COMMISSION OF THE EUROPEAN COMMUNITIES

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2001/0176 (COD)
2001/0177 (COD)

Amended 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

Amended proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the control of salmonella and other specified food-borne zoonotic agents

(presented by the Commission pursuant to Article 250(2) of the EC-Treaty)

EXPLANATORY MEMORANDUM

A. Procedure

In August 2001 the Commission submitted proposals for a Directive of the European Parliament and the Council on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC and for a Regulation of the European Parliament and 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 (COM(2001) 452 final – 2001/0176(COD)-2001/0177(COD)) for adoption by the co-decision procedure laid down in Article 251 of the Treaty establishing European Community.

On 15 May 2002 the European Parliament took position in the first reading. The Parliament adopted 66 Amendments (respectively 30 on the proposed Directive and 36 on the proposed Regulation), of which 54 (respectively 28 and 26) were accepted by the Commission in the entirety or in part or on conditions or after reformulation.

In the light of these developments, the Commission has drafted these amended proposals. The amendments are in 'bold' and 'underlined', where adding or modifying, and in "bold" and "strikeout', where deleting text. Only extensive linguistic changes will be mentioned below. Editorial changes made pursuant to B III below are not marked in the text.

B. Explanations of the amendments

I. Proposed Directive on monitoring of zoonoses and zoonotic agents

1. Scope to cover products of plant origin (and mixtures)

The European Parliament's amendments 1, 6 and 12 wholly or partly require zoonotic agents to be monitored not only in animals, feed and food of animal origin as foreseen in the Commission proposals, but also in food of plant origin and food of mixed origin. The Commission has accepted these amendments. Monitoring of products of plant origin is a useful addition, as vegetables and fruits are increasingly found to harbour zoonotic agents and to form a source of human infections. The new wording in these revised proposals is not the same as the European Parliament's amendments, but is consistent with them: it refers to "food", which according to Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, means any substance or product intended to be, or reasonably expected to be ingested by humans.

2. Collection of comparable data

The European Parliament's amendments 5, 12, 14, 28 and 31 wholly or partly aiming to strengthen the collection of comparable and uniform data on zoonoses from the Member States, have been taken into account by amending the relevant articles. These amendments follow the objective of the proposal and are largely along the lines followed by the Council working group.

3. Co-operation between national authorities

The European Parliament's amendments 9 and 10 ask for a non-exhaustive list of authorities (including competent authorities for legislation on animal feed) and organisations to be included in the co-operation required in the collecting of zoonoses data at the national level. The Commission has introduced these amendments in the relevant article. The amendments improve the proposal from a technical and editorial point of view and they are globally in line with the developments in the Council working group.

4. Reporting and publication of reports

The European Parliament's amendments 4, 8 and part of amendment 20 requesting that the national reports on zoonoses should be published without delay, are incorporated in the relevant articles. The other part of the amendment 20 seeking to shorten the time allowed for the Member States to submit their reports to the Commission is not accepted. Although the tightening of the reporting schedule would be desirable as such, it is unrealistic in the light of the experience with the existing Directive. However amendment 29 and 32, which would shorten the time for the European Food Safety Authority to compile the Community report, seems to be realistic and this amendment is included in the new proposal. Finally, the revised proposal lays down that the Member States will send their national reports to the Commission only, which will then send them to the European Food Safety Authority. The latter will produce the general report.

5. Responsibilities of food business operators to keep samples and testing results

The European Parliament's amendments 17 and 19 tightening the responsibilities of food businesses to keep relevant food samples in case of food-borne outbreaks and the testing results on zoonotic agents are included in the proposed text. The amendments are largely along the lines followed by the Council working group.

6. Broadening the scope of monitoring of anti-microbial resistance

The European Parliament's amendments 28-33 wholly or partly broadening the scope of the monitoring of antimicrobial resistance to agents other than zoonotic ones are included in the proposed text, subject to editorial change in the light of the development in the Council.

7. Comitology procedure

The European Parliament's amendment 23 requests that the Committee on the Communicable Diseases Network should also be consulted where appropriate, in addition to the Standing Committee on the Food Chain and Animal Health. Although it would create stronger linkage between the veterinary matters and public health, it would not be consonant with the principles and rules laid down in Council Decision 1999/468/EC, as required by Article 202, third indent, of the Treaty. Only one committee may assist the Commission in the exercise of the powers that the Council has delegated to it. Therefore, the wording of the relevant article has been revised, so that the Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, or where appropriate, by the other Committee.

8. Criteria for zoonoses and other agents to be included in monitoring

The European Parliament's amendments 13, 25, 26, 28 and 31 transferring certain criteria from annexes to articles have been taken into account in the proposal. The amendments would enable the European Parliament and the Council to be involved if further amendments would be proposed to the criteria. These criteria concern the addition and deletion of zoonoses subject to monitoring or to the need for the monitoring of anti-microbial resistance to complement the monitoring of human isolates.

9. Consultation of European Food Safety Authority

The European Parliament's amendment 16 making the consultation of the European Food Safety Authority compulsory when establishing co-ordinated monitoring programmes is incorporated in the proposal. This type of scientific input would always be useful. However, the amendment 22 seeking for systematic prior consultation before amending the annexes or taking transitional measures is rejected. This is because scientific advice is not necessary when establishing purely administrative measures.

10. Various topics

The European Parliament's amendment 18 is rejected as it would require systematic microbiological studies (instead of "as far as possible") during investigation of food-borne outbreaks. This may not always be possible if the suspected food is not available any longer.

European Parliament's amendments 2, 3, 6, 7, 11, 24, 27 improve the proposal from a technical and editorial point of view. They have been taken into account in the revised proposal.

II. Proposed Regulation on the control of salmonella and other food-borne zoonotic agents

11. Overall objective of Regulation

The European Parliament's amendment 7 adding an overriding long-term objective to avoid completely the presence of zoonotic agents in the feed and food chain, is rejected. This kind of objective is unrealistic; it is impossible to achieve total absence of zoonotic agents in the food and feed chain irrespective the control measures taken.

12. Involvement of the feed business operators in controls

The European Parliament's amendments 11, 15, 17, 18, 19 and 20 involving feed industry together with the food industry in the control measures to combat zoonoses, are taken into account in the proposal. The amendments clarify and strengthen the Regulation and are in line with the developments in the Council working groups.

13. Exclusion of production for own use from the scope

The European Parliament's amendment 8 exempting the production for domestic use from the scope of the Regulation is introduced in the proposal. This is in line with Article 1.3 of Regulation (EC) No 178/2002 of 28 January 2002.

14. Inclusion of products (food) of plant origin in the scope

The European Parliament's amendments 1 and 16 seeking to add controls of food and other products of plant origin in the scope of controls, is rejected. Feed of plant origin is already covered by the Regulation. The control measures similar to those in animal populations foreseen in this Regulation are not possible in plant production. The controls of food of plant origin is tackled in the recast of food hygiene legislation (COM(2000) 438).

15. National control programmes to take into account economic repercussions

The European Parliament's amendment 14 requiring Member States, when drawing up their national control programmes, to take into account the cost and benefits in order to achieve appropriate distribution of costs, is introduced in the relevant article.

16. Prohibition on use of antibiotics

The European Parliament's amendment 3 adding an objective to prohibit the use of any antibiotics for preventive purposes or to promote growth in animals is rejected. The Commission already announced the total phasing out of antimicrobials used for growth promoting purposes in a separate proposal. The use of antibiotics as veterinary medicines for preventive purposes does not fall into the scope of this Regulation. However, the Commission intends to ask for a scientific opinion on the risks and benefits of the use of antimicrobials to control salmonella in animal populations.

17. Additional guarantees in intra-Community trade

The European Parliament's amendments 2 and 22 aiming to grant transitional additional guarantees for regions with lower prevalence of zoonotic agents were rejected. These additional guarantees would have applied to all zoonotic agents in live animals, hatching eggs and foodstuffs. The proposal already includes the possibility to set additional guarantees for salmonella as regards the trade of live animals and hatching eggs. However, extending this option to cover also other zoonotic agents may create barriers to trade and would be premature as no pathogen reduction targets and control programmes are proposed for them in the current proposal**.** Additional guarantees for food fall under the recast of food hygiene legislation (COM(2000) 438) currently subject to first reading in co-decision procedure. However, amendment 23 is taken into account as it has no impact on the implementation of the Regulation.

18. Sanctions in intra-Community trade

The European Parliament's amendment 24 requiring Member States without an approved control programme to be excluded from intra-Community trade in the relevant animals or products is rejected. Sanctions will be dealt with in a separate proposal for a Regulation on official feed and food control.

19. Importation from third countries

The European Parliament's amendment 25 requiring the European Food Safety Authority (EFSA) and the Food and Veterinary Office (FVO) to be closely involved in monitoring that equivalent control programmes exist in third countries, is taken into account only as regards the FVO. This is because such a task would not fall within the remit of EFSA.

20. Salmonella reduction targets, sampling schemes and timetable to implement them

The European Parliament's amendments 29, 32, 36 and 38 aiming to tighten and add salmonella reduction targets are partly taken into account in the proposal. The target for laying hens is extended to cover all salmonella serotypes with public health significance and a new target for slaughter pigs is added. The possibility to adopt a progressive approach for pigs is foreseen. These changes are in accordance with the developments in the Council. The European Parliament's proposal to add new targets for calves, other cattle, sheep is dismissed. Before setting such targets scientific advice is needed. Especially as cattle and sheep seem to be minor contributors to human salmonellosis. The amendment seeking to change the minimum sampling frequency for laying hens from every 9 weeks to every 15 weeks is introduced. The new frequency would still ensure an adequate level of control and is in line with a past opinion of the EC Scientific Veterinary Committee. As regards slaughter pigs, the sampling scheme needs further work on the issue and it is proposed to decide on it when the salmonella reduction target is established. Finally, the column titled "data" in Annex II.B.1 of the proposal is deleted from the original text as it did not establish substantial requirements and discussions in the Council showed that it may lead to confusion.

21. Specific measures in infected poultry flocks

The European Parliament's amendment 34 broadening certain predefined control measures for salmonella positive flocks of laying hens is taken into account in the proposal. The corresponding amendment 33 as regards breeding flocks is rejected.

22. Reporting and publication of reports

The European Parliament's amendment 10 seeking to shorten the time allowed for the Member States to submit their reports to the Commission is not accepted.

The experience of the existing data collection system has shown that the Member States have difficulties to meet the current deadline, which is the same as the one in the proposal.

23. Laboratories

European Parliament's amendment 26 shortening the deadline for laboratories to apply international standards for quality assurance schemes is rejected. Shortening the deadline seems unrealistic, considering the time needed to prepare and reach accreditation and because laboratories have not been warned adequately in advance.

24. Criteria for zoonoses and other agents to be included in monitoring

The European Parliament's amendments 12, 13, 30 and 31 transferring certain criteria from annexes to articles have been taken into account in the proposal. The amendments would enable the European Parliament and the Council to be involved if further amendments would be proposed to the criteria. These criteria concern the addition and deletion of pathogen reduction targets for zoonotic agents.

25. Consultation of the European Food Safety Authority

The European Parliament's amendment 21 making the consultation of the European Food Safety Authority compulsory before adopting decisions concerning specific control measures has been introduced in the proposal. Scientific advice is necessary for the preparation of such decisions. However, amendment 27 seeking systematic consultation before amending the annexes or taking transitional measures is rejected. This is because scientific advice is not necessary when adopting purely administrative measures.

26. Editorial amendments

The European Parliament's amendments 4, 5, 6, 9, 17 and 28 improve the proposal from the technical and editorial point of view. They include also the re-wording of the provisions for on-the-spot checks by the Commission. They have been taken into account in the revised proposal.

III. Other changes

Certain technical changes have been made to the text to ensure its conformity with the Interinstitutional Agreement of 22 December 1998 on common guidelines for the quality of drafting of Community legislation (OJ C 73, 17.3.1999, p. 1), drawn up pursuant to Declaration No 39 annexed to the Final Act of Amsterdam on the quality of the drafting of Community legislation. In accordance with points (b) and (g) of that Agreement, the text has been revised to take account of the common guidelines and the Joint Practical Guide drawn up under point (a) thereof.

2001/0176 (COD)

Amended 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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

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

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

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[4],

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

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1 OJ C ...
2 OJ C ...
3 OJ C ...
4 OJ C ...
5 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).

(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[6], 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[7], 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*][8] 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[9] 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 **and plant** origin and in humans is necessary to determine the trends and sources of zoonoses.

(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.

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

7 OJ L 46, 19.2.1991, p. 19. Directive as last amended by Commission Decision 2002/261/EC (OJ L 91, 6.4.2002, p. 31).

8 OJ L ...

9 OJ L 268, 3.10.1998, p. 1.

(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 specified food-borne zoonotic agents*][10]. 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 **178/2002** of the European Parliament and of the Council of **28 January 2002** laying down the general principles and requirements of food law, establishing the European Food **Safety** Authority, and laying down procedures in matters of food **safety**[11]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 agents.

(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 zoonoses and zoonotic agents.

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

(16) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of monitoring zoonoses and zoonotic agents of importance at Community level, to lay down rules on the provision of data in a harmonised way and monitoring measures. This Directive does not go beyond what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.

(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 to Regulation (EC) No…./… [*on the control of salmonella and other specified food-borne zoonotic agents*].

(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.

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10 OJ L ...

11 **OJ L 31, 1.2.2002, p. 1.**

(19) Transmissible spongiform encephalopathies are subject to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies[12]. Therefore they should be excluded from the scope of this Directive.

(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 **Safety** Authority in the form of reports, which should also be made available to the public in an appropriate way **without delay**.

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

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

(23) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field[13], should be amended as regards 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 and for the adoption of implementing and transitional measures.

(25) The EFSA should be consulted as appropriate, and particular on matters having significant impact on public health.

(26) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[14].

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

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

14 OJ L 184, 17.7.1999, p. 23.

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**, foodborne outbreaks and antimicrobial resistance of zoonotic agents** are properly monitored so that the necessary information may be collected in the Community to evaluate **their** trends and sources ~~**of zoonoses and zoonotic agents**~~. Those evaluations shall provide a basis for **effective risk assessment and 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**~~ **in connection with the** primary production of animals, and~~**, where necessary,**~~ at other stages of **the** food chain, including the production of feedingstuffs and further preparation and production of ~~**products of animal origin,**~~ **food**;

   (b) the monitoring of antimicrobial resistance;

   (c) the epidemiological investigation of foodborne outbreaks;

   (d) the exchange of information related to zoonoses and zoonotic agents.

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

Article 2
Definitions

For the purposes of this Directive, the definitions set out in Article 2 and Article 3 of Regulation (EC) No 178/2002 shall apply.

The following definitions shall also apply:

(a) "*zoonosis*" means any disease and/or infection which is naturally transmissible directly or indirectly from animals to humans;

(b) "*zoonotic agent*" means any virus, bacterium, fungus, parasite or other biological entity which is likely to cause a zoonosis;

(c) "*antimicrobial resistance*" means the ability of micro-organisms ~~**of certain species**~~ to survive or even to grow in the presence of a given concentration of an antimicrobial agent, that is usually sufficient to inhibit or kill micro-organisms of the same species;

(d) "*communicable diseases*" means diseases caused by zoonotic agents occurring in humans which are covered by Decision No 2119/98/EC;

(e) "*foodborne 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;

(f) "*monitoring*" means a system of collecting, analysing and disseminating data on the occurrence of zoonoses, zoonotic agents and antimicrobial resistance related thereto;

Article 3
General obligations

1. Member States shall ensure that data on the occurrence of zoonoses and zoonotic agents, food-borne outbreaks, and antimicrobial resistance ~~**related thereto**~~ are collected, analysed and ~~**disseminated**~~ **published without delay** 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 (hereinafter referred to as "the competent authority") 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 and:

(a) the competent authorities designated for the purpose of Community legislation on feed;

(b) the competent authorities designated for the purposes of the Community legislation on animal health;

(c) the competent authorities designated for the purposes of the Community legislation on food hygiene;

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

(e) other authorities and organisations concerned.

4. Each Member State shall ensure that the relevant officials of the competent authority designated for the purposes of this Directive are suitably qualified to undertake their duties and, where necessary, are trained in microbiology and epidemiology **and receive regular up-to-date training which reflects scientific progress in those areas**.

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 **and comparable** 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 **food~~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 **to make the 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 diseases. Those detailed rules shall specify in particular:

   (a) the animal populations 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**,** in accordance with the requirements set out in Annex II**,** ensure that the monitoring provides **comparable** data on the occurrence of antimicrobial resistance in zoonotic agents **and, insofar as they present a threat to public health, other agents**.

   Monitoring shall be coordinated with the surveillance of antimicrobial resistance conducted in accordance with Decision No 2119/98/EC.

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 **Safety** 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 to Regulation (EC) No …/… [*on the control of salmonella and other specified food-borne zoonotic agents*].

3. The minimum rules concerning the establishment of co-ordinated monitoring programmes shall be those set out in Annex III.

4. The results of the co-ordinated monitoring programmes shall be provided to the European Food **Safety** 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**, or has reason to believe,** that a foodstuff produced or processed by him has caused, or is likely to cause, a foodborne outbreak, he shall inform the competent authority without delay. The foodstuff, or ~~**an appropriate sample**~~ **a relevant number of samples** thereof, shall be preserved in a way which neither impedes its investigation in a laboratory, nor a further epidemiological 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 epidemiological investigation shall provide data on the epidemiological profile, the foodstuffs potentially implicated and the potential causes of the food-borne outbreak. The epidemiological 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 epidemiological investigations carried out, containing the information referred to in Annex IV, Part E, to this Directive.

Detailed rules concerning the epidemiological 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 more specific Community provisions on product safety, early warning and response systems for the prevention and control of communicable diseases and food hygiene.

Chapter IV
Exchange of information

Article 8
Examinations for zoonotic agents at the level of food business operators

Where food business operators carry out examinations for the presence of the zoonoses and zoonotic agents pursuant to Annex I, Member States shall ensure that food business operators keep, for a period to be specified by the competent authority, and communicate to the competent authority at its request, the results of such 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, food-borne outbreaks and antimicrobial resistance

1. Member States shall assess trends and sources of zoonoses, zoonotic agents, food-borne outbreaks and antimicrobial resistance ~~related thereto~~ in their territory.

Each Member State shall transmit to the Commission every year by the end of May a report on trends and sources of zoonoses, zoonotic agents, food-borne outbreaks and antimicrobial resistance ~~related thereto~~, covering the data collected pursuant to Articles 4 to 7 during the previous year. The reports, ~~or~~ **and** summaries of them, shall be made publicly available **without delay**.

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 specified food-borne zoonotic agents*].

The minimum requirements concerning the reports shall be those set out 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.

Within six months of receipt of those reports, **the European Food Safety Authority** shall ~~**each year and within nine months after receiving them shall**~~ publish a summary report on the trends and sources of zoonoses, zoonotic agents, food-borne outbreaks and antimicrobial resistance in the Community.

When preparing the summary report, the European Food **Safety** Authority may take into consideration other data on zoonoses, zoonotic agents, food-borne outbreaks 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[15];

– 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. 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).

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[15] 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
Implementation

Article 11
Amendments to the Annexes and transitional and implementing measures

The Annexes may be amended or any appropriate transitional or implementing measures may be adopted in accordance with the procedure referred to in Article 12(2).

The Commission shall consult the European Food Safety Authority on any matter that could have a significant impact on public health.

Amendments to Annex I shall take into account in particular the following:

(a) the occurrence of the relevant zoonosis or zoonotic agent in animal and human populations, feed and food;

(b) its gravity in humans;

(c) its economic consequences for health care and feed and food businesses;

(d) epidemiological trends in animal and human populations, feed and food.

Article 12
Committee

1. The Commission shall be assisted by the **Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002** ~~**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 safety]**~~ **or, where appropriate, by the Committee instituted by Article 7 of Decision No 2119/98/EC**.

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

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

Chapter VII
Final and Transitional provisions

Article 14
Repeal and transitional provisions

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 specified food-borne zoonotic agents*].

Article 15
Amendment of Decision 90/424/EEC

Decision 90/424/EEC is amended as follows:

1. Article 29 is replaced by the following

"Article 29

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 specified food-borne zoonotic agents*] [*].

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 specified food-borne zoonotic agents*] 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.

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* 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 specified food-borne zoonotic agents*]."

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.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

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

Influenza virus

Rabies

~~**Tick borne**~~ Viruses **spread by arthropods**

2. Bacterial zoonoses

Borreliosis and agents thereof

Botulism and agents thereof

Leptospirosis and agents thereof

Psittacosis and agents thereof

Tuberculosis other than in Point A

Vibriosis and agents thereof

Yersiniosis and agents thereof

3. Parasitic zoonoses

   Anisakiasis and agents thereof

   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 the relevant information to detect the emergence of and to identify the trends in antimicrobial resistance in zoonotic **and other relevant** 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

8. the production system from which data was collected

B. Specific requirements

Member States shall ensure that the monitoring as set out in Part A 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 provided for 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

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

The report as provided for in Article 9(1) shall provide at least for the following information:

A. Initially the following shall be described for each zoonosis and zoonotic agent (subsequently only changes are required 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 Member State.

B. Each year the report shall include the following:

(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 methods of characterization used 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 recognized that could be used to prevent or minimize transmission of the zoonotic agent to humans;

(h) Need of any specific action in the Member State or at Communitylevel 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 during the 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 why it is impossible 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.

2001/0177 (COD)

Amended proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the control of salmonella and other specified food-borne zoonotic agents

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

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

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

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[4],

Whereas:

(1) The protection of human health against diseases and infections transmissible directly or indirectly 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[5] was adopted in order to establish monitoring systems for certain zoonoses and to establish controls on salmonella in poultry flocks.

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1 OJ C ...
2 OJ C ...
3 OJ C ...
4 OJ C ...
5 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).

(5) Directive 92/117/EEC required the Member States to submit to the Commission the national measures that they are taking to achieve the objectives of the Directive. Member States were also required to draw up plans for monitoring salmonella in poultry. That requirement was, however, suspended by Council Directive 97/22/EC[6] amending Directive 92/117/EEC, pending the review provided for in Article 15a of Directive 92/117/EEC.

(6) Several Member States have already submitted their plans for the monitoring of salmonella, which the Commission has approved. Moreover, all Member States were required, with effect from 1 January 1998, to fulfil the minimum measures laid down for salmonella in Annex III, Section I, to Directive 92/117/EEC, and to establish rules specifying the measures to be taken in order to avoid the introduction of salmonella onto a farm.

(7) Those minimum measures focused on monitoring and control of salmonella in breeding flocks of the species *Gallus gallus*. When serotypes *Salmonella* Enteritidis or *Salmonella* Typhimurium were detected and confirmed in samples taken, specific measures to control the infection were required by Directive 92/117/EEC.

(8) 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[7] 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[8] as regards ovine and caprine brucellosis.

(9) Moreover, Regulation (EC) No…./… of the European Parliament and of the Council of …. [*on the hygiene of foodstuffs*][9] covers specific elements necessary for the prevention, control and monitoring of zoonoses and zoonotic agents, and includes specific requirements for the microbiological quality of food.

(10) Directive 92/117/EEC provided for the collection of data on the occurrence of zoonoses and zoonotic agents in feedingstuffs, animals, food, and humans. That data collection system, although not harmonised and therefore not allowing comparisons between Member States, does provide a basis for evaluating the current situation concerning zoonoses and zoonotic agents in the Community.

(11) The results of the data collection system show that certain zoonotic agents, namely *Salmonella* spp. and *Campylobacter* spp., cause the majority of cases of zoonoses in humans. There seems to be a decreasing trend of human cases of salmonellosis, in particular due to *Salmonella* Enteritidis and *Salmonella* Typhimurium, thus reflecting the success of related control measures taken in the Community. Nevertheless, it is assumed that many cases remain unreported and therefore the data collected does not necessarily give the full picture of the situation.

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6 OJ L 113, 30.4.1997, p. 9.

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

8 OJ L 46, 19.2.1991 p. 19. Directive as last amended by CommissionDecision 2002/261/EC (OJ L 91, 6.4.2002, p. 31).

9 OJ L ...

(12) 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.

(13) It is, therefore, necessary to improve the existing control systems for specific zoonotic agents, starting with salmonella. Simultaneously, the monitoring and data collection systems established by Directive 92/117/EEC will be replaced by the rules laid down in Directive …/… of the European Parliament and of the Council of ….. [*on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC*][10].

(14) The principle should be established of controls covering the whole food chain from farm to table.

(15) The rules governing such controls should generally be those laid down under Community legislation on feedingstuffs, animal health and food hygiene.

(16) However, for certain food-borne zoonoses and zoonotic agents it is necessary to lay down specific requirements for controls.

(17) Those specific requirements should be based on Community targets for the reduction of the prevalence of food-borne zoonoses and zoonotic agents.

(18) The Community targets should be established for food-borne zoonoses and zoonotic agents in animal populations taking into account in particular their incidence and epidemiological trends in animal and human populations, their gravity for humans, their potential economical consequences for health care and for food businesses, and the existence of appropriate measures to reduce their prevalence. Community targets may also be established in respect of other parts of the food chain, where necessary.

(19) To ensure the achievement of the Community targets in good time, the Member States should set up specific national control programmes, which should be approved by the Community.

(20) The main responsibility for the safety of food should lie with business operators. Member States should, therefore, encourage the creation of business-wide control programmes.

(21) Within their control programmes Member States or businesses may wish to use specific control methods. However, certain methods may not be acceptable, in particular if they hamper the achievement of the Community target in general, interfere specifically with necessary testing systems, or give rise to potential threats to public health. Appropriate procedures should therefore be laid down enabling the Commission to decide that certain control methods should not be used as part of control programmes.

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[10] OJ L

(22) Control methods may also exist or be developed which as such do not fall under any specific Community legislation on product approval, but would help to achieve the targets for the reduction of prevalences of specified food-borne zoonoses and zoonotic agents. The Commission should, therefore, have the authority to approve the use of such methods at Community level.

(23) It is essential to ensure that restocking of animals takes place from flocks or herds that have been subject to controls in accordance with the requirements of this Regulation. When a specific control programme is in force, the results of testing should be forwarded to the purchaser of animals. To that end, specific requirements should be added to the corresponding Community legislation on intra-Community trade and imports from third countries, in particular as regards consignments of live animals and hatching eggs. Directive 64/432/EEC, Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine, ovine, caprine animals and swine, fresh meat or meat products from third countries[11] and Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs[12] should be amended accordingly.

(24) As regards control of salmonella*,* available information tends to show that poultry products are a major source of human salmonellosis. Control measures should, therefore, be applied to production of those products, thus extending the measures initiated under Directive 92/117/EEC. As regards the production of table eggs, it is important to establish specific measures concerning the placing on the market of products originating from flocks that have not been tested free of relevant salmonella. As regards poultry meat, the aim is to place on the market poultry meat with reasonable assurance that it is free from relevant salmonella. A transitional period is necessary for the food business operators to adapt to the foreseen measures, which may be adapted further in particular in the light of scientific risk assessment. Equivalent **control programmes for the control of zoonoses should also be implemented in third countries exporting to the Community at the same time as measures are applied in the Community** ~~**guarantees should be required from third countries, in due course**~~.

(25) It is appropriate to designate National and Community Reference Laboratories for giving guidance and assistance on matters falling within the scope of this Regulation.

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11 OJ L 302, 31.12.1972, p. 28. Directive as last amended by Regulation (EC) No 1452/2001 (OJ L 198, 21.7.2001, p. 11).

12 OJ L 303, 31.10.1990, p. 6. Directive as last amended by Commission Decision 2001/867/EC (OJ L 323, 7.12.2001, p. 29).

(26) In order to ensure the uniform application of the provisions of this Regulation, provision should be made for the organisation of Community audits and inspections in accordance with **Community legislation in this field**. ~~**Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States and Commission Decision 98/140/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in third countries.**~~

(27) Appropriate procedures should be laid down for the amendment of certain provisions of this Regulation taking into account technical and scientific progress, and for the adoption of implementing and transitional measures.

(28) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring public health, to lay down rules on the control of salmonella and other food-borne zoonoses and zoonotic agents of importance at Community level. This Regulation does not go beyond what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.

(29) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[13].

HAVE ADOPTED THIS REGULATION:

Chapter I
Introductory provisions

Article 1
Subject-matter and scope

1. The purpose of this Regulation is to ensure that proper and effective measures are taken to control specified food-borne zoonotic agents in order to reduce their prevalence and the risk they pose to public health.

2. This Regulation covers:

   (a) the adoption of targets for the reduction of prevalences of specified food-borne zoonoses, in animal populations, in particular at the stage of primary production of animals, but also, where necessary, at other stages in the food chain**, but excluding the primary production for private domestic use**;

   (b) the approval of specific control programmes established by Member States and food business operators;

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

(c) the adoption of specific rules concerning certain control methods applied in the reduction of prevalences of food-borne zoonoses and zoonotic agents;

(d) the adoption of rules concerning intra-Community trade and imports from third countries of certain animals and products thereof.

Article 2
Definitions

For the purposes of this Regulation the definitions in Article 2 and Articles 3 of Regulation (EC) No 178/2002 and in Article 2 (a) and (b) of Directive …/… [*on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC*] shall apply.

The following definitions shall also apply:

(a) "*prevalence"* means the number of cases of epidemiological units tested positive for a given zoonosis or zoonotic agent in a given population over a clearly defined period of time;

(b) "*herd"* means an animal or group of animals as defined in Article 2(2)(a) of Directive 64/432/EEC;

(c) "*flock"* means an animal or group of animals as defined in Article 2(2)(7) of Directive 90/539/EEC.

Article 3
Competent authorities

1. Each Member State shall designate its competent authority **or authorities** for the purpose of this Regulation ~~**and notify the Commission thereof**~~. **Each Member State shall designate one of those authorities to be responsible for liasing with the Commission.**

2. The competent authority shall be responsible in particular for:

(a) drawing up the programmes provided for in Article 5(1) and preparing any amendments thereto which prove necessary, in particular in the light of data and results obtained;

(b) collecting the data needed to evaluate the means used and the results obtained in carrying out the national control programmes provided for in Article 5 and for submitting those data and results yearly, including the results of any surveys undertaken, to the Commission and to the European Food **Safety** Authority by 31 May of the following year, having regard to the rules laid down pursuant to Article 9(1) of Directive …/…/EC [*on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC*];

(c) carrying out regular checks on the premises of **feed and** food business operators for the purpose of checking compliance with this Regulation.

Chapter II
Community targets

Article 4
Community targets for the reduction of prevalences of food-borne zoonoses and zoonotic agents

1. Community targets shall be established for the reduction of prevalences of food-borne zoonoses and zoonotic agents listed in Annex I, ~~**Part A,**~~ column 1 in the animal populations listed in Annex I, ~~**Part A,**~~ column 2, taking into account:

   (a) the experience gained under existing national measures;

   (b) information forwarded to the Commission or to the European Food **Safety** Authority under existing Community requirements, in particular in the framework of reports provided for in Article 9(1) of Directive …/…/EC [*on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC*];

   (c) **the following criteria:** ~~**laid down in Annex I, Part B.**~~

      (i) their occurrence in animal and human populations, feed and food,

      (ii) their gravity in humans,

      (iii) the economic consequences for health care and food businesses,

      (iv) epidemiological trends in animal and human populations, feed and food,

      (v) management options foreseen at the relevant stage of the Community target, and

      (vi) breeding systems and production methods.

   Community targets may be established for other stages in the food-chain in accordance with the procedure laid down in Article 14(2).

2. Community targets shall at least include the **following** details**:** ~~**set out in Annex I, Part C**~~.

   (a) a numerical expression of either:

      (i) the maximum percentage of epidemiological units remaining positive, and / or

      (ii) the minimum percentage of reduction in a number of positive epidemiological units,

   (b) the maximum time limit within which the Community target shall be achieved,

(c) a definition of epidemiological units referred to in point (a) (i), and

(d) a definition of the testing schemes necessary to verify the achievement of the Community target.

3. Community targets shall be established for the first time before the respective dates indicated in Annex I, ~~**Part A,**~~ column 4.

The Community targets, as well as any amendments to them, shall be adopted in accordance with the procedure referred to in Article 14(2), and after consultation of the European Food **Safety** Authority.

4. Without prejudice to Community rules on animal nutrition, animal health, or food hygiene, the reduction of prevalences of food-borne zoonoses and zoonotic agents listed in Annex I shall be conducted in accordance with the rules laid down in this Regulation and any other rules adopted pursuant to it.

Chapter III
Control programmes

Article 5
National control programmes

1. Member States shall, in particular in the light of the Community targets provided for in Article 4**,** ~~**and**~~ the geographical distribution of food-borne zoonoses in their territory, **and the economic repercussions for primary producers, and feed and food business operators, which ensue from effective control**, establish national control programmes for each food-borne zoonosis and zoonotic agent listed in Annex I.

2. National control programmes shall be continuous and cover a period of at least three consecutive years.

3. National control programmes shall:

(a) provide for the detection of food-borne zoonoses and zoonotic agents in accordance with the requirements and minimum sampling rules laid down in Annex II, Part B;

(b) define the responsibilities of **the competent authorities and feed and** food business operators concerned, especially in terms of their control programmes as provided for in Article 7;

(c) specify the control measures to be taken following the detection of food-borne zoonoses and zoonotic agents, in particular to protect public health, including at least the implementation of the specific requirements laid down in Annex II;

(d) allow for the progress under their provisions to be evaluated and for those programmes to be reviewed, in particular in the light of results obtained from the detection of food-borne zoonoses and zoonotic agents.

4. National control programmes shall cover at least the following stages of the food chain:

   (a) feedingstuff production;

   (b) primary production of animals;

   (c) processing and preparation of foodstuffs of animal origin.

5. National control programmes shall contain, where relevant, the provisions laid down in relation to testing methods and criteria against which the results of these tests shall be assessed, for testing animals and hatching eggs to be dispatched within the national territory, as part of the official controls provided for in Annex II, Part A, point 1.6.

6. Within 6 months of the establishment of the Community targets provided for in Article 4, Member States shall submit their national control programmes to the Commission and set out the measures to be implemented.

Article 6
Approval of the national control programmes

1. The Commission shall, within six months of submission of a national control programme, establish whether it complies with the relevant rules including in particular this Regulation. The Commission may ask Member States to modify or supplement their national control programmes so that they conform with Community law. When the Commission has established the conformity of the national control programmes, they shall be approved in accordance with the procedure referred to in Article 14(2).

2. Amendments to a national control programme previously approved pursuant to paragraph 1, in order to take account of the evolution in the situation in the Member State concerned, in particular in the light of the results referred to in Article 5(3)(d), may be approved in accordance with the procedure referred to in Article 14(2).

3. Where the Commission has requested further information from a Member State, the six month time-limit referred to in paragraph 1 shall be suspended until that information is provided.

Article 7
*Control programmes of **feed and food** business operators*

1. Member States shall encourage **feed and** food business operators or organisations representing such operators, ~~**which have full responsibility for the production of certain animals or products of animal origin**~~ to establish one or more control programmes**, which shall incorporate as far as possible all stages of production, processing and distribution.**

   Those control programmes shall cover at least feedingstuff production and primary production of animals.

2. **Feed and** food business operators or their representative organisations shall submit their control programmes and any amendments thereto for the approval of the competent authority of the Member State in which they are located. If the primary production of animals takes place in different Member States, these programmes shall be approved individually for each Member State.

3. The competent authority may approve the control programmes submitted pursuant to paragraph 2 only if it is satisfied, after an inspection visit, that the control programmes comply with the minimum requirements set out in Annex II whenever these requirements are relevant, and with the objectives of the relevant national control programme.

4. Member States shall maintain up-to-date lists of approved control programmes of **feed and** food business operators or their representative organisations.

   Those lists shall be made available to the Commission upon request.

5. **Feed and food** business operators or their representative organisations shall communicate regularly the results of their control programmes to the competent authorities.

Chapter IV
Control methods

Article 8
Specific control methods

1. At the initiative of the Commission or at the request of a Member State and~~, where necessary,~~ after consultation of the European Food **Safety** Authority, the following may be adopted in accordance with the procedure referred to in Article 14(2):

   (a) decisions that specific control methods may or shall be applied to reduce the prevalence of food-borne zoonoses and zoonotic agents at the stage of the primary production of animals and other stages in the food chain;

   (b) rules concerning the conditions for the use of the control methods referred to in point (a);

   (c) detailed rules concerning the necessary documents and procedures as well as minimum requirements for the control methods referred to in point (a);

   (d) decisions that certain specific control methods shall not be used as a part of control programmes.

2. The provisions referred to in paragraph 1(a), (b) and (c) shall not apply to control methods using substances or techniques covered by other Community legislation on animal nutrition, food additives or veterinary medicinal products.

Chapter V
Trade

Article 9
Intra-Community trade

1. As from the dates mentioned in Annex I, ~~**Part A,**~~ column 5 at the latest, flocks and herds of origin of the species listed in column 2 shall be tested for the food-borne zoonoses and zoonotic agents listed in column 1 prior to any dispatching of the live animals, or hatching eggs, from the food business of origin. The date and the result of testing shall be included in the relevant health certificates.

2. A Member State of destination may, in accordance with the procedure referred to in Article 14(2), be authorised for a transitional period to require that the relevant health certificates for consignments of animals and hatching eggs subject to testing in the Member State of dispatch, fulfil the same criteria relating to results of testing as those laid down under its approved national control programme for consignments of animals and hatching eggs to be dispatched within its territory.

   The authorisation may be withdrawn in accordance with the same procedure.

3. Specific rules concerning the setting by Member States of the criteria referred to in Article 5(5) and in paragraph 2, may be laid down in accordance with the procedure referred to in Article 14(2).

~~**4. The provisions of paragraphs 1 and 2 shall not apply to dispatching of eggs for packaging or processing.**~~

Article 10
Imports from third countries

1. As from the dates mentioned in Annex I, ~~**Part A,**~~ column 5, admission to or retention from the lists of third countries provided for in Community legislation, for the relevant species or category, from which Member States are authorised to import those animals or hatching eggs covered by this Regulation shall be subject to submission to the Commission by the third country concerned of an official control programme equivalent to those provided for under Article 5. The programme shall give details of the guarantees offered by the third country as regards inspections and controls for food-borne zoonoses and zoonotic agents. Those guarantees must be at least equivalent to the guarantees provided for by this Regulation.

   The Food and Veterinary Office of the Commission shall monitor the equivalence of control programmes in such third countries.

2. The programmes submitted under paragraph 1 shall be approved in accordance with the procedure referred to in Article 14(2), provided that the equivalence of the guarantees described under the programme, with the relevant requirements applicable under Community rules, is objectively demonstrated. Alternative guarantees to those provided for in this Regulation may be allowed in accordance with that procedure, provided that they are not more favourable than those applicable to intra-Community trade.

3. For third countries with which a regular trade flow is established, the provisions of Article 5(7) and Article 6(1) and (3) concerning time periods for the submission and approval of national control programmes shall apply. For third countries establishing or resuming a trade flow, the time periods provided for in Article 6 shall apply.

4. Flocks and herds of origin of species listed in Annex I, ~~**Part A,**~~ column 2 shall be tested for the food-borne zoonoses and zoonotic agents listed in Annex 1, column 1, prior to any dispatching of the live animals or hatching eggs from the food business of origin. The date and the result of testing shall be included in the relevant import certificates, for which the models laid down by Community legislation shall be amended accordingly.

5. A Member State of final destination may, in accordance with the procedure referred to in Article 14(2), be authorised for a transitional period to require that the relevant health certificates for consignments of animals and hatching eggs subject to testing in the third country of dispatch, fulfil the same criteria relating to results of testing as those laid down under its approved national control programme, for consignments of animals and hatching eggs to be dispatched within its territory.

   The authorisation may be withdrawn in accordance with the same procedure.

6. Admission to or retention from the lists of third countries provided for in Community legislation, for the relevant category of products, from which Member States are authorised to import those products covered by this Regulation shall be subject to submission to the Commission by the third country concerned of guarantees equivalent to those provided for by this Regulation.

Chapter VI
Laboratories

Article 11
Reference laboratories

1. Community Reference Laboratories for the analysis and testing of food-borne zoonoses and zoonotic agents listed in Annex I, column 1, shall be designated in accordance with the procedure referred to in Article 14(2).

2. 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 14(2).

3. Member States shall designate National Reference Laboratories for zoonoses and food-borne zoonotic agents referred to in Annex I, column 1. The names and addresses of such laboratories shall be communicated to the Commission.

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 14(2).

Article 12
Approval of laboratories, quality requirements and approved testing methods

1. Laboratories participating in control programmes pursuant to Articles 5 and 7 where samples are analysed for the testing of the presence of food-borne zoonoses and zoonotic agents referred to in Annex I, column 1 shall be approved by the competent authority.

2. At the latest from 1 January 2005, each Member State shall ensure that the laboratories referred to in paragraph 1 apply quality assurance systems which conform to the requirements of ~~**Standard**~~ **the current** EN/ISO ~~**17025**~~ **standard.**

   The laboratories shall regularly participate in collaborative testing organised or co-ordinated by the National Reference Laboratory.

3. Testing for the presence of zoonoses and food-borne zoonotic agents referred to in Annex I, column 1 shall be carried out using the methods and protocols recommended by international standardisation bodies, as reference methods.

   Alternative methods may be used if they have been validated in accordance with internationally recognised rules and offer equivalent results to those obtained by the relevant reference method referred to in the first subparagraph.

   Where necessary, other methods for testing may be approved in accordance with the procedure referred to in Article 14(2).

Chapter VII
Implementation

Article 13
Amendments to Annexes, implementing and transitional measures

The Annexes may be amended or appropriate transitional or implementing measures, including the necessary amendments to the relevant health certificates, may be adopted in accordance with the procedures referred to in Article 14(2).

The Commission shall consult the European Food Safety Authority on any matter that could have a significant impact on public health.

Article 14
Committee

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002.

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

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

Chapter VIII
General and final provisions

Article 15
Community controls

1. ~~**The**~~ Commission **experts** shall carry out on-the-spot checks ~~**in accordance with Decisions 98/139/EC and 98/140/EC**~~ in the Member States and in third countries in order to ensure that the provisions of this Regulation, rules adopted pursuant thereto and any safeguard measures are applied uniformly.

Such checks shall be carried out in co-operation with the competent authorities of the Member State concerned and the Member State shall provide all necessary assistance to the Commission experts to enable them to carry out their tasks.

The Commission shall inform the competent authority of the Member State concerned of the results of the checks carried out.

2. **Detailed rules for the implementation of this Article, in particular as regards the co-operation with the competent authorities of the Member States, shall be laid down in accordance with the procedure referred to in Article 14(2).**

Article 16
Entry into force

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

It shall apply as from 1 January 2003.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

Specified food-borne zoonoses and zoonotic agents for which Community targets for the reduction of prevalence shall be established pursuant to Article 4

1. Food-borne Zoonosis / zoonotic agent	2. Animal population	3. Stage of food-chain	4. Target to be established by (date)	5. Mandatory testing and certification for trade shall apply as from
All salmonella serotypes with public health significance[a]	Breeding flocks of *Gallus gallus*	Primary production	31.12.2003	1.1.2005
~~***Salmonella* Enteritidis and *Salmonella* Typhimurium**~~ **All salmonella serotypes with public health significance[a]**	Laying hens	Primary production	31.12.2004	1.1.2006
All salmonella serotypes with public health significance[a]	Broilers	Primary production	31.12.2005	1.1.2007
All salmonella serotypes with public health significance[a]	Turkeys	Primary production	31.12.2006	1.1.2008
All salmonella serotypes with public health significance[(a)]	**Slaughter pigs and** breeding herds of pigs	Primary production	31.12.2006[(b)]	1.1.2008

(a) Serotypes shall be defined when the Community target is established.

(b) **This date shall apply to one or both categories of animal populations. Following consultation of the European Food Safety Authority, a progressive approach may be decided.**

B. Criteria for laying down the list of zoonoses and stages in the food chain in Part A above

When necessary, zoonoses or zoonotic agents may be added in or deleted, or different stages in the food chain may be specified, 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, and**
- **management options foreseen at the relevant stage of the target.**

C. Details of targets

The Community targets referred to in Article 4(1) shall consist at least of:

1. **A numerical expression of either**
   a) **the maximum percentage of epidemiological units remaining positive, and / or**
   b) **the minimum percentage of reduction in a number of positive epidemiological units,**
2. **The maximum time limit within which the target shall be achieved,**
3. **Definition of epidemiological units referred to in point 1, and**
4. **Definition of the testing schemes necessary to verify the achievement of the target**.

ANNEX II

Control of food-borne zoonoses and zoonotic agents listed in Annex I, column 1

A. GENERAL REQUIREMENTS FOR NATIONAL CONTROL PROGRAMMES

The programme shall take into account the nature of the zoonosis and / or agent thereof concerned and the specific situation in the Member State and it shall:

(a) state the aim of the programme taking into consideration the importance of the zoonosis concerned;

(b) specify the following

1. General

1.1 The occurrence of the zoonosis concerned in the Member State with specific reference to the results obtained in the framework of monitoring according to Article 4 of Directive …/…/EC [*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*],

1.2 the geographical area or, where appropriate, the epidemiological units, in which the programme will be implemented,

1.3 the infrastructure of the relevant competent authorities,

1.4 a list of approved laboratories, where samples collected within the programme are analysed,

1.5 the methods used in the examination of the food-borne zoonotic agents,

1.6 official controls (including sampling schemes) at feedingstuff, flock and / or herd level,

1.7 official controls (including sampling schemes) at other stages of the food chain, and at feedingstuffs level

1.8 the type of measures laid down by the competent authorities with regard to animals or products in which food-borne zoonoses and zoonotic agents have been detected, in particular to protect public health,

1.9 relevant national legislation;

2. Concerning food businesses covered by the programme

2.1 the structure of the production of the given species and products thereof,

2.2 the structure of the production of feedingstuffs,

2.3 relevant guides for good animal husbandry practices or other guidelines (mandatory or voluntary) defining at least

– hygiene management at farms,

– measures to prevent incoming infections carried by animals, feed material, drinking water, people working at farm,

– hygiene in transporting animals to and from farms,

2.4 routine veterinary supervision of farms,

2.5 registration of farms,

2.6 record keeping at farms,

2.7 documents to accompany animals when dispatched,

2.8 other relevant measures to ensure the traceability of animals;

(c) comply with the minimum sampling rules and levels laid down in Part B;

(d) where relevant, comply with the specific requirements laid down in Parts C to E.

B. MINIMUM REQUIREMENTS OF SAMPLING

1. After the respective national control programme referred to in Article 5 has been approved, the food business operator must, at his own expense, have samples taken for analysis for the detection of food-borne zoonosis or zoonotic agents listed in Annex I, with the minimum scope of sampling indicated below being respected.

Food-borne Zoonosis / zoonotic agent	Animal species	~~**Data**~~	Sampling shall cover at least these phases of production
All salmonella serotypes with public health significance[a]	1. Breeding flocks of *Gallus gallus* 1.1 Rearing flocks 1.2. Adult breeding flocks	~~**a)feedingstuffs**~~ ~~**b) live animals**~~ ~~**a) feedingstuffs**~~ ~~**b) live animals**~~	i) Day-old chicks ii) 4 week old birds iii) 2 weeks before moving to laying phase or laying unit i) every second week during the laying period
~~*Salmonella* Enteritidis and *Salmonella* Typhimurium~~ **All salmonella serotypes with public health significance[a]**	2. Commercial layers 2.1 Rearing flocks 2.2 Laying flocks	~~**a) feedingstuffs**~~ ~~**b) live animals**~~ ~~**a) feedingstuffs**~~ ~~**b) live animals**~~	i) Day-old chicks ii) pullets 2 weeks before moving to laying phase or laying unit i) every ~~**9**~~ **15** weeks during the laying phase
All salmonella serotypes with public health significance[a]	3. Broilers	~~**a) feedingstuffs**~~ ~~**b) live animals**~~ ~~**c) Ante-mortem inspection**~~	i) Birds leaving for slaughter
All salmonella serotypes with public health significance[a]	4. Turkeys 5. **Breeding** pigs	~~**a) Ante-mortem inspection**~~ ~~**a) Ante-mortem inspection**~~	i) Birds leaving for slaughter i) Animals leaving for slaughter
All salmonella serotypes with public health significance[(a)]	**6. Slaughter pigs**		**Shall be defined when the target is established**

[(a)] Serotypes shall be defined when the Community target is established.

2. The data collected shall be accompanied with the following information:

(a) Date and place of sampling;

(b) Identification of the flock / herd.

3. Immunological testing may not be used if the animals have been vaccinated unless it has been proved the vaccine used does not interfere with the testing method applied.

C. SPECIFIC REQUIREMENTS CONCERNING BREEDING FLOCKS OF GALLUS GALLUS

Where, as a result of an investigation carried out in accordance with Point 1 of the Table in Part B, the presence of *Salmonella* Enteritidis or *Salmonella* Typhimurium is confirmed in the birds in a breeding flock of *Gallus gallus*, the following measures must be taken:

Non-incubated eggs from the flock must be destroyed or be intended for the manufacture of egg products or subject to an equivalent treatment to guarantee the elimination of *Salmonella*–Enteritidis and *Salmonella* Typhimurium, in accordance with Regulation (EC) No …/… [*on the hygiene of foodstuffs*];

Without prejudice to the requirements under Part E, all the birds - including day-old chicks - in the flock must be slaughtered or destroyed so as to reduce as much as possible the risk of spreading salmonella. Slaughtering must be carried out in accordance with [Annex II, Section II, Chapter IV, point 11] (*the relevant provisions*) of Regulation (EC) No …/… of the European Parliament and of the Council of …[*laying down specific hygiene rules for food of animal origin*][14], and with [Annex II, Chapter III, Section I, point 5] (*the relevant provisions*) of Regulation (EC) No …/… of the European Parliament and of the Council [*laying down detailed rules for the organisation of official controls on products of animal origin intended for human consumption*][15].

Where eggs for hatching from flocks in which the presence of *Salmonella* Enteritidis or *Salmonella* Typhimurium has been confirmed are still present in a hatchery, they must be destroyed or treated as category 3 material in accordance with Regulation (EC) No …/… of the European Parliament and of the Council of … [*laying down the health rules concerning animal by-products not intended for human consumption*][16].

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14 OJ L ...

15 OJ L ...

16 OJ L ...

D. SPECIFIC REQUIREMENTS CONCERNING FLOCKS OF LAYING HENS

As from 1 January 2008, eggs shall not be used for direct human consumption (table eggs) unless they originate from a commercial flock of laying hens subject to the testing scheme in accordance with the Table of Part B and subsequently found non contaminated.

The eggs originating from flocks with unknown status, suspected of being contaminated or from contaminated flocks must be intended for the manufacture of egg products or subject to an equivalent treatment to guarantee the elimination of ~~**Salmonella Enteritidis and Salmonella Typhimurium**~~ **all salmonella serotypes with public health significance**, in accordance with Regulation (EC) No …/… *[on the hygiene of foodstuffs*]:.

Without prejudice to the requirements under Part E, all the birds in the flock must be slaughtered or destroyed so as to reduce as much as possible the risk of spreading ~~**salmonella**~~ **zoonoses**. Slaughtering must be carried out in accordance with [Annex II, Section II, Chapter IV, point 11] (*the relevant provisions*) of Regulation (EC) No …/… of the European Parliament and of the Council of …[*laying down specific hygiene rules for food of animal origin*] and with [Annex II, Chapter III, Section I, Point 5] (*the relevant provisions*) of Regulation (EC) No …/… of the European Parliament and of the Council [*laying down detailed rules for the organisation of official controls on products of animal origin intended for human consumption*].

E. SPECIFIC REQUIREMENTS CONCERNING FLOCKS OF BROILERS

As from 1 January 2009, the following criterion will apply for placing on the market of fresh poultry meat, unless it is destined for an industrial heat treatment or another treatment able to eliminate salmonella, in accordance with Regulation (EC) No …/… *[on the hygiene of foodstuffs*]:

"Salmonella: absence in 25 grammes"

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s):Health and Consumer Protection

Activity(ies): veterinary public health

TITLE OF ACTION:

1. 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

2. 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

1. BUDGET LINE(S) + HEADINGS

B1-330 Animal disease eradication and monitoring programmes and monitoring of the physical conditions of animals that could pose a public-health risk linked to an external factor.

This Chapter will cover co-ordinated monitoring programmes as referred to in Article 6 of the above proposal for a Directive and certain actions under national control programmes to be implemented in Member States, pursuant to the above proposal for a Regulation. The financial provisions are established in the new Chapter on zoonoses of Council Decision 90/424/EEC on expenditure in the veterinary field[1], as revised pursuant to the above proposal for a Directive.

B1-331 Other measures in the veterinary, animal welfare and public health field.

This Chapter will cover financing of the relevant Community Reference Laboratories.

2. OVERALL FIGURES

2.1 Total allocation for action (Part B): 2.4 € millions in EC

2.2 Period of application: 2003-

The existing Zoonosis Directive (92/117/EEC) is reviewed. The aim is to enhance the monitoring and control of zoonoses in the Community in order to protect public health. Expenses are due to

– activities of Community Reference Laboratories

– co-financing of Community co-ordinated monitoring programmes

– co-financing of certain specified control measures.

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

As regards financing of specified control measures, Community financing will be continued on the basis of the existing rules in Directive 92/117/EEC. See also 5.1.2 below.

Only co-financing of co-ordinated monitoring programmes is a technical measure additional to the measures already established under existing Council Directive 92/117/EEC and financed under Council Decision 90/424/EEC. For this measure, it is foreseen to allocate yearly 0.4 Mio€. That is why financing of this new measure only is included in the estimate for the proposals.

2.3 Overall multiannual estimate on expenditure :

a) Schedule of commitment appropriations/payment appropriations (financial intervention) *(see point 6.1.1)*

€ million (*to 3rd decimal place)*

	Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and subs. years	Total
Commitments	0.4	0.4	0.4	0.4	0.4	0.4	2.4
Payments	0.4	0.4	0.4	0.4	0.4	0.4	2.4

b) Technical and administrative assistance and support expenditure *(see point 6.1.2)*

NO

Commitments/ payments							

Subtotal a+b							
Commitments							
Payments							

c) Overall financial impact of human resources and other administrative expenditure
(see points 7.2 and 7.3)

Commitment/ payments	0.432	0.432	0.432	0.432	0.432	0.432	2.592

TOTAL a+b+c	0.432	0.432	0.432	0.432	0.432	0.432	2.592
Commitments							
Payments							

These resources in the Commission services will be used for the overall management of the implementation of the proposals. It will consist in particular in technical management of the programmes to be submitted by Member States and non-Member Countries and to be approved by the Commission, and in supervision/management of the (co-)financing of actions in Member States.

2.4 Compatibility with the financial programming and the financial perspective

X Proposal compatible with the existing financial programming

☐ This proposal will entail reprogramming of the relevant heading in the financial perspective

☐ This may entail application of the provisions of the Interinstitutional Agreement.

2.5 Financial impact on revenue

No

☐ No financial implications (involves technical aspects regarding implementation of a measure)

OR

☐ Financial impact – the effect on revenue is as follows:

Note: All details and observations pertaining to the method of calculating the effect on revenue should be included in a separate annex.

€ million *(to 1 decimal place)*

		Prior to action (Year n-1)	Situation following action					
Budget line	Revenue		Year n	n+1	n+2	n+3	n+4	n+5
	a) Revenue in absolute terms							
	b) Change in Revenue	Δ						

(Please state each budget line involved, adding the appropriate number of rows to the table if there is an effect on more than one budget line)

3. BUDGET CHARACTERISTICS

Type of expenditure		**New**	**EFTA participation**	**Participation applicant countries**	**Heading Financial Perspective**
Comp	**Non-diff**	**YES***	**NO**	**NO**	**N° 1 A**

***: only co-ordinated monitoring programmes**

4. LEGAL BASIS

Legal basis for the proposals: Article 152 of Treaty.

Financial instrument: Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field.

5. DESCRIPTION AND GROUNDS

5.1 Need for Community intervention [2]

5.1.1 Objectives pursued

Preliminary: a revision of the current legislation on the prevention of zoonoses (Directive 92/117/EEC) was foreseen pursuant to article 15a of the Directive and in that framework, expansion of controls to laying hens was foreseen. The proposals are part of the programme foreseen in the White paper on Food Safety adopted by the Commission on 12 January 2000. It is essential that the proposals respect the main principles of the White paper on Food Safety, in particular: assuring a high standard of food safety; creating an integrated policy from 'farm to table'; being based on risk analysis, including possibilities to take into account the precautionary principle and other legitimate factors.

The essential aim is to increase protection of public health, essentially by decreasing seriously the number of human cases of salmonellosis, due to food consumption. This will be achieved by decreasing prevalence of salmonella in the main animal populations source of salmonella (breeding flocks of *Gallus gallus,* then commercial flocks, then turkeys and breeding herds of pigs). Decreasing the prevalence in animal populations will decrease the concentration in primary products and further down the food chain.

The cost of food-borne salmonellosis (impact of human disease) is estimated to yearly 560-2840Mio€. Given the very high economic costs occasioned by zoonoses, not only to operators but also to society at large, public financing of measures to reduce or eliminate the diseases/infections is justified. The need for a Community dimension to financial support is also clear. Community financial participation provides a means for ensuring that all Member States affected by a given disease/infection make co-ordinated efforts which, taken together, will be much more effective at reducing or eliminating that threat throughout the Community, while at the same time permitting States to continue to address problems that are particularly important on their territory. In the absence of Community participation, they will naturally tend to prefer to address only their own priorities. As regards financing of certain specified control measures, Community financing will be continued on the basis of the existing rules in Directive 92/117/EEC, as established in the proposals.

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2 For further information see a separate guidance paper .

The only new measure for Community co-financing in the proposals is relating to co-ordinated monitoring programmes, which are an important element to enhance monitoring and define baseline values of pathogens (salmonella). It will be a preliminary step for setting or reviewing pathogen reduction targets as required under the proposals.

5.1.2 Measures taken in connection with ex ante *evaluation*

As indicated above, public financing of measures to reduce or eliminate the diseases/infections is justified. The effectiveness of programmes in a Member State can be limited or undermined where in others higher levels of infection persist either directly through contamination across borders or indirectly due to economic pressures resulting from unequal financial efforts of authorities and operators in different States. Moreover, for geographical and historical reasons, national priorities are not the same. Even if progress in reducing or eliminating diseases/infections has been uneven and too limited, measures taken have proved to be effective in many cases and show that, where these are properly managed, substantial improvements are feasible.

Only co-financing of co-ordinated monitoring programmes is a technical measure additional to the measures already established under existing Council Directive 92/117/EEC and financed under Council Decision 90/424/EEC. For this new measure, it is foreseen to allocate yearly 0.4 € millions.

As regards financing of certain specified control measures, Community financing will be continued on the basis of the existing rules in Directive 92/117/EEC. It is likely that more and more Member States will present a request for co-financing of their plans. Financing of the plans will be handled in the framework of the budgetary procedures and the yearly programming. A maximum limit of 50% for co-financing of certain measures has been included in the proposed revision of the Chapter on zoonoses of the financial instrument (Council Decision 90/424/EEC).

5.1.3 Measures taken following ex post *evaluation*

5.2 Actions envisaged and arrangements for budget intervention

Three areas:

– Community Reference Laboratories (CRL): 100% Community financing of the CRL, as already established under Council Decision 90/424/EEC. The yearly technical work-programmes and estimated costs to be discussed, before a Commission Decision is adopted each year. Payment to the competent authorities in the relevant Member States.

– Co-ordinated monitoring programmes: Community co-financing (50%), pursuant to Council Decision 90/424/EEC. Programmes to be established in Commission Decisions.

– Certain specified control measures: the beneficiaries are the farmers, when their flocks or products thereof have to be slaughtered or disposed of under specified conditions, to prevent risks for public health. Financing of programmes is subject to the procedures in Council Decision 90/424/EEC: in particular, programmes for financing have to be submitted by Member States on a yearly basis; a technical and financial evaluation is carried out by the Commission services before adoption by Commission Decision. Payment to the competent authorities in the Member States. Maximum limit of 50% for co-financing.

5.3 Methods of implementation

Direct management of technical and financial approval of the actions by Commission staff. Payment of actions subject to the procedures in Council Decision 90/424/EEC. Reimbursement of expenses in Member States by payment to the Competent authorities. See also 5.2 above.

6. FINANCIAL IMPACT

6.1 Total financial impact on Part B - (over the entire programming period)

(The method of calculating the total amounts set out in the table below must be explained by the breakdown in Table 6.2.)

6.1.1 Financial intervention in € million (to the 3rd decimal place)

Only financing of new measures in the proposals, i.e. co-ordinated monitoring programmes is included.

Breakdown	Year n	n + 1	n + 2	n + 3	n+ 4	n + 5 and subs. years	Total
Action 1	0.400	0.400	0.400	0.400	0.400	0.400	2.400
Action 2							
Etc.							
TOTAL	0.400	0.400	0.400	0.400	0.400	0.400	2.400

6.1.2 Technical and administrative assistance, support expenditure and IT expenditure

	Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and subs. years	Total
1) Technical and administrative assistance							
a) Technical assistance offices							
b) Other technical and administrative assistance: - intra muros : - extra muros : *of which for construction and maintenance of computerised management systems*							
Subtotal 1							
2) Support expenditure							
a) Studies							
b) Meetings of experts							
c) Information and publications							
Subtotal 2							
TOTAL							

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)[3]

Only financing of new measures in the proposals, i.e. co-ordinated monitoring programmes is included. See calculation example in Annex

Commitments in € million (to the 3rd decimal place)

Breakdown	Type of outputs (projects, files)	Number of outputs (total for years 1…n)	Average unit cost	Total cost (total for years 1…n)
	1	2	3	4=(2X3)
Action 1 - *Measure 1* - *Measure 2* Action 2 - *Measure 1* - *Measure 2* - *Measure 3* *Etc.*	tests	6x35.000	50 % of 24 €	2.400 (6x0,400)
TOTAL COST				2.400

See calculation in the annex

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

7.1. Impact on human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Permanent officials or Temporary staff	A B C	2	1 1		*If necessary, a fuller description of the tasks may be annexed.*
Other human resources					
Total					

[3] For further information see a separate guidance paper.

7.2 Overall financial impact of human resources

Type of human resources	Amount €	Method of calculation *
Officials Temporary staff	0.216 0.216	2*0.108 2*0.108
Other human resources (give budget line)		
Total	0.432	

The amounts are total expenditure for twelve months.

7.3 Other administrative expenditure deriving from the action

Budget line (number and heading)	Amount €	Method of calculation
Overall allocation (Title A7) A0701 – Missions A07030 – Meetings A07031 – Compulsory committees (1) A07032 – Non-compulsory committees (1) A07040 – Conferences A0705 – Studies and consultations … Other expenditure (state which)		
Information systems (A-5001/A-4300)		
Other expenditure - Part A (state which)		
Total		

The amounts are total expenditure for twelve months.

(1) Specify the type of committee and the group to which it belongs.

I.	Annual total (7.2 + 7.3)	€
II.	Duration of action	Years
III.	Total cost of action (I x II)	€

8. FOLLOW-UP AND EVALUATION

8.1 Follow-up arrangements

– Financing of Community Reference Laboratories (CRL): The yearly technical work-programmes and estimated costs are evaluated between the Commission services and the relevant CRL; they are revised if necessary, before a Commission Decision is adopted each year.

– Co-ordinated monitoring programmes: the programme, as established through Commission Decisions will be performed whenever possible during one year. It is very likely that the authorities in the Member States will have to perform sampling and examinations themselves. The industry may be involved.

– Co-financing of certain specified control measures: the financial contribution will be introduced as part of a national plan submitted to and approved by the Commission. Financing of the control measures is subject to the procedures in Council Decision 90/424/EEC: in particular, the national plans containing measures for financing have to be submitted by Member States on a yearly basis; a technical and financial evaluation is carried out by the Commission services before adoption by Commission Decision. Rules are foreseen at Article 5.3.(d) of the proposed Regulation to allow progress with the control plans to be evaluated. When the pathogen reduction targets are established, the Commission decides on the timeframe within which the target shall be achieved.

To verify the implementation of the relevant national plans, Article 16 lays down that the Commission shall carry out on-the-spot checks.

8.2 Arrangements and schedule for the planned evaluation

For Community Reference Laboratories as well as for control plans implemented by Member States, a documentary evaluation is performed on a yearly basis (see above). In addition, the EU Food and Veterinary Office performs on-the-spot missions to assess implementation of Community legislation, including the national plans. The frequency of the missions will depend on the priority set for the relevant issue. So far, missions for major animal diseases control programmes have been carried out regularly, up to once per year. In addition, financial audit missions are carried out by the relevant service in Directorate General for Health and Consumer Protection. A prioritisation system is in place. Corrections are made in case of deficiencies.

9. ANTI-FRAUD MEASURES

See 8.1 and 8.2 above.

Also, OLAF may intervene on its own initiative or following information from different sources, in particular those mentioned under 8.2 above.

ANNEX TO FINANCIAL STATEMENT

Method of calculation of the estimated costs:

1. CO-ORDINATED MONITORING PROGRAMMES

Article 6 of the proposal for a Directive on the monitoring of zoonoses creates the possibility for establishing co-ordinated monitoring programmes. These programmes will serve to create sets of harmonised data which will be used as a reference when pathogen reduction targets are established according to the proposal for a Regulation on control of salmonella and other food-borne zoonotic agents. Since the Commission would need to request the Member States to carry out specified sampling and testing schemes, which possibly differ from the procedures of the national monitoring system, it is deemed necessary that the Community could finance such co-ordinated programmes.

For example, a single study on the exact prevalence of salmonella in the poultry population in the different member States would need testing of a representative number of samples. On the basis of around 35,000 samples within the EU and taking into account the estimated cost of a salmonella bacteriological test: EUR 24, it is estimated that the financing of such a study would be yearly EUR 800 000, of which the Community would co-finance 50%. It is foreseen that such studies would be needed yearly, in conjunction with the establishment of pathogen reduction targets for specified combinations of pathogen/commodities.