* from cattle, pigs and poultry and food of animal origin derived from those species.

ANNEX III

Coordinated monitoring programmes as referred to in Article 5

When a coordinated monitoring programme is established, at least the following characteristics of the programme must be defined:

— its purpose;
— its duration;
— its geographical area or region;
— the zoonoses and/or zoonotic agents concerned;
— the type of samples and other data units requested;
— minimum sampling schemes;
— the type of laboratory testing methods;
— the tasks of competent authorities;
— the resources to be allocated;
— the estimation of its costs and how they will be covered; and
— the method and time of reporting the results.

ANNEX IV

Requirements for the reports to be submitted pursuant to Article 9(1)

The report referred to in Article 9(1) must provide at least the following information. Parts A to D apply to reports on monitoring carried out in accordance with Article 4 or 7. Part E applies to reports on monitoring carried out in accordance with Article 8.

A. Initially the following must be described for each zoonosis and zoonotic agent (later only changes have to be reported):

(a) monitoring systems (sampling strategies, frequency of sampling, kind of specimen, case definition, diagnostic methods used);

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(b) vaccination policy and other preventive actions;

(c) control mechanism and, where relevant, programmes;

(d) measures in case of positive findings or single cases;

(e) notification systems in place;

(f) history of the disease and/or infection in the country.

B. Each year the following must be described:

(a) relevant susceptible animal population (together with the date the figures relate to):
- — number of herds or flocks,
- — total number of animals, and
- — where relevant, methods of production involved;

(b) number and general description of the laboratories and institutions involved in monitoring.

C. Each year the following details on each zoonotic agent and data category concerned must be described with their consequences:

(a) changes in the systems already described;

(b) changes in previously described methods;

(c) results of the investigations and of further typing or other method of characterisation in laboratories (for each category reported on separately);

(d) national evaluation of the recent situation, the trend and the sources of infection;

(e) relevance as zoonotic disease;

(f) relevance to human cases, as a source of human infection, of findings in animals and food;

(g) control strategies recognised that could be used to prevent or minimise transmission of the zoonotic agent to humans;

(h) if necessary, any specific action decided in the Member State or suggested for the Community as a whole on the basis of the recent situation.

D. Reporting of results of examinations

Results shall be given by stating the number of epidemiological units investigated (flocks, herds, samples, batches) and the number of positive samples according to the case definition. The results shall, when necessary, be presented in a way which shows the geographical distribution of the zoonosis or the zoonotic agent.

E. For food-borne outbreak data:

(a) total number of outbreaks over a year;

(b) number of human deaths and illnesses in these outbreaks;

(c) the causative agents of the outbreaks, including, where possible, serotype or other definitive description of the agents. Where the identification of the causative agent is not possible, the reason for such unidentifiability should be stated;

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(d) foodstuffs implicated in the outbreak and other potential vehicles;

(e) identification of the type of place where the foodstuff incriminated was produced/ purchased/acquired/consumed;

(f) contributory factors, for example, deficiencies in food processing hygiene.

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(**1**) OJ C 304 E, 30.10.2001, p. 250.

(**2**) OJ C 94, 18.4.2002, p. 18.

(**3**) Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 161), Council common position of 20 February 2003 (OJ C 90 E, 15.4.2003, p. 9) and position of the European Parliament of 19 June 2003 (not yet published in the Official Journal).

(**4**) OJ L 62, 15.3.1993, p. 38. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

(**5**) OJ 121, 29.7.1964, p. 1977. Directive as last amended by Commission Regulation (EC) No 1226/2002 (OJ L 179, 9.7.2002, p. 13).

(**6**) OJ L 46, 19.2.1991, p. 19. Directive as last amended by Commission Decision 2003/708/EC (OJ L 258, 10.10.2003, p. 11).

(**7**) OJ L 268, 3.10.1998, p. 1.

(**8**) See page 1 of this Official Journal.

(**9**) OJ L 31, 1.2.2002, p. 1.

(**10**) OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 1494/2002 (OJ L 225, 22.8.2002, p. 3).

(**11**) OJ L 224, 18.8.1990, p. 19. Decision as last amended by Decision 2001/572/EC (OJ L 203, 28.7.2001, p. 16).

(**12**) OJ L 184, 17.7.1999, p. 23.

(**13**) Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (OJ L 186, 30.6.1989, p. 23).

(**14**) OJ L 325, 12.12.2003, p. 1.’