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ADDENDUM TO REPORT

from: Working Party of Veterinary Experts (Public Health) on: 5 April 2002

to: S April 2002

to: Coreper

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No. Cion prop.: 11405/01 – COM(2001) 452 final

Subject: Zoonoses and zoonotic agents:

proposed Directive of the European Parliament and of the Council on monitoring
 proposed Regulation of the European Parliament and of the Council on control

At its meetings on 11 March and 5 April 2002, the <u>Working Party</u> reviewed the draft text of the proposed Directive on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC, as annexed to document 13799/1/01 REV 1.

The revised text in the **Annex** reflects the outcome of the discussions.

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REVISED DRAFT DIRECTIVE

CHAPTER I

INTRODUCTORY PROVISIONS

Article 1

Subject-matter and scope 1

- 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 a 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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Paragraph 1 now provides a more precise summary of the purpose of the Directive as regards antimicrobial resistance and food-borne outbreaks. Unnecessary details have been deleted from paragraph 2.

Definitions

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

- 1. the definitions laid down in Regulation (EC) No 178/2002 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 <u>between</u> animals <u>and</u> humans;
 - (b) "zoonotic agent" means any virus, bacterium, fungus, parasite or other biological entity which is likely to cause a zoonosis;
 - "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 ¹, that is usually sufficient to inhibit or kill micro-organisms of the same species;

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- (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.

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The representative of the Commission explained that the term "antimicrobial agent" was intended to refer to medicinal products and antimicrobial feed additives, not to other products, such as disinfectants and preservatives, with antimicrobial properties.

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 <u>a competent authority or competent authorities</u> for the purposes of this Directive and notify the Commission thereof. <u>If a Member State</u> <u>designates more than one competent authority, it shall:</u>
 - (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;
 - (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, or competent authorities, referred to in paragraph 2 undertake suitable initial and ongoing training in veterinary science, microbiology or epidemiology, as necessary.

The <u>Working Party</u> agreed that the requirement for officials of competent authorities to be suitably qualified was unnecessary, but that there should be a requirement for suitable initial and ongoing training. It noted that the draft Community legislation on food hygiene currently under discussion contained duties for food business operators regarding staff training.

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 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 <u>at the stage or stages of the food chain most appropriate to the zoonosis or zoonotic agent concerned; that is:</u>
 - (a) at the level of primary production, and/or
 - (b) at other stages of the food chain, including in food and feed. 1
- 3. Monitoring shall cover zoonoses and zoonotic agents listed in Annex I, <u>Part A</u>. Where the epidemiological situation in a Member State so warrants, zoonoses and zoonotic agents listed in Annex I, <u>Part B</u> shall also be monitored.
- 4. 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;
 - (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.

The <u>Working Party</u> agreed this revised wording to make clear that monitoring in populations of live animals may not always be possible or appropriate.

<u>5.</u> 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 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 <u>schemes</u> 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. ¹

While accepting that the desirability of further harmonisation of routine monitoring to ensure the comparability of data, <u>several delegations</u> believed that Article 4 should more clearly state its objectives. Paragraphs 5 and 6 seek to do this. In addition, paragraph 6, or a declaration, could clarify that the Commission should take account of the principles of subsidiarity and proportionality, and the need to avoid creating undue financial or administrative burdens for competent authorities, before making any proposal.

Co-ordinated monitoring programmes ¹

- 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 [-] 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.

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<u>Article 6</u>

Food business operators' duties³

- 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).

This Article previously appeared in the Chapter on the exchange of information. A requirement to keep relevant isolates has been added.

One delegation asked how it would be possible to establish control targets under Regulation before base-line values had been established through co-ordinated monitoring programmes. The representative of the Commission explained that his Institution was considering funding a study, which would take place before the adoption of the Directive, to gather the data needed for the adopt of the first control targets under the Regulation.

The Working Party agreed to move the provision on the exchange of information to Article 9.

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 data on the occurrence of antimicrobial resistance in zoonotic agents [and, insofar as they present a threat to public health, other agents]. 1
- 2. Such monitoring shall complement the monitoring of human isolates conducted according to Council Decision 2119/98/EC. ²
- <u>3.</u> Detailed rules for the implementation of <u>this Article</u> shall be laid down in accordance with the procedure referred to in Article 12(2).

The <u>Commission representative</u> has indicated that his Institution is ready to modify its proposal to widen 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.

A <u>large majority of delegations</u> support or can accept such a modification. In particular, a <u>majority of delegations</u> agree that monitoring should cover indicator organisms in addition to zoonotic agents. (Indicator or "commensal" bacteria are considered to constitute a reservoir of resistance genes, which they can transfer to pathogenic bacteria.) However, <u>several delegations</u> have stressed that the precise scope of monitoring and its implications would require careful consideration. <u>Some delegations</u> would prefer to restrict monitoring to zoonotic agents.

This paragraph appeared in Annex II in the Commission's proposal.

CHAPTER IV

FOOD-BORNE OUTBREAKS

Article 8

Epidemiological investigation of food-borne outbreaks ¹

- 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 implicated foodstuff, 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. <u>The competent authority shall investigate food-borne outbreaks</u> 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 (who 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 Annex IV, Part E, to this Directive.
- <u>3.</u> 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.

The revised drafting of this Article avoids duplication of the requirements of the general food law Regulation.

One delegation regretted the fact that the Article was not tailored to deal with food-borne outbreaks such as listeriosis, where it was often difficult to trace individual cases back to a common source. The representative of the Commission suggested that the adoption of harmonised rules for routine monitoring under Article 4, or of a revised Article on examination for zoonoses by food business operators, could provide a solution.

CHAPTER V

EXCHANGE OF INFORMATION

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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 <u>transmit to the Commission</u> 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 <u>Articles 4, 7 and 8</u> during the previous year. The reports, or 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/... [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].

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.

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The former Article 8 now appears in Chapter II.

2. <u>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 each year a summary report on the trends and sources of zoonoses, zoonotic agents and antimicrobial resistance related thereto in the Community.</u>

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.
- 3. Member States shall provide the Commission with the results of co-ordinated monitoring programmes established in accordance with Article 5. The Commission shall send the results to the European Food Safety Authority. The results, or summaries of them, shall be made publicly available.²

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).)

This paragraph combines the former Article 5(4) and part of Article 9(1) (which, as a consequence, no longer refers to Article 5).

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

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

Committee

- 1. The Commission shall be assisted by the Committee on *the Food Chain* and Animal Health instituted by Regulation (EC) No 178/2002.
- 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.

<u>Article 13</u>

Consultation of the European Food Safety Authority ¹

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.

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.

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Some delegations wondered whether, in view of the wide scope of the Directive, it would always be appropriate to consult the EFSA. The <u>representative of the Commission</u> undertook to check this point.

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 1

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).

Some delegations have reservations on the financial aspects of the Commission's proposals.

- 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.
- * 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]."

- 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."

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

A. Zoonoses and zoonotic agents to be included in monitoring ¹

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

Some delegations objected to the inclusion of cryptosporidiosis, on the grounds that it was a regional and mainly water-borne disease. One of these delegations also wanted echinococcosis and trichinellosis transferred to Part B.

<u>Some delegations</u> argued that it was necessary to specify which agents of the listed zoonoses monitoring should cover and to clarify the relationship with existing Community legislation, such as Directive 64/432/EEC.

The Commission representative explained that the proposal for a Directive departed from current practice only in providing for systematic monitoring of cryptosporidiosis. The list in Part A of Annex I contained 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. While it also covered brucellosis and tuberculosis, this would not require any duplication of effort within Member States. It would be possible to amend the list through comitology in the light of experience and new scientific advice.

The <u>Working Party</u> agreed that the recitals should contain a reference to existing vertical legislation and make clear that there was no intention to duplicate current requirements.

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

1. <u>Viral zoonoses</u>

Calicivirus

Hepatitis A virus

Influenza virus

Rabies

Viruses transmitted by ticks

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. <u>Parasitic zoonoses</u>

Anisakiasis and agents thereof

Cysticercosis and agents thereof

Toxoplasmosis and agents thereof

4. Other zoonoses and zoonotic agents

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

ANNEX II

Requirements for monitoring of antimicrobial resistance pursuant to Article 7

A. General requirements

[-] 1

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;
- 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 <u>monitoring system</u> provides relevant information at least with regard to [-] a representative number of isolates of *Salmonella* spp. ², *Campylobacter jejuni* and *Campylobacter coli* from cattle, pigs and poultry <u>and food of animal origin derived from those species.³</u>

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

The reference to antibiograms has been deleted to permit the use of other appropriate methods. One delegation requested clarification of the term "representative number". Another delegation argued that the text should make clear that priority ought to be given to truly zoonotic salmonella serotypes.

The Working Party agreed to widen the requirements to include food of animal origin in line with the principle of an integrated "farm to fork" policy.

One delegation suggested that this requirement also apply to the most important animal pathogens in the Member State concerned and *Escherichia coli* and Enterococciae 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; 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 for the following information. <u>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.</u>

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 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;
- (b) <u>number and general description of the</u> laboratories and institutions involved in <u>monitoring</u>.

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) <u>relevance to human cases, as a source of human infection, of findings in animals and</u> food;
- (g) control strategies recognised that could be used to prevent or minimise transmission of the zoonotic agent to humans;
- (h) <u>if necessary</u>, any specific action <u>decided</u> in the Member State or <u>suggested for the</u> 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 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 *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 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.