Proposal for a Directive of the European Parliament and of the Council on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC

(2001/C 304 E/18)

(Text with EEA relevance)

COM(2001) 452 final — 2001/0176(COD)

(Submitted by the Commission on 1 August 2001)

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,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The protection of human health against diseases and infections directly or indirectly transmissible from animals to man (zoonoses) is of paramount importance.

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

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

(4) 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 [1] provided for the establishment of a monitoring system for certain zoonoses both at the level of Member States and at Community level.

(5) The results of the monitoring are collected yearly from the Member States and compiled by the Commission, with the assistance of the Community Reference Laboratory for the epidemiology of zoonoses. The results have been published yearly since 1995 and they provide a basis for the evaluation of the current situation concerning zoonoses and zoonotic agents. However, the data collection systems are not harmonised and therefore do not permit comparisons between Member States.

(6) Monitoring and control of certain zoonoses in animal populations has been provided for by other Community legislation, in particular Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine [2], as regards bovine tuberculosis and bovine brucellosis and Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals [3], as regards ovine and caprine brucellosis.

(7) Moreover, Regulation (EC) No .../... of the European Parliament and of the Council of ... [on the hygiene of foodstuffs] covers specific elements necessary for prevention, control and monitoring of zoonoses and zoonotic agents, and includes specific requirements for the microbiological quality of food.

(8) Directive 92/117/EEC provides for collection of data on human cases of zoonoses. 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 [4] was adopted in order to reinforce the collection of such data and to contribute to improving the prevention and control, in the Community, of communicable diseases.

(9) The collection of data on the occurrence of zoonoses and zoonotic agents in feedingstuffs, animal populations, products of animal origin and in humans is necessary to determine the trends and sources of zoonoses.

---

[1] OJ L 62, 15.3.1993, p. 38. Directive as last amended by Directive 1999/72/EC of the European Parliament and of the Council (OJ L 210, 10.8.1999, p. 12).

[2] OJ 121, 29.7.1964, p. 1977. Directive as last amended by Directive 2000/20/EC (OJ L 163, 4.7.2000, p. 35).

[3] OJ L 46, 19.2.1991, p. 19. Directive as last amended by Commission Decision 94/953/EC (OJ L 371, 31.12.1994, p. 14).

[4] OJ L 268, 3.10.1998, p. 1.

(10) The Scientific Committee on Veterinary Measures relating to Public Health has, in its Opinion on zoonoses adopted on 12 April 2000, considered that the current measures to control food-borne zoonotic infections are insufficient and that the epidemiological data as currently collected by Member States are incomplete and not fully comparable. On that basis, 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.

(11) It is, therefore, necessary to improve the existing monitoring and data collection systems established by Directive 92/117/EEC. Simultaneously, the specific control measures established by Directive 92/117/EEC will be replaced by the rules laid down in Regulation (EC) No .../... of the European Parliament and of the Council of ... [on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC]. Directive 92/117/EEC should therefore be repealed.

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

(13) Where necessary, procedures should be created which provide data on a harmonised basis, making 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.

(14) 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.

(15) Alongside emerging new zoonoses and zoonotic agents, known zoonotic organisms may be converted into new strains. The emergence of resistance to antimicrobial agents is a characteristic that should be monitored.

(16) Since providing data in a harmonised way, to form the basis for risk assessment of zoonotic organisms of importance at Community level cannot be sufficiently achieved by the Member States and can therefore, be better achieved at Community level, the Community may 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.

(17) In addition to general monitoring, specific needs may be recognised which may necessitate the establishment of co-ordinated monitoring programmes. Attention should be paid in particular to zoonoses listed in Annex I, part A of Regulation (EC) No .../... [on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC].

(18) Food-borne outbreaks of zoonoses, if thoroughly investigated, 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 a close co-operation between the various authorities.

(19) Transmissible spongiform encephalopathies are subject to Regulation (EC) No .../... of the European Parliament and of the Council of ... [laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies].

(20) In order 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 and to the European Food Authority in the form of reports, which should also be made available to the public in an appropriate way.

(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 [1], 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.

(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) Since the said measures are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [2], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision. The Commission should be assisted by the Committee on Food Safety and Animal Health set up by Regulation (EC) No .../... of the European Parliament and of the Council [laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food],

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 and zoonotic agents are properly monitored so that the necessary information may be collected in the Community to evaluate trends and sources of zoonoses and zoonotic agents. That evaluation shall provide a basis for the action to be taken to prevent and control zoonoses and zoonotic agents relevant to the Community.

2. This Directive covers:

(a) the monitoring of zoonoses and zoonotic agents, taking into account specific features such as antimicrobial resistance related to zoonotic agents, in animal populations at the stage of primary production of animals, and, where necessary, at other stages of food chain, including the production of feedingstuffs and further preparation and production of products of animal origin;

(b) the epidemiological investigation of food-borne outbreaks;

(c) the exchange of information related to zoonoses and zoonotic agents;

(d) the adoption of specific rules on monitoring.

3. This Directive shall apply without prejudice to more specific Community provisions on animal health, animal nutrition, food hygiene, communicable diseases, health and safety at workplace and gene technology.

4. This Directive shall not apply to transmissible spongiform encephalopathies.

Article 2

Definitions

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

1. 'zoonosis' means any disease and/or infection which is naturally transmissible directly or indirectly from animals to humans;

2. 'zoonotic agent' means any virus, bacterium, fungus, parasite or other biological entity which is likely to cause a zoonosis;

3. '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;

4. 'communicable diseases' means diseases caused by zoonotic agents occurring in humans which are covered by Decision No 2119/98/EC;

5. 'food business' means a business as defined in Article 2 of Regulation (EC) No .../... [on the hygiene of foodstuffs];

6. 'food business operator' means the person or persons responsible for ensuring that the requirements of this Directive are met within the food business under his/her or their supervision;

7. 'food-borne outbreak' means the observation under given circumstances of an incidence of two or more human cases of the same disease and/or infection, or the situation when the observed number of cases exceeds the expected number and where the cases are linked, or are probably linked, to the same food source;

[1] OJ L 224, 18.8.1990, p. 19. Decision as last amended by Council Decision 2001/12/EC (OJ L 3, 6.1.2001, p. 27).

[2] OJ L 184, 17.7.1999, p. 23.

8. 'monitoring' means a system of collecting, analysing and disseminating data on the occurrence of zoonoses, zoonotic agents and antimicrobial resistance related thereto;

9. 'primary production' means production as defined in Article 2 of Regulation (EC) No .../... [on the hygiene of foodstuffs].

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 disseminated in accordance with the requirements of this Directive and of any provision adopted pursuant to it.

2. Each Member State shall designate its competent authority for the purposes of this Directive and notify the Commission thereof.

3. Each Member State shall ensure that effective and continuous co-operation based on a free exchange of general information and, where necessary, of specific data, shall be established between its competent authority designated for the purposes of this Directive and:

(a) the competent authorities for the purposes of the Community legislation on animal health,

(b) the competent authorities for the purposes of the Community legislation on food hygiene,

(c) the structures and/or authorities referred to in Article 1 of Decision No 2119/98/EC.

4. Each Member State shall ensure that the relevant officials of the competent authority for the purposes of this Directive are suitably qualified to undertake their duties and, where necessary, are trained in microbiology and epidemiology.

CHAPTER II

MONITORING OF ZOONOSES AND ZOONOTIC AGENTS

Article 4

General rules on monitoring of zoonoses and zoonotic agents

1. The Member States shall collect data that is relevant in order to identify and characterise hazards, to assess exposures and to characterise risks related to zoonoses and zoonotic agents. The monitoring shall take place in animal populations, especially at the stage of primary production but also, where necessary, at the other stages in the food chain including the production of feedingstuffs and further preparation and production of products of animal origin.

2. The monitoring shall cover zoonoses and zoonotic agents listed in Annex I, part 1.A.

Where the epidemiological situation in a Member State so warrants, zoonoses and zoonotic agents listed in Annex I, part 1.B shall also be monitored.

3. The monitoring shall be based on the systems in place in Member States. Where necessary, 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 diseases. Those detailed rules shall specify in particular:

(a) the animal population or sub-populations 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 methods to be used;

(e) laboratory methods to be used in testing;

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

Article 5

Monitoring of antimicrobial resistance

1. Member States shall ensure that the monitoring provides data on the occurrence of antimicrobial resistance in zoonotic agents in accordance with the requirements set out in Annex II.

2. Detailed rules for the implementation of paragraph 1 shall be laid down in accordance with the procedure referred to in Article 12(2).

Article 6

Co-ordinated monitoring programmes

1. Co-ordinated monitoring programmes concerning one or more zoonoses and/or zoonotic agents may be established in accordance with the procedure referred to in Article 12(2), where appropriate after consultation of the European Food Authority. Co-ordinated monitoring programmes may be established especially when specific needs are identified to assess risks, or in order to establish base-line values related to zoonoses and/or zoonotic agents at the level of Member States and/or at Community level.

2. Where a co-ordinated monitoring programme is established, special reference shall be made to zoonoses and zoonotic agents in animal populations referred to in Annex I, part A, of Regulation (EC) No .../... [on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC].

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

4. The results of the co-ordinated monitoring programmes shall be provided to the European Food Authority.

CHAPTER III

FOOD-BORNE OUTBREAKS

Article 7

Epidemiological investigation of food-borne outbreaks

1. Member States shall ensure that when a food business operator becomes aware that a foodstuff produced or processed by him has caused, or is likely to cause, a food-borne outbreak, he shall inform the competent authority without delay. The foodstuff, or an appropriate sample thereof, shall be preserved in a way which neither impede its investigation in a laboratory, nor a further investigation of the suspected outbreak.

2. When a competent authority receives information pursuant to paragraph 1 or is otherwise informed of a food-borne outbreak, it shall investigate the outbreak in co-operation 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 and to the European Food Authority a summary report on the results of the investigations carried out, containing the information referred to in Annex IV, Part E, to this Directive. Detailed rules concerning the investigation of food-borne outbreaks may be laid down in accordance with the procedure referred to in Article 12(2).

3. 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 diseases and food hygiene.

4. Measures concerning the suspected foods and their production environment shall be laid down in accordance with Article 12 of Regulation (EC) No .../... [on the hygiene of foodstuffs].

CHAPTER IV

EXCHANGE OF INFORMATION

Article 8

Examinations for zoonoses at the level of food business operators

Member States shall ensure that food business operators keep, for a period to be specified by the competent authority, and communicate to the latter at its request, the results of examinations for the presence of the zoonoses and zoonotic agents listed in Annex I, part 1.A.

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 related thereto in their territory.

Each Member State shall transmit to the Commission and to the European Food Authority every year by the end of May a report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance related thereto, covering the data collected pursuant to Articles 4 to 7 during the previous year. The reports, or summaries of them, shall be made publicly available.

The reports shall also contain the information referred to in Article 3(2)(b) of Regulation (EC) No .../... [on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC].

The 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 which 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 European Food Authority shall each year examine the reports referred to in paragraph 1 and within nine months after receiving them shall publish a summary report on the trends and sources of zoonoses, zoonotic agents and antimicrobial resistance related thereto in the Community.

When preparing the summary report, the European Food Authority may take into consideration other data on zoonoses, zoonotic agents and antimicrobial resistance related thereto such as those provided for in the framework of the Community legislation on animal health, food control, food hygiene and communicable diseases, and in particular:

— Article 8 of Directive 64/432/EEC,

— Article 14(2) of Council Directive 89/397/EEC ([1]),

— Article 24 of Decision 90/424/EEC,

— Article 4 of Decision 2119/98/EC.

CHAPTER V

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 in Decision 90/424/EEC, the responsibilities and tasks of the Community Reference Laboratories, in particular with regard to co-ordination 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 co-ordination of their activities and those of the relevant laboratories in the Member States, may be laid down in accordance with the procedure referred to in Article 12(2).

CHAPTER VI

IMPLEMENTATION

Article 11

Amendments to the annexes and transitional measures

Where appropriate after consultation of the European Food Authority, the annexes may be amended or any appropriate transitional measures may be adopted in accordance with the procedure referred to in Article 12(2).

Article 12

Committee

1. The Commission shall be assisted by the Committee on Food Safety and Animal Health instituted by Regulation (EC) No .../... of the European Parliament and of the Council [laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food].

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 13

Transposition

1. Member States shall adopt and publish before 1 November 2002 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 January 2003.

When Member States adopt those provisions, 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.

([1]) OJ L 186, 30.6.1989, p. 23 (to be replaced in due course by a Regulation on official food and feed safety controls; referred to as Action No 4 in the White Paper on food safety (COM(1999) 719 final)).

CHAPTER VII

FINAL PROVISIONS

Article 14

Repeal

Directive 92/117/EEC is repealed with effect from 1 January 2003.

However, measures which Member States have adopted pursuant to Article 8(1) of that Directive and 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 6 of Regulation (EC) .../... [on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC].

Article 15

Amendment of Decision 90/424/EEC

Decision 90/424/EEC is amended as follows:

1. Article 29 is replaced by the following:

'1. A Community financial contribution may be requested by Member States 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 plan referred to in Article 6 of Regulation (EC) No .../... of the European Parliament and of the Council [on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC] (*).

The level of Community financial participation for measures provided for in Annex II, point C, to Regulation (EC) No .../... [on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC] shall be fixed at a maximum of 50 % of the cost incurred in the Member State by way of compensation for owners for the slaughter and destruction measures of breeding flocks of Gallus gallus because of the infection concerned.

(*) OJ L ...'.

2. The following Article 29a 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 .../... [Regulation of the European Parliament and of the Council on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC].'

3. In the Annex, the following indents are added to the list under Group 2:

'— Campylobacteriosis

— Cryptosporidiosis

— Listeriosis

— Salmonellosis (zoonotic salmonella)

— Trichinellosis

— Verotoxigenic Escherichia coli.'

Article 16

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 17

Addressees

This Directive is addressed to the Member States.

ANNEX I

Part 1. Zoonoses and zoonotic agents to be monitored pursuant to Article 4

A. **Zoonoses and zoonotic agents to be included in monitoring**

Brucellosis and agents thereof

Campylobacteriosis and agents thereof

Cryptosporidiosis 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

   Influenzavirus

   Rabies

   Tick borne viruses

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

   Cysticercosis and agents thereof

   Toxoplasmosis and agents thereof

4. Other zoonoses and zoonotic agents

Part 2. Criteria for addition or deletion of zoonoses in the list in Part 1

When necessary, zoonoses or zoonotic agents may be added or deleted as regards the list in Part 1 taking into account especially

— their occurrence in animal and human populations, feed and food

— their gravity in humans,

— their economic consequences for health care and food businesses,

— epidemiological trends in animal and human populations, feed and food.

ANNEX II

Requirements for monitoring of antimicrobial resistance pursuant to Article 5

A. **General requirements**

Monitoring of antimicrobial resistance should provide relevant information to detect the emergence of and to identify the trends in antimicrobial resistance in zoonotic agents.

Monitoring should be complementary to the monitoring of human isolates conducted according to Council Decision 2119/98/EC.

The Member States shall ensure that the monitoring system for antimicrobial resistance provided for in Article 5 provides at least following information:

1. animal species included in monitoring

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 shall ensure that the above monitoring provides relevant information at least with regard to:

— Antibiograms for a representative number of isolates of Salmonella spp., Campylobacter jejuni and Campylobacter coli from cattle, pigs and poultry.

ANNEX III

Co-ordinated monitoring programmes as referred to in Article 6

When a co-ordinated monitoring programme is established, at least the following characteristics of the programme shall be defined:

— its purpose

— its time period

— 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 responsibility of competent authorities

— the resources to be allocated

— the estimation of its costs and how they will be covered

— the method and time of reporting the results to the Commission and to other Member States.

ANNEX IV

Requirements for the reports to be submitted pursuant to Article 9

The report referred to in Article 9(1) must provide at least for the following information:

A. **Initially the following shall 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)

(b) Vaccination policy and other preventive actions

(c) Control 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 shall be reported:**

(a) Relevant susceptible animal population (and date the figures are related to)

— Number of herds or flocks

— Total number of animals

(b) Laboratories and institutions involved in reporting

C. **Each year the following details on each zoonotic agent and data category concerned shall 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 of findings in animals and foodstuff to human cases, source of human infection

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

(h) Need of any specific action in the Member State or at EU level on the basis of the recent situation

D. **Reporting of results of examinations**

Results shall be given by stating the number of investigated epidemiological units (flocks, herds, samples, batches) and the number of positive samples according to the case definition. The results shall be, when necessary, 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 ill and dead persons in these outbreaks

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

(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