



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 22 January 2002

**Interinstitutional Files:
2001/0176 (COD)
2001/0177 (COD)**

**13799/1/01
REV 1**

**AGRILEG 250
CODEC 1157**

OUTCOME OF PROCEEDINGS

of:	Working Party of Veterinary Experts (Public Health)
on:	26 October, 29/30 November & 6/7 December 2001
No. Cion prop.:	11405/01 – COM(2001) 452 final
Subject:	Report to the European Parliament and to the Council on the measures to be put in force for the control and prevention of zoonoses accompanied by: <ul style="list-style-type: none">– a 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– a proposal for a 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

I. INTRODUCTION

At the beginning of August the Commission sent the Council a report and two proposals – both subject to the codecision procedure with the European Parliament – on zoonoses (diseases transmissible from animals to humans).

*The Commission report describes experience acquired in recent years and concludes that changes need to be made to the current legislation.
The Commission therefore proposes:*

- *a **Directive** obliging Member States to introduce more efficient and more co-ordinated monitoring systems; and*
- *a **Regulation** to improve monitoring of salmonella and other zoonotic agents present in the food chain.*

II. GENERAL COMMENTS

A. Structure of the proposals

The Working Party approved the Commission's approach of splitting the provisions on zoonoses into two: one act on monitoring and another on control. However, one delegation reserved its position on the form of the acts, preferring two directives.

B. Timing

While welcoming the proposals as a whole, several delegations regretted that the Commission had proposed that some obligations regarding control of zoonoses apply only some years hence. Other delegations commented that the Commission's proposals were ambitious and would be costly for the sectors concerned.

The Commission representative said that the timing proposed was ambitious, but realistic if the control of zoonoses were given the priority that it deserved. In addition, the Commission proposal would maintain the status quo as regards Community cofinancing, initially at least.

C. Miscellaneous

Delegations also asked:

- whether a system of controls carried out by food business operators was an appropriate measure;
- what was to happen to the current system of additional guarantees; and
- whether it would not be better to treat antimicrobial resistance horizontally.

The Commission representative explained that the Commission had no problem with the principle of additional guarantees as applied by Finland and Sweden. These guarantees would, however, have to be reconsidered when the Community as a whole reached the level of control that now existed in those two Member States. Introducing an obligation to monitor antimicrobial resistance in zoonoses was without prejudice to any horizontal proposal that might be made in future.

III. EXAMINATION OF THE DRAFT DIRECTIVE

The Working Party examined the provisions of the draft Directive. In the light of the discussion, the Presidency suggested the amended text **annexed** hereto. The footnotes contain explanations of the amendments and comments made by delegations.

All delegations have scrutiny reservations on the amended text, since no interpretation was available when the Working Party discussed it on 30 November.

AMENDED DRAFT DIRECTIVE

CHAPTER I

INTRODUCTORY PROVISIONS

Article 1

Subject-matter and scope

1. The purpose of this Directive is to ensure that zoonoses, zoonotic agents, food-borne outbreaks and antimicrobial resistance are properly monitored so that the necessary information may be collected in the Community to evaluate relevant trends and sources.
[-]¹
2. This Directive covers:
 - (a) the monitoring of zoonoses and zoonotic agents:
 - (i) at the level of primary production, and
 - (ii) where appropriate to the zoonosis or zoonotic agent concerned, at other stages of the food chain, including in food and feed;
 - (b) the monitoring of antimicrobial resistance;
 - (c) the epidemiological investigation of food-borne outbreaks;
 - (d) the exchange of information related to zoonoses and zoonotic agents; and
 - (e) 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 human diseases, health and safety in the workplace, gene technology and transmissible spongiform encephalopathies.

¹ In the Commission's proposal, the first sentence of this paragraph referred only to the monitoring of zoonoses and zoonotic agents. The amended text better reflects the scope of the proposed Directive and would be consistent with paragraph 2. The second sentence was superfluous. It contained a political statement with no legal effect.

Article 2

Definitions

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

1. *the definitions laid down in Regulation (EC) .../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]; and*

2. *the following definitions:*

(a) “zoonosis” means any disease and/or infection which is naturally transmissible directly or indirectly between animals¹ 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;

[]²

(d) “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; and

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

[]

¹ One delegation wondered why there was no definition of "animals".
The Commission representative said that the term had to be interpreted widely since the Directive would apply to zoonoses such as rabies, which affected wild animals.

² The new paragraph 1 permits the deletion of the definitions of “food business”, “food business operator” and “primary production”, since the “general food law” Regulation defines these terms. The term “communicable diseases” gave rise to political and linguistic concerns. The definition has therefore been dropped and consequential changes have made to the few provisions using the term.

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 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 co-operate so as to guarantee the proper implementation of the requirements of this Regulation.*
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 *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;¹*
 - (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 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 *suitably trained in veterinary science, microbiology or epidemiology, as necessary.*

¹ The Working Party agreed to add a reference to feed, to comply with the "farm to fork" principle.

CHAPTER II

MONITORING OF ZOOSES AND ZOONOTIC AGENTS

Article 4

General rules on monitoring of zoonoses and zoonotic agents

1. 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. Monitoring shall take place:
 - (a) at the level of primary production, and*
 - (b) where appropriate to the zoonosis or zoonotic agent concerned, at other stages of the food chain, including in food and feed;*
2. The monitoring shall cover zoonoses and zoonotic agents listed in Annex I, *Part A*. Where the epidemiological situation in a Member State so warrants ¹, zoonoses and zoonotic agents listed in Annex I, *Part B* shall also be monitored.
3. *Annex I may be amended in accordance with the procedure referred to in Article 12(2) 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) their gravity in humans;*

¹ One delegation suggested replacing "warrant" with "necessitate".

(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.¹

4. The monitoring shall be based on the systems in place in Member States. However, where necessary to make the data easier to examine and summarise², 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 certain communicable human 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 schemes³ 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.

¹ These criteria previously appeared in Annex I. Moving them here gives them greater permanence, since they can no longer be amended by the Committee procedure.

² Expanded to explain the purpose of the harmonised rules.

³ “Schemes” is wider than the previous “methods”. The characteristics of co-ordinated monitoring programmes listed in Annex III already refer to “sampling schemes”.

Article 5

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) [-]. Co-ordinated monitoring programmes may be established especially when specific needs are identified to assess risks, or to establish base-line values related to zoonoses or zoonotic agents at the level of Member States 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

ANTIMICROBIAL RESISTANCE

Article 6

Monitoring of antimicrobial resistance

1. Member States shall ensure, in accordance with the requirements set out in Annex II, that monitoring provides data on the occurrence of antimicrobial resistance in zoonotic agents [and, insofar as they present a threat to public health, other agents].¹
2. Detailed rules for the implementation of paragraph 1 shall be laid down in accordance with the procedure referred to in Article 12(2).

¹ The Presidency suggested making this Article a Chapter in its own right. Its scope could then extend beyond zoonotic agents to linked organisms. However, for this to be possible, the wording of Article 6, and possibly the title of the Directive, would need to be amended. Some delegations agree in principle with a widening of the scope of the provision, at least to cover indicator organisms. However, several delegations have reserved their positions or expressed doubts about the desirability of a wider scope. The Commission representative advocated widening the potential scope of the monitoring of antimicrobial resistance to permit the gradual extension of the requirements of Annex II to other animal populations and other relevant agents.

CHAPTER *IV*

FOOD-BORNE OUTBREAKS

Article 7

*Epidemiological investigation of food-borne outbreaks*¹

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 impedes neither 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 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 Safety 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).

¹ One delegation questioned the point of Article 7, on the grounds that the food hygiene rules already make provision for the necessary measures.
Other delegations asked for clarification.
The Commission representative explained that the investigations referred to in Article 7 would be wider in scope than the existing "early warning" system, and that the data would be collected for a different purpose. The early warning system was designed to enable the authorities concerned to react as quickly as possible to any risk to human health, whereas the aim of investigations of food-borne outbreaks was to identify the main causes of food-borne illnesses and draw conclusions therefrom. The Commission would strive to ensure that the Community system was consistent with the WHO system.

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 human diseases, food hygiene and the general requirements of Community food legislation, in particular those concerning emergency measures and procedures for withdrawing food and feed from the market.¹

CHAPTER V

EXCHANGE OF INFORMATION

Article 8

Examinations for zoonoses at the level of food business operators

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:

1. keep the results for a period to be specified by the competent authority; and
2. communicate them to the latter at its request.²

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.

Every year³ each Member State shall transmit to the Commission 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.

¹ The new wording of this paragraph obviates the need for paragraph 4 of the Commission proposal.

² At the request of some delegations, the new wording of Article 8 makes it clear that Member States are not obliged to make food business operators carry out examinations and that the examinations may also concern zoonoses and zoonotic agents listed in Annex I, Part B.

³ The Presidency suggests consigning the time-limits to Annex IV to simplify the text.

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 Commission shall send the reports referred to in paragraph 1 to the European Food Safety Authority, which shall examine them and publish each year 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 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 2119/98/EC.

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 **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 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 **VII**

IMPLEMENTATION

Article 11

Amendments to the annexes and transitional measures

Annexes II to IV may be amended and any appropriate transitional measures adopted in accordance with the procedure referred to in Article 12(2).¹

¹ The new Article 13 clarifies the circumstances in which it is necessary to consult the European Food Safety Authority.

Article 12

Committee

1. The Commission shall be assisted by the Committee on *the Food Chain* and Animal Health instituted by Regulation (EC) No .../... [*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 6 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.
3. The period provided for in Article 6(6) of Decision 1999/468/EC shall be three months.

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 co-ordinated monitoring programme in accordance with Article 5.*¹

Article 14

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 The aim of the new wording of this Article is to clarify the circumstances in which the Commission would have to consult the European Food Safety Agency.

CHAPTER VIII

FINAL PROVISIONS

Article 15

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 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)..../.... [*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 16

Amendment of Decision 90/424/EEC

Decision 90/424/EEC is amended as follows:

1. Article 29 is replaced by the following:
 - "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 plan referred to in Article 5 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 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. ¹

* 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 5 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*]."

¹ Several delegations wondered whether measures other than slaughtering and destroying infected flocks could not be considered. The Commission representative said that the draft Directive preserved the status quo as regards control measures cofinanced by the Community, initially at least. Under the current rules the destruction of flocks was not compulsory: marketing processed products was also a possibility. However, it would be dangerous to permit alternative measures offering lesser guarantees of public health protection.

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 17

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 18

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

[-]

A. Zoonoses and zoonotic agents to be included in monitoring¹

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*

¹ The Commission representative explained that the proposal for a Directive departed from current practice in providing for systematic monitoring of cryptosporidiosis. The list in Part A of Annex I contains all zoonoses and zoonotic agents deemed priorities in the report of 12 April 2000 by the Scientific Committee on Veterinary Measures Relating to Public Health. One delegation objected that cryptosporidiosis was mainly water-borne. Another delegation wanted echinococcosis and cryptosporidiosis transferred to Part B.

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

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

[]¹

¹ The criteria for amending the lists of zoonoses now appear in Article 4.

ANNEX II

Requirements for monitoring of antimicrobial resistance pursuant to Article 6

A. General requirements

[–]¹

Member States must ensure that the monitoring system for antimicrobial resistance provided for in Article 6 provides at least the 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 must ensure that the monitoring system 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 and food of animal origin derived from those species.²

¹ These provisions contained only recommendations and duplicated binding provisions in the Articles.

² The Working Party agreed to widen the requirements to include by-products in line with the principle of an integrated "farm to fork" policy. One delegation suggests that this requirement also apply to the most important animal pathogens in the Member State concerned and *Escherichia coli* and Enterococci and to all animals (farmed, companion and wild) and all food of animal origin.

ANNEX III

Co-ordinated monitoring programmes as referred to in Article 5

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

- its purpose
- its time period 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 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 and *their addressees*.

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 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);
- (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 the following must be described:

- (a) relevant susceptible animal population (and date the figures 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 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 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 agents. 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.

F. Time limits

Member States shall forward their annual reports to the Commission and the European Food Authority by the end of May. If the date of receipt of these reports so permits, the Authority shall publish a summary report by the end of that year.