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REPORT TO THE EUROPEAN PARLIAMENT AND TO THE COUNCIL
on the measures to be put in force for the control and prevention of zoonoses

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

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

(presented by the Commission)

REPORT TO THE EUROPEAN PARLIAMENT AND TO THE COUNCIL

on the measures to be put in force for the control and prevention of zoonoses

A. SUMMARY

The report describes the current situation as regards the presence of zoonoses (diseases transmissible from animals to man) and zoonotic organisms and the legislative framework in force in the Community to combat zoonoses. Experiences gained during the implementation of specific zoonoses legislation are particularly referred to. It is concluded that although certain progress has been observed in the monitoring and controlling of zoonoses, these measures need to be intensified. The review of the current legislation should lead to a system where more appropriate and comparable data on the occurrence of zoonoses is available to be used, for example, in risk assessments. The policy of controlling zoonoses, in particular in farm animal populations, should be changed in a manner whereby Member States are obliged to reach certain common targets for the reduction of zoonotic pathogens. The means of attaining the targets should be selected and expressed in a national control programme. Finally, the impacts of the proposed new approach are discussed.

B. INTRODUCTION

Article 15a of Council Directive 92/117/EEC of 17 December 1992 concerning measures for protection against specified zoonoses and specific zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications¹, as amended by Directive 97/22/EC², provides for the Commission to submit a report to the Council concerning the measures to be implemented for the control and prevention of zoonoses. This report shall refer in particular to:

- the new rules for the reporting system for zoonoses,
- the methods for collecting samples and for examinations in approved national laboratories,
- the control of salmonella in poultry laying flocks,
- the control of salmonella in poultry breeding flocks and in compound feedingstuffs for poultry, and
- any measures to combat zoonoses other than salmonellosis.

The report shall be accompanied by proposals concerning zoonoses, especially in the context of the review of the Directive. As amended by Directive 97/22/EC, the Directive required that the Council should act on the proposals by a qualified majority before 1 June 1998. Later on, Directive 92/117/EEC was amended for the second time by Directive 1999/72/EC³, which provided for the Commission to present the report and accompanying proposals by 30 March 2000.

¹ OJ L 62, 15.3.1993, p. 38.

² OJ L 113, 30.4.1997, p. 9.

³ OJ L 210, 10.8.1999, p. 12.

This report and the accompanying two proposals are part of the programme foreseen in the White Paper on Food Safety (COM(1999) 719 final) adopted by the Commission on 12 January 2000. It is essential that the proposals concerning monitoring and control of zoonoses respect the main principles of the White Paper, in particular

- assuring a high standard of food safety,
- laying the responsibility for food safety primarily with food businesses, including feed manufacturers and farmers,
- creating an integrated policy from 'farm to table',
- permitting traceability,
- ensuring transparency, and
- being based on risk analysis, including possibilities to take into account the precautionary principle and other legitimate factors.

The report and proposals accompanying this report, a proposal for a Parliament and Council Directive on the monitoring of zoonoses and zoonotic agents and a proposal for a Parliament and Council Regulation on the control of specified zoonoses and zoonotic agents, are submitted somewhat later than provided for in Directive 92/117/EEC. However, the extra time taken has enabled the Commission to take into consideration the opinion of the Scientific Committee on Veterinary Measures relating to Public Health on Zoonoses adopted on 12 April 2000, as well as the proposal for a Regulation 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 (COM(2000) 716 final).

C. PRESENT SITUATION ON THE CONTROL AND PREVENTION OF ZOOSE

C.1. Epidemiological situation on zoonoses in the EU

In co-operation with the Community Reference Laboratory for the Epidemiology of Zoonoses, the Commission has prepared the Annual Report on Trends and Sources of Zoonotic Agents in animals, feeding stuff, food and man in the European Union. The first report covered year 1994 and the report concerning the year 1999 was presented in March 2001. The goals regarding the collection of epidemiological data have been achieved with increasing success each year and currently all 15 Member States submit their annual reports. However, the quality of the data still suffers from unharmonised surveillance systems, rendering it difficult at present to draw valuable conclusions on the trends of zoonotic agents within the EU.

All Member States provided a report on trends and sources of zoonotic agents in 1999 according to Article 5 of Directive 92/117/EEC, which contained at least some information on the zoonotic situation in animals, feedingstuffs, food and man. Community rules forming a basis for comparable data were in force for bovine tuberculosis, bovine, ovine and caprine brucellosis, *Salmonella* Enteritidis and *Salmonella* Typhimurium in poultry breeding flocks, *Trichinella* and *Echinococcus* sp. (meat inspection). For other zoonoses, a valuable overview is available on the national approaches to tackle zoonoses and the results thereof.

As regards human illnesses, two zoonoses caused the major part of the reported cases: *Salmonella* and *Campylobacter*, with 165 659 and 126 981 reported cases in 1999, respectively. Of the other zoonoses, for which information is collected, 8309 cases were reported for *Yersinia*, 3843 for *Brucella*, 665 for *Listeria*, 554 for *Echinococcus*, 309 for *Toxoplasma*, 155 for *Mycobacterium bovis* and 48 for *Trichinella*. No human rabies cases occurred in 1999. The EU report of 1999 included also information on human cases of verotoxigenic *E.coli* (VTEC) infections with 1892 cases.

However, these figures have to be interpreted carefully, since it is likely that many human infections go unrecorded with either patients failing to present to health services, or no laboratory diagnosis being made, or the diagnosis not being reported centrally. The cases reported may in fact only represent the severe end of the spectrum of the disease. Despite this underreporting, it appears that the magnitude of these human health problems is significant.

As regards details on the gravity of these zoonoses, the total number of fatalities is not recorded. However, certain data are known:

- According to the SCVPH opinion on zoonoses of 12 April 2000, in approximately 5% of salmonellosis cases, sequelae (like reactive arthritis) arise. In around 2% of these complicated cases (i.e. 1 in every 1000 salmonellosis cases), the patient dies. This ratio would lead to an estimate of around 200 fatalities per year in the EU. Reduced sensitivity of certain salmonella strains to antibiotics may not only prolong the duration of clinical disease but also affect the incidence of sequelae or death.
- Still according to the above scientific opinion, *Campylobacter* has shown to cause a serious disease, Guillain-Barré syndrome, a disorder resulting in acute neuromuscular paralysis. It is estimated to occur about once in every 1000 cases of campylobacteriosis.
- As regards listeriosis, the incidence is much lower than for the two other zoonoses above, but the case fatality rate (proportion of cases that die) is reported being between 20 and 40%. In immuno-compromised individuals, the reported case fatality rates may approach 75% according to the above scientific opinion.
- As regards VTEC (verotoxigenic *E.coli*) infections, around 5% of cases progress into haemolytic uraemic syndrome and of these cases, 3-5% die and a similar proportion develop major sequelae.

As regards the sources of salmonella, the principal reservoir of the common *Salmonella* spp. is the gastrointestinal tract of mammals and birds. *S. Enteritidis* and *S. Typhimurium* are by far the most common serotypes in human isolates in the EU: according to the data forwarded by the Member States through the zoonoses reporting system in 1998, both serotypes represented between 60 and over 90% of all notified human cases (*S. Enteritidis* being No1 in all but one member States). *S. Enteritidis* and *S. Typhimurium* are the serotypes most frequently associated with eggs or poultry and other farm animals respectively.

C.2. THE COMMUNITY LEGISLATION REGARDING THE CONTROL OF ZOO NOTIC INFECTIONS

C.2.1. Directive 92/117/EEC

Council Directive 92/117/EEC seeks to establish a reliable reporting system on the occurrence of zoonoses generally, and to bring about also monitoring, control, and ultimately eradication of some invasive serotypes of salmonella in poultry breeding flocks. It also provides for the development of control measures for other zoonotic agents than salmonella.

Currently the control measures cover only salmonella in poultry breeding flocks since in the late 1980's the increasing number of the cases of human salmonellosis caused by *Salmonella* Enteritidis derived from table eggs was regarded as the most alarming issue. A top-down approach was adopted by firstly providing for measures to eradicate *Salmonella* Enteritidis (and *Salmonella* Typhimurium) in breeding flocks to reduce the vertical transmission to commercial flocks. Measures in commercial flocks were foreseen for the future.

C.2.2. Other legislation

Reduction of the incidence of zoonoses and zoonotic agents in order to prevent food-borne infections requires a concerted multi-disciplinary approach including control measures at all stages of the food chain:

- in animal waste and feed processing,
- at farm level,
- in processing and distribution of foodstuffs of animal origin, and
- at consumer level.

Directives 90/667/EEC⁴ and 92/118/EEC⁵ and the corresponding Commission Decisions cover the control of zoonotic agents in animal waste and feed processing. These provisions cover substances with ingredients of animal origin. A proposal for a fundamental review of this legislation has been adopted by the Commission (COM(2000) 574 final). No rules concerning zoonotic organisms exist yet in the Community legislation for feedingstuffs comprising solely ingredients of vegetable origin. The establishment of such legislation is however foreseen as a part of the legislative programme of the White Paper on Food Safety since it is evident that feedingstuffs of vegetable origin can harbour zoonotic agents.

Provisions on the control of certain zoonoses at farm level have been laid down in various directives regarding animal health conditions in trade of live animals, e.g. provisions on bovine tuberculosis and brucellosis in Directive 64/432/EEC⁶. Furthermore, there are rules in certain hygiene directives providing for the control of zoonoses at farm level, e.g. in Directive 92/46/EEC⁷ regarding dairy herds.

⁴ OJ L 363, 27.12.1990, p. 51.

⁵ OJ L 62, 15.3.1993, p. 49.

⁶ OJ 121, 29.7.1964, p. 1977.

⁷ OJ L 268, 14.9.1992, p. 1.

Measures on the control of zoonotic agents in processing and distribution of foodstuffs of animal origin are provided in the corresponding hygiene directives. These provisions range from the specific, for example, ante and post mortem inspection of animals in abattoirs, through to the general, for example, requirements for hygienic construction and operation of food processing premises and provisions for minimum processing conditions and storage/transport temperatures.

Control of zoonoses at consumer level is mainly beyond the scope of legislative actions. Progress in that field may be achieved by intensifying general consumer advice on hygienic food handling and increasing the awareness of certain specific risk groups, like pregnant women.

The Community legislation on food hygiene is currently being restructured and revised in order to establish a coherent and consistent body of hygiene rules based on an integrated approach covering the whole food chain “from stable to table”. This approach will be realised by proposing a legal instrument on food hygiene covering the entire production chain of all foodstuffs both of animal and of plant origin. One of the main objectives of the new legislation is to prevent food-borne infections. Efforts will be directed to highlighting producers’ liability in ensuring food safety and establishing HACCP-type principles in controls. Risk-based systems are intended to cover primary agricultural production at farm level. A general obligation will be proposed providing for the Member States to ensure that Good Animal Husbandry Practices (GAHP) are complied with in the production of animals. From the point of view of zoonoses control this means that an individual farmer will be obliged to take the necessary preventive actions against zoonotic infections.

The European Parliament and the Council adopted on 24 September 1998 Decision 2119/98/EC setting up a network for the epidemiological surveillance and control of communicable diseases in the Community⁸. Thus, the Commission shall facilitate close co-operation among the authorities responsible for public health in the Member States. One of the main activities foreseen in Decision 2119/98/EC is the establishment of an information system for the surveillance, prevention and control of communicable diseases at Community level. To that end, the Commission adopted Decision 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network⁹. In the Decision a number of food- and water-borne and other zoonoses are listed. In particular it is stipulated that where specific surveillance networks are put in place for zoonoses for which surveillance of human cases is required under Directive 92/117/EEC, surveillance shall be performed in accordance with Decision 2119/98/EC and such data required for the implementation of Directive 92/117/EEC shall be made fully available for that purpose. To this end, case definitions and surveillance methods for human disease shall be drawn up, as far as possible, in such a way that the data collected serve also Directive 92/117/EEC.

⁸ OJ L 282, 20.10.1998, p. 76.

⁹ OJ L 28, 3.2.2000, p. 50.

C.3. THE EXPERIENCE GAINED UNDER THE CURRENT PROVISIONS

Community legislation on the monitoring and control of zoonoses has been developed gradually. It was, however, soon realised that not all Member States were able to fully implement the system foreseen by the Zoonoses Directive. Indeed, only six Member States have been recognised as fully implementing the provisions on salmonella control of breeding flocks (Table 1). However, pending the review of Directive 92/117/EEC, the obligation to submit plans for monitoring and control of salmonella in fowl flocks has been suspended through Directive 97/22/EC, for those Member States which have not yet submitted such plans. Even though certain deadlines of the Directive were postponed by Directive 97/22/EC, a number of Member States still have not submitted their national plans for attaining the objectives of the Directive nor implemented the above provisions. Nevertheless, it should be noted that authorities have taken effective measures against salmonella and other zoonotic organisms in all Member States either alone or in co-operation with private businesses. The Commission will continue to take the necessary steps to ensure that the current Directive is implemented in all Member States, as this is a prerequisite for proposals to improve the measures for controlling zoonoses.

Table 1. National salmonella control plans submitted and approved according to Directive 92/117/EEC.

Member State	Reference of approval
Denmark	94/507/EC, 96/692/EC
Ireland	96/389/EC
Finland	96/390/EC
Sweden	96/502/EC
Austria	2000/60/EC
France	2000/629/EC

Several advantages have followed the implementation of the Directive. Firstly, the obligation to monitor certain zoonoses and subsequently to report the findings at the national level and to the Commission has created new activity in this field. In many Member States the co-operation between responsible authorities for feedingstuffs control, animal and public health, and human medicine has developed favourably, creating also better possibilities to combat zoonoses. As the result of monitoring, the awareness of the presence of zoonotic agents in different parts of the food chain, as well as in wild and pet animal populations, has increased, necessitating preventive and control measures.

Secondly, the incidence of salmonella, the major target of the controls laid down by Directive 92/117/EEC, in human population in many Member States seems to be stabilised and even decreasing. Although it is difficult to speculate on what has been the direct effect of the specific control requirements towards *Salmonella* Enteritidis and *Salmonella* Typhimurium in the breeding flocks of domestic fowl, it may be stated that the action taken throughout the Community, based on both mandatory and voluntary programmes, has brought success.

One important aspect of the implementation of the control provisions of Directive 92/117/EEC has been the possibility for the co-financing of national control programmes. The co-financing corresponds to 50 % of the costs incurred from the measures for slaughter and destruction and official sampling. Since 1995, the Community has co-financed the control of salmonella in poultry, as indicated in Table 2.

Table 2. The Community's financial contribution towards the measures for slaughter and destruction and official sampling according to Article 9 of Directive 92/117/EEC

Year	Member State	Programme	Maximum financial contribution from the Community (ECU / EUR)	Amount finally paid (ECU / EUR)
1994	Denmark	Salmonella in poultry	330 000	330 000
1995	Denmark	Salmonella in poultry	660 000	-
1996	Denmark	Salmonella in poultry	470 000	203 476
1997	Denmark	Salmonella in poultry	200 000	200 000
1998	Denmark	Salmonella in poultry	500 000	48 619
1999	Denmark	Salmonella in poultry	500 000	162 989
2000	Denmark	Salmonella in poultry	400 000	
	Ireland	Salmonella in poultry	50 000	
2001	Denmark	Salmonella in poultry	200 000	
	Austria	Salmonella in poultry	100 000	
	France	Salmonella in poultry	3 000 000	

Financial contributions have been awarded to Member States also in the framework of the programmes for the eradication and monitoring of animal diseases, based on Council Decision 90/424/EEC on expenditure in the veterinary field¹⁰. This co-financing has contributed to the control and monitoring of several zoonoses, notably bovine, ovine and caprine brucellosis, bovine tuberculosis and rabies, and periodically hydatidosis (echinococcosis) and enterohaemorrhagic *E. coli* (EHEC). The maximum Community financial contributions towards co-financing of bovine brucellosis, ovine and caprine brucellosis, bovine tuberculosis and rabies for the year 2000 are EUR 14 250 000, EUR 14 000 000, EUR 8 235 000, and EUR 2 895 000, respectively.

¹⁰ OJ L 224, 18.8.1990, p. 19. Decision as last amended by Council Decision 2001/12/EC (OJ L 3, 6.1.2001, p. 27).

The difficulties in the implementation of Directive 92/117/EEC were recognised by the Commission and subsequently modifications to the Directive were proposed, which lead to two sets of amendments, in Directive 97/22/EC and Directive 1999/72/EC. According to provisions laid down in Directive 97/22/EC, Member States should have implemented as from 1 January 1998 the minimum measures laid down for salmonella control in poultry breeding flocks. Most Member States seem to have implemented the main features of these requirements by 1999. The Commission's Food and Veterinary Office (FVO) has recently finalised a series of missions on the production of poultry meat and in that context also salmonella control was evaluated. A general report is due to be issued subsequently.

A number of other factors call for the review of Directive 92/117/EEC. Trends in food-borne infections show that the current situation is far from satisfactory. The numbers of human infections caused by “traditional” pathogens like salmonella remain high and, in addition, there are emerging “new” pathogens (e.g. *Campylobacter*, VTEC). Although these trends may be partially explained by improved diagnostic methods and reporting systems, it is obvious that effective and strict measures at Community level are needed to respond to the increasing threat posed by food-borne infections to human health.

Community legislation on food hygiene will cover in the future the entire food production chain “from stable to table” and will also introduce certain obligations at farm level. One of its main objectives is to safeguard human health from food-borne infections. This new environment necessitates ensuring the coherence between the specific zoonoses legislation and the general food hygiene and food control legislation.

Various situations and attitudes in various Member States as regards food-borne pathogens could seriously jeopardise the intra-Community market in the future. There could be pressure in Member States with high standards to introduce unilateral measures to protect their obtained level. To prevent such a threat, more uniform measures offering sufficient guarantees to protect animal populations from zoonotic organisms, and thus protecting consumer health from food-borne infections, should be introduced at Community level.

Food safety issues are of increasing importance in world trade. A clear policy in the Community is needed when these issues are addressed in trade negotiations with third countries.

D. NEW APPROACH TOWARDS CONTROL AND PREVENTION OF ZONOSSES

D.1. Basic elements of the approach

With a view to preparing a proposal to improve the measures for monitoring and controlling zoonoses, the Commission together with the experts of the Member States and other interested parties has reflected upon a fundamental change to the current policy and on the objectives of possible future strategies. As a result, a number of objectives and concerns have been identified such as to:

- create a system of monitoring of zoonoses based on harmonised rules, when necessary,
- develop measures according to “farm to table” principle, by producing safe food from healthy animals,
- take account of the level of prevalence of zoonotic agents in the Member States,

- give guarantees for the improvement of the safety of consumers by introducing pathogen reduction programmes to be implemented by the Member States,
- give the flexibility needed for the Member States to achieve common targets, and
- take account of concerns with regard to the spreading of zoonotic agents through animal trade.

The means of attaining these objectives and in particular the pathogen reduction schemes need to be set up according to scientifically based risk assessments. However, even if such risk assessments have not yet been undertaken for certain zoonoses or zoonotic agents, this should not justify that no action is taken in that respect. In order to allow the Commission to follow-up the progress of such schemes, Member States have to submit national programmes concerning the pursuance and achievement of these targets. However, an individual Member State will have the possibility to choose the tools that it deems necessary to obtain the targets. Since actions to control zoonotic agents start with primary production, the implementation of principles of Good Animal Husbandry Practices will play a key role.

D.2. Intensified monitoring and extended control

A critical issue for the optimal implementation of the Community strategy will be the continuing collection of epidemiological data on zoonoses: in the future the measures intended to combat zoonoses should be based on risk assessments and this will increase the importance of accurate information on zoonoses and zoonotic agents at all stages of the food chain. The new framework for scientific advice and scientific support in matters of food safety set up following the proposal for a Regulation 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 (COM(2000) 716 final) and subsequent collection and analysis of data relating to biological risks, will be used. Moreover, efforts should be directed to build on the existing monitoring provisions under the current Directive 92/117/EEC and harmonise, where necessary, the reporting system by introducing certain fixed criteria concerning, for example, the case definitions. Since zoonotic agents can present new and emerging features, like antimicrobial resistance, which are making them more harmful, their monitoring should in particular be emphasised. To permit targeted monitoring which could lay the basis, for example, for base-line values capable of being used as starting prevalences for pathogen reduction, co-ordinated monitoring programmes may be needed.

While Directive 92/117/EEC includes only control measures for certain types of salmonella, the new approach would allow for the establishment of control targets for other food-borne pathogens too. With regard to the impact on human health and the feasibility to target the control measures at the farm level, bacteria like *Campylobacter* and verotoxigenic *E. coli* could be addressed, once the necessary scientific basis for controlling them has been established.

The new approach would mean an improvement in the safety of consumers especially having regard to the pathogens with the greatest importance to health. As regards salmonella, the data tend to show that *S. Enteritidis* and *S. Typhimurium* are the prominent serotypes in human food-borne salmonellosis and the main sources are poultry products, followed by other meat products, pork in particular. In order to improve the level of safety for consumers, and prolong the actions already initiated under Directive 92/117/EEC, there is a need to take appropriate measures, starting from egg and poultry meat production.

D.3. Impacts of the approach

The main impact expected of the proposal would be the amelioration of public health by decreased number of human cases of zoonoses, in particular salmonellosis.

Although the measures envisaged to reduce the prevalence of zoonotic agents would incur costs both to authorities and to food businesses, the selected approach would profit businesses. The gain is expected to follow from increased confidence in both live animals and food produced from animals covered by control programmes. The EU food business would also gain from increased exports to world market due to a clearer and more comprehensive zoonoses control policy and high quality live animals and foods. Moreover, on the medium-term, the reduced level of pathogens means less need for product recalls, and a preventive approach will also help to reduce the need to use antibiotics.

This chapter aims to describe the benefits and costs of the approach proposed. Particular attention is paid to the effects on trade.

D.3.1. Health costs

Within certain Member States and third countries cost-benefit analyses on specific control programmes have been undertaken, in particular for salmonella. In general, these analyses have shown that the economic impact of human disease caused by salmonella is considerable. A recent study made in the USA (Frentzen, P.D. et al. Food Review, 22 (2), 1999, 10-15) estimates that the cost of a single case of salmonellosis varies from EUR 24 (case recovering without medical care) to EUR 3.8 million (fatal case calculated using so-called labour market approach). Assuming that the incidence of the disease and the share of different categories of the gravity are similar in Europe, it can be estimated that the costs of human salmonellosis in the EU are yearly MEUR 620 - 3160. It is generally assumed that 90 % of cases of salmonellosis are food-borne. Thus, the cost of food-borne salmonellosis would be yearly MEUR 560 - 2840.

D.3.2. Costs of financing of monitoring and control

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 is justified. Moreover, even if progress in that direction 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. The need for a Community dimension to financial support is also clear. 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. Community financial participation provides a means for ensuring that all Member States affected by a given disease 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.

At the same time, the question of how to use limited Community funds most effectively is far from straightforward. Every effort needs to be made to maximise the return on the Community's investment in effective disease reduction. This means not only identifying priorities for concentrated common efforts but also providing incentives for authorities and operators to manage programmes as rigorously as possible. Possibilities include raising the level of Community support where programmes are proving their effectiveness by reference to properly controlled benchmarks for the reduction of infection levels. The same might apply where Member States have ensured a certain financial participation from operators, including perhaps the development of insurance regimes to address acute outbreaks.

Such possibilities require further study and discussion with all concerned and the Commission will shortly launch a consultation exercise on the subject in relation to both zoonoses and other animal diseases. Once the consultation exercise is complete, it intends to amend those rules if it appears, as seems likely, that there are possibilities for improving the effectiveness of Community spending.

In the meantime, it is proposed to continue Community financing on the basis of the existing rules, not least to allow programmes already launched to be funded as expected. Provisions in this respect, established in Council Decision 90/424/EEC on expenditure in the veterinary field, need to be amended.

D.3.3. Impact on trade

One of the main objectives of the proposal on the control of zoonoses is to ensure that any contamination or re-contamination carried by live animals or hatching eggs transferred from one holding to another can be eliminated. Also, information concerning animals for slaughter will be necessary. As to the purchases within a country, Member States should create necessary tools for that purpose within their national control programmes. But to ensure that live animals or hatching eggs purchased from other Member States or from third countries comply with the objectives of the corresponding national programme, it is proposed that in the appropriate health certificates the status of the flock or herd of origin should be stated. The appropriate amendments to the relevant health certificates will be established in due course by Commission Decisions. For breeding flocks of *Gallus gallus* infected by *Salmonella* Enteritidis or *Salmonella* Typhimurium, no eggs or birds shall leave the establishment other than for slaughter, special treatment or destruction. Ultimately, when the prevalence of a given zoonosis in a certain animal population is reasonably low, it is nonetheless necessary to require that animals or hatching eggs purchased for production purposes derive from flocks or herds with a negative status. Therefore it is proposed that a Member State, with the approval of the Commission, could require certain criteria to be observed, based on the results of testing, to preserve the low level of prevalence which has been obtained.

Since such a provision could affect the free circulation of goods, it is necessary that the Commission has the power to decide on common criteria which the Member States could apply. Moreover, it is foreseen that when the results of the improved monitoring activities are available, the differences in prevalences will be such as to create a stronger demand to improve the situation.

Also for table eggs, once the transitional period before full implementation of the control measures concerning laying hens has elapsed, eggs will not be allowed to be marketed for direct human consumption unless they originate from a flock subject to relevant testing, and subsequently found free of *S. Enteritidis* and *S. Typhimurium*. For poultry meat, a criterion of "absence of salmonella in 25g" will apply after a transitional period.

Concerning laying hens and broilers, until the transitional period before full implementation of the control measures has elapsed, the proposal would have no impact on the additional guarantees given to Finland and Sweden upon their accession, as regards salmonella in those categories of production.

As to trade with third countries, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) plays a key role. The Agreement provides that Members shall ensure that any sanitary or phytosanitary measure:

- is applied only to the extent necessary to protect human, animal or plant life or health,
- is based on scientific principles, and
- is not maintained without scientific evidence.

Measures based on international standards, guidelines or recommendations, where they exist, are presumed to be consistent with the relevant provision of the Agreement.

Since such international standards do not exist, sanitary or phytosanitary measures shall be based on an assessment, appropriate to the circumstances, of the risks to human, animal or plant life or health. In the assessment of specific risks, Member States shall take into account, in accordance with the SPS agreement: available scientific evidence; relevant process and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions and quarantine or other treatment. The Appellate Body report in the Hormones case stated that the risk that is to be evaluated in a risk assessment is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also factors not susceptible of quantitative analysis. Such risk assessment regarding food-borne bacteria along the food chain in particular, belongs to that category of risk assessment that is more qualitative than quantitative.

In order to maintain the high level of protection required by the Treaty in the Community, equivalent measures should be required from exporting third countries including the presentation of control programmes and health certification, where relevant. Although the evaluation of programmes presented by third countries will cause a heavy workload for the Commission services, the experience gathered with similar mechanisms shows that this approach is feasible.

E. CONCLUSIONS

The provisions of Directive 92/117/EEC need to be revised in the light of the experiences gained in their implementation. Poultry products still host a major source of human salmonellosis. Nevertheless, in the future the results of risk assessment may reveal other important sources of zoonotic agents, or new types of organisms may emerge. Therefore a global framework for control of zoonoses must be established.

The policy against zoonotic infections needs to be based on risk analysis including three elements: risk assessment, risk management and risk communication. The Commission makes two proposals for a new legislative framework in this field:

- 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 and
- 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.

Of these proposals, the first proposal aims to cover the areas of data collection in relation to incidence and prevalence of biological risks and transparency of these data, while the second proposal deals mainly with the aspects of risk management. Separating these issues into two legal texts should facilitate their practical implementation. However, it is necessary to stress that these proposals form an inseparable unity. The European Food Authority will play an essential role in the area of data collection in relation to food safety and in the communication of these data.

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**

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**

EXPLANATORY MEMORANDUM

1. PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE MONITORING OF ZOOSES AND ZOONOTIC AGENTS, AMENDING COUNCIL DECISION 90/424/EEC AND REPEALING COUNCIL DIRECTIVE 92/117/EEC

1. A. Chapter I (Introductory provisions)

The proposed Directive would cover the monitoring aspects provided for in Directive 92/117/EEC. In principle, no zoonoses are excluded from the scope of the Directive. However, because a specific set of rules is foreseen for transmissible spongiform encephalopathies, these are excluded from the scope of this Directive. The monitoring activity proposed should take place in animal populations and, where necessary, at other stages of food chain. Member States should nominate a competent authority for the purposes of the Directive and ensure sufficient co-operation between authorities responsible for animal health, food hygiene, communicable diseases and zoonoses monitoring.

1. B. Chapter II (Monitoring of zoonoses and zoonotic agents)

The proposal would oblige the Member States to undertake action in monitoring zoonotic organisms in general. The list of organisms covered by the monitoring is mainly based on the opinion on zoonoses of 12 April 2000 of the Scientific Committee on Veterinary Measures relating to Public Health. The monitoring systems would be primarily based on existing systems in Member States. However, there would be procedures available to establish common criteria for data collection. Also as a new element it is proposed to create a basis for co-ordinated Community monitoring programmes. These co-ordinated monitoring programmes would last for a relevant, but limited time period (1-3 years), and the results of surveys could be used as the basis for possible modification of the pathogen reduction targets. However, any control action based on this monitoring data is, in principle, regulated by Member States themselves.

The collection of human data on the incidence of zoonotic diseases is of paramount importance to base food safety legislation on scientific advice and to obtain feedback on the effectiveness of the control applied and, when necessary, to redirect these measures. Decision 2119/98/EC¹¹, which entered into force on 1.1.1999, creates a framework for this data collection. Furthermore, Decision 2000/96/EC¹² defines those zoonoses to be progressively covered. This communicable diseases network should also be used for the purposes of zoonoses monitoring and control. Therefore the proposed Directive requires close co-operation between human, veterinary and food safety authorities in Member States.

In the light of the increasing importance of antibiotic resistance in zoonotic organisms, it is proposed to include its monitoring within the proposed Directive.

¹¹ OJ L 268, 3.10.1998, p. 1.

¹² OJ L 28, 3.2.2000, p. 50.

1.C. Chapter III (Food-borne outbreaks)

As a separate requirement, the monitoring of foodborne outbreaks is proposed. At the moment, epidemiological outbreak data is collected by a WHO-based Europe-wide system, which is a slow way to gather this data. The monitoring and associated reporting of outbreaks would give important information on the main causes of foodborne diseases. However, the measures concerning suspected foods and their production environment lie outside the scope of this Directive.

1.D. Chapter IV (Exchange of information)

Food business operators would be obliged to keep the results of testing of zoonoses and to communicate these results to the competent authority upon request. Member States shall prepare a yearly report on trends and sources of zoonoses, which they must transmit to the Commission and to the European Food Authority set up following the proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority (EFA), and laying down procedures in matters of food (COM(2000) 716 final). The EFA shall compile a synthesis report, which may include also relevant information from other Community-wide sources, like animal disease eradication programmes and communicable disease networks.

1.E. Chapter V (Laboratories)

The proposal establishes the framework for designating the Community Reference Laboratories and National Reference Laboratories and to define their respective tasks.

1.F. Chapter VI (Implementation)

It lays down the regulatory procedure and transposition provisions.

1.G. Chapter VII (final provisions)

The proposal encompasses provisions for repealing Directive 92/117/EEC and for amending Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field¹³.

Since the provisions of Directive 92/117/EEC will be covered by the proposed Directive and the proposed Regulation 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, it is proposed to repeal the current Council Directive. However, to ensure a smooth transition and continuous control it is proposed that certain obligations based on Directive 92/117/EEC would remain in force until corresponding provisions laid down in the proposed Regulation will take effect.

The proposal lays down certain provisions relating to Community's financial contribution towards certain actions relating to the monitoring and control of zoonoses and zoonotic agents, by amending the Chapter on "zoonoses" in Decision 90/424/EEC.

¹³ OJ L 224, 18.8.1990, p. 19. Decision as last amended by Council Decision 2001/12/EC (OJ L 3, 6.1.2001, p. 27).

2. PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE CONTROL OF SALMONELLA AND OTHER FOOD-BORNE ZOOBOTIC AGENTS AND AMENDING COUNCIL DIRECTIVES 64/432/EEC, 72/462/EEC AND 90/539/EEC

2.A. Chapter I (Introductory provisions)

The proposal encompasses a fundamental review concerning the approach towards the control of zoonotic diseases. It follows the principles of the White Paper on Food Safety (COM(1999) 719 final) adopted by the Commission on 12 January 2000. Account is also taken of the opinion on zoonoses issued by the Scientific Committee on Veterinary Measures relating to Public Health on 12 April 2000.

The 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 would cover, in principle, all zoonoses. However, the specific control requirements are covering only certain types of salmonella. Further extension to cover other pathogens, would be possible, when the epidemiological situation so warrants. The control activities are foreseen to take place primarily at the primary production of animals, and where necessary, at the subsequent stages at the food chain.

2.B. Chapter II (Community targets)

The proposal creates a framework for a pathogen reduction policy. The practical form of this policy would be the establishment of Community pathogen reduction targets for selected zoonotic agents in selected farming animal populations. Before the adoption of pathogen reduction targets, scientific – and political – scrutiny is needed. Therefore it is proposed that the Commission within a fixed timeframe will establish the targets.

The proposal enables future modification of pathogen reduction targets. The targets would progressively be set for certain salmonella serotypes in laying hens, broilers, and their breeders, and for turkey and pig breeders. Other emerging pathogens could be selected as targets, based on scientific evidence and a sufficient knowledge on the potential means to reduce their prevalence in animal populations. It would be also possible to establish separate targets for the different stages of food chain.

2.C. Chapter III (Control programmes)

The level of details of the prescriptive rules concerning control measures at breeder flocks would be minimised compared to the existing Zoonosis Directive. However, this would not mean lowering the required level of safety. The concrete method for implementing pathogen reduction systems would be the establishment of national control programmes. The Commission shall approve the programmes, but to be effective, it is clear that national authorities should bear the greatest responsibility. However, taking into consideration that animal production systems are nowadays more and more integrated (i.e. the same company or organisation governs the supply of feedingstuffs, breeding and/or production animals, and even slaughter) there should be a possibility for own-initiative private sector actions. Therefore it is proposed that the Member States should encourage food businesses to establish their own control programmes.

2.D. Chapter IV (Control methods)

The proposal lays down the possibility for the Commission to decide that certain control methods should not be used as part of control programmes, or to decide on certain conditions for their use. In particular, the use of antibiotics or vaccination may in future need to be further reflected upon. Further control methods may need to be considered in the future.

2.E. Chapter V (Trade)

The basic element in the proposal is to ensure that the purchaser of live animals or hatching eggs knows the status of the holding of origin of the animals. Nationally this can be achieved through national control programmes. However, concerning intra-Community trade there is a need to use a health certification system. Since the existing certificates based on animal health legislation (Directives 64/432/EEC¹⁴ and 90/539/EEC¹⁵) can be amended by comitology procedure (for Directive 64/432/EEC, a proposal to that effect has been prepared by the Commission), these will be amended by Commission Decisions in due course, in order to add information concerning zoonosis control into these certificates. After a certain transitional period, the results of testing for salmonella in the flock or herd of origin should be presented in the certificate. With the approval of the Commission, for a transitional period, the Member State of destination could decide that for dispatches from other Member States it could apply the same results requirements as are applied domestically as a part of the respective control programme.

For table eggs, once the transitional period before full implementation of the control measures concerning laying hens has elapsed, table eggs will only be allowed to be marketed for direct consumption when originating from flocks tested negative for *S. Enteritidis* and *S. Typhimurium*. For poultry meat, a criterion of "absence of salmonella in 25g" will apply after a transitional period.

As regards third countries, equivalent measures would be required for importation of relevant live animals and hatching eggs into the Community. Where appropriate, control programmes should be required. The certification requirements presented above would apply to imports from third countries and specific certificates for third country trade shall be established or amended, in due course, by Commission Decisions. Certification requirements for products like table eggs or poultry meat will also be established in due course.

2.F. Chapter VI (Laboratories)

The proposal establishes the framework for designating the Community Reference Laboratories and National Reference Laboratories and to define their respective tasks. It also lays down the quality requirements for laboratories participating in control programmes.

2.G. Chapter VII (Implementation)

It lays down the regulatory procedure.

¹⁴ OJ 121, 29.7.1964, p. 1977. Directive as last amended by Directive 2000/20/EC (OJ L 163, 4.7.2000, p. 35).

¹⁵ OJ L 303, 31.10.1990, p. 6. Directive as last amended by Directive 1999/90/EC (OJ L 300, 23.11.1999, p. 19).

2.H. Chapter VIII (General and final provisions)

The proposal encompasses provisions for Community controls and for amending certain Directives on health conditions governing intra-Community trade and/or importation from third countries.

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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 Commission¹⁶,

Having regard to the opinion of the Economic and Social Committee¹⁷,

Having regard to the opinion of the Committee of the Regions¹⁸,

Acting in accordance with the procedure laid down in Article 251 of the Treaty¹⁹,

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 intoxications²⁰ provided for the establishment of a monitoring system for certain zoonoses both at the level of Member States and at Community level.

¹⁶ OJ C ...

¹⁷ OJ C ...

¹⁸ OJ C ...

¹⁹ OJ C ...

²⁰ 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 swine²¹, 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 animals²², 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*]²³ 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 Community²⁴ was adopted in order to reinforce the collection of such data and to contribute to improving the prevention and control, in the Community, of communicable diseases.
- (9) The collection of data on the occurrence of zoonoses and zoonotic agents in feedingstuffs, animal populations, products of animal origin and in humans is necessary to determine the trends and sources of zoonoses.
- (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.

²¹ OJ 121, 29.7.1964, p. 1977. Directive as last amended by Directive 2000/20/EC (OJ L 163, 4.7.2000, p. 35).

²² OJ L 46, 19.2.1991, p. 19. Directive as last amended by Commission Decision 94/953/EC (OJ L 371, 31.12.1994, p. 14).

²³ OJ L ...

²⁴ 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 food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC*]²⁵. Directive 92/117/EEC should therefore be repealed.
- (12) The new framework for scientific advice and scientific support in matters of food safety set up by Regulation (EC) No .../... of the European Parliament and of the Council of ... [*laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food*]²⁶ should be used to collect and analyse the relevant data.
- (13) Where necessary, procedures should be created which provide data on a harmonised basis, making it possible to evaluate trends and sources of zoonoses and zoonotic agents within the Community. The data collected, together with data from other sources, should form the basis for risk assessment of zoonotic organisms.
- (14) Priority should be given to those zoonoses posing the greatest risk to human health. However, the monitoring systems should also facilitate the detection of emerging or newly emerging zoonotic diseases.
- (15) Alongside emerging new zoonoses and zoonotic agents, known zoonotic organisms may be converted into new strains. The emergence of resistance to antimicrobial agents is a characteristic that should be monitored.
- (16) Since providing data in a harmonised way, to form the basis for risk assessment of zoonotic organisms of importance at Community level cannot be sufficiently achieved by the Member States and can therefore, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives. The responsibility for establishing and maintaining monitoring systems should lie with Member States.
- (17) In addition to general monitoring, specific needs may be recognised which may necessitate the establishment of co-ordinated monitoring programmes. Attention should be paid in particular to zoonoses listed in Annex I, part A of Regulation (EC) No.../... [*on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC*].
- (18) Food-borne outbreaks of zoonoses, if thoroughly investigated, provide the opportunity to identify the pathogen, the food vehicle involved and the factors in the food preparation and handling that contributed to the outbreak. It is, therefore, appropriate to make provision for such investigations and for a close co-operation between the various authorities.

²⁵ OJ L ...

²⁶ OJ L ...

- (19) Transmissible spongiform encephalopathies are subject to Regulation (EC) No .../... of the European Parliament and of the Council of ...*[laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies]*²⁷.
- (20) In order to ensure that information collected on zoonoses and zoonotic agents can be used effectively, appropriate rules should be laid down concerning the exchange of all relevant information. That information should be collected in Member States and transmitted to the Commission and to the European Food Authority in the form of reports, which should also be made available to the public in an appropriate way.
- (21) The reports should be submitted on an annual basis. However, additional reports may be appropriate, when warranted by circumstances.
- (22) It may be appropriate to designate National and Community Reference Laboratories for giving guidance and assistance for analysis and testing in relation to zoonoses and zoonotic agents falling within the scope of this Directive.
- (23) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field²⁸, should be amended in so far as concerns the detailed rules governing the Community's financial contribution towards certain actions relating to the monitoring and control of zoonoses and zoonotic agents.
- (24) Appropriate procedures should be laid down for amending certain provisions of this Directive to take account of technical and scientific progress and for the adoption of implementing and transitional measures.
- (25) Since the said measures are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission²⁹, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision. The Commission should be assisted by the Committee on Food Safety and Animal Health set up by Regulation (EC) No .../... of the European Parliament and of the Council *[laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food]*,

HAVE ADOPTED THIS DIRECTIVE:

²⁷ OJ L ...

²⁸ OJ L 224, 18.8.1990, p. 19. Decision as last amended by Council Decision 2001/12/EC (OJ L 3, 6.1.2001, p. 27).

²⁹ OJ L 184, 17.7.1999, p. 23.

Chapter I

Introductory provisions

Article 1

Subject-matter and scope

1. The purpose of this Directive is to ensure that zoonoses and zoonotic agents are properly monitored so that the necessary information may be collected in the Community to evaluate trends and sources of zoonoses and zoonotic agents. That evaluation shall provide a basis for the action to be taken to prevent and control zoonoses and zoonotic agents relevant to the Community.
2. This Directive covers:
 - a) the monitoring of zoonoses and zoonotic agents, taking into account specific features such as antimicrobial resistance related to zoonotic agents, in animal populations at the stage of primary production of animals, and, where necessary, at other stages of food chain, including the production of feedingstuffs and further preparation and production of products of animal origin;
 - b) the epidemiological investigation of foodborne outbreaks;
 - c) the exchange of information related to zoonoses and zoonotic agents;
 - d) the adoption of specific rules on monitoring.
3. This Directive shall apply without prejudice to more specific Community provisions on animal health, animal nutrition, food hygiene, communicable diseases, health and safety at workplace and gene technology.
4. This Directive shall not apply to transmissible spongiform encephalopathies.

Article 2

Definitions

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

1. “*zoonosis*” means any disease and/or infection which is naturally transmissible directly or indirectly from animals to humans;
2. “*zoonotic agent*” means any virus, bacterium, fungus, parasite or other biological entity which is likely to cause a zoonosis;
3. “*antimicrobial resistance*” means the ability of micro-organisms of certain species to survive or even to grow in the presence of a given concentration of an antimicrobial agent, that is usually sufficient to inhibit or kill micro-organisms of the same species;

4. “*communicable diseases*” means diseases caused by zoonotic agents occurring in humans which are covered by Decision No 2119/98/EC;
5. “*food business*” means a business as defined in Article 2 of Regulation (EC) No .../... [*on the hygiene of foodstuffs*];
6. “*food business operator*” means the person or persons responsible for ensuring that the requirements of this Directive are met within the food business under his/her or their supervision;
7. “*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;
8. “*monitoring*” means a system of collecting, analysing and disseminating data on the occurrence of zoonoses, zoonotic agents and antimicrobial resistance related thereto;
9. “*primary production*” means production as defined in Article 2 of Regulation (EC) No .../... [*on the hygiene of foodstuffs*].

Article 3 *General obligations*

1. Member States shall ensure that data on the occurrence of zoonoses and zoonotic agents and antimicrobial resistance related thereto are collected, analysed and disseminated in accordance with the requirements of this Directive and of any provision adopted pursuant to it.
2. Each Member State shall designate its competent authority for the purposes of this Directive and notify the Commission thereof.
3. Each Member State shall ensure that effective and continuous co-operation based on a free exchange of general information and, where necessary, of specific data, shall be established between its competent authority designated for the purposes of this Directive and:
 - a) the competent authorities for the purposes of the Community legislation on animal health,
 - b) the competent authorities for the purposes of the Community legislation on food hygiene,
 - c) the structures and/or authorities referred to in Article 1 of Decision No 2119/98/EC.
4. Each Member State shall ensure that the relevant officials of the competent authority for the purposes of this Directive are suitably qualified to undertake their duties and, where necessary, are trained in microbiology and epidemiology.

Chapter II

Monitoring of zoonoses and zoonotic agents

Article 4

General rules on monitoring of zoonoses and zoonotic agents

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

Where the epidemiological situation in a Member State so warrants, zoonoses and zoonotic agents listed in Annex I, part 1.B shall also be monitored.
3. The monitoring shall be based on the systems in place in Member States. Where necessary, detailed rules for the monitoring of zoonoses and zoonotic agents listed in Annex I may be laid down in accordance with the procedure referred to in Article 12(2) and taking into consideration other Community rules laid down in the fields of animal health, food hygiene and communicable diseases. Those detailed rules shall specify in particular:
 - a) the animal population or sub-populations or stages in the food chain to be covered by monitoring;
 - b) the nature and type of data to be collected;
 - c) case definitions;
 - d) sampling methods to be used;
 - e) laboratory methods to be used in testing;
 - f) the frequency of reporting, including guidelines for reporting between local, regional and central authorities.

Article 5

Monitoring of antimicrobial resistance

1. Member States shall ensure that the monitoring provides data on the occurrence of antimicrobial resistance in zoonotic agents in accordance with the requirements set out in Annex II.
2. Detailed rules for the implementation of paragraph 1 shall be laid down in accordance with the procedure referred to in Article 12(2).

Article 6
Co-ordinated monitoring programmes

1. Co-ordinated monitoring programmes concerning one or more zoonoses and/or zoonotic agents may be established in accordance with the procedure referred to in Article 12(2), where appropriate after consultation of the European Food Authority. Co-ordinated monitoring programmes may be established especially when specific needs are identified to assess risks, or in order to establish base-line values related to zoonoses and/or zoonotic agents at the level of Member States and/or at Community level.
2. Where a co-ordinated monitoring programme is established, special reference shall be made to zoonoses and zoonotic agents in animal populations referred to in Annex I, part A, of Regulation (EC) No .../... [*on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC*].
3. Minimum rules concerning the establishment of co-ordinated monitoring programmes are laid down in Annex III.
4. The results of the co-ordinated monitoring programmes shall be provided to the European Food Authority.

Chapter III
Food-borne outbreaks

Article 7
Epidemiological investigation of food-borne outbreaks

1. Member States shall ensure that when a food business operator becomes aware that a foodstuff produced or processed by him has caused, or is likely to cause, a foodborne outbreak, he shall inform the competent authority without delay. The foodstuff, or an appropriate sample thereof, shall be preserved in a way which neither impede its investigation in a laboratory, nor a further investigation of the suspected outbreak.
2. When a competent authority receives information pursuant to paragraph 1 or is otherwise informed of a food-borne outbreak, it shall investigate the outbreak in co-operation with the authorities referred to in Article 1 of Decision No 2119/98/EC. The investigation shall provide data on the epidemiological profile, the foodstuffs potentially implicated and the potential causes of the outbreak. The investigation shall include, as far as possible, adequate epidemiological and microbiological studies. The competent authority shall transmit to the Commission and to the European Food Authority a summary report on the results of the investigations carried out, containing the information referred to in Annex IV, Part E, to this Directive. Detailed rules concerning the investigation of food-borne outbreaks may be laid down in accordance with the procedure referred to in Article 12(2).

3. Paragraphs 1 and 2 shall apply without prejudice to Community provisions on product safety, early warning and response systems for the prevention and control of communicable diseases and food hygiene.
4. Measures concerning the suspected foods and their production environment shall be laid down in accordance with Article 12 of Regulation (EC) No/..... [*on the hygiene of foodstuffs*].

Chapter IV

Exchange of information

Article 8

Examinations for zoonoses at the level of food business operators

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

Article 9

Assessment of trends and sources of zoonoses, zoonotic agents and antimicrobial resistance

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

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

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

The minimum requirements concerning the reports are laid down in Annex IV. Detailed rules concerning the assessment of those reports, including the formats and the minimum information which they must include, may be laid down in accordance with the procedure referred to in Article 12(2).

Where the circumstances warrant it, the Commission may request specific additional information and the Member States shall submit reports to the Commission upon such request, or on their own initiative.

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

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

- Article 8 of Directive 64/432/EEC,
- Article 14(2) of Council Directive 89/397/EEC³⁰,
- Article 24 of Decision 90/424/EEC,
- Article 4 of Decision 2119/98/EC.

Chapter V

Laboratories

Article 10

Community and national reference laboratories

1. One or more Community Reference Laboratories for the analysis and testing of zoonoses and zoonotic agents and antimicrobial resistance related thereto may be designated in accordance with the procedure referred to in Article 12(2).
2. Without prejudice to the relevant provisions in Decision 90/424/EEC, the responsibilities and tasks of the Community Reference Laboratories, in particular with regard to co-ordination of their activities and those of the National Reference Laboratories, shall be laid down in accordance with the procedure referred to in Article 12(2).
3. Member States shall designate National Reference Laboratories for each field where a Community Reference Laboratory has been established and inform the Commission thereof.
4. Certain responsibilities and tasks of the National Reference Laboratories, in particular with regard to co-ordination of their activities and those of the relevant Laboratories in the Member States, may be laid down in accordance with the procedure referred to in Article 12(2).

³⁰ 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 measures

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

Article 12

Committee

1. The Commission shall be assisted by the Committee on Food Safety and Animal Health instituted by Regulation (EC) No .../... of the European Parliament and of the Council [*laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food*].
2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.
3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 13

Transposition

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

They shall apply those provisions from 1 January 2003.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law that they adopt in the field covered by this Directive.

Chapter VII

Final provisions

Article 14

Repeal

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

However, measures which Member States have adopted pursuant to Article 8(1) of that Directive and implemented in accordance with Article 10(1) thereof and plans approved in accordance with Article 8(3) thereof shall remain in force until corresponding control programmes have been approved in accordance with Article 6 of Regulation (EC)..../.... [*on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC*].

Article 15

Amendment of Decision 90/424/EEC

Decision 90/424/EEC is amended as follows:

1. Article 29 is replaced by the following:

- “1. A Community financial contribution may be requested by Member States for the monitoring and control of the zoonoses specified in the Annex, Group 2, in the framework of the provisions referred to in Article 24 (2) to (11).
2. As regards control of zoonoses, the Community financial contribution shall be introduced as part of a national plan referred to in Article 6 of Regulation (EC) No/... of the European Parliament and of the Council [*on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC*] [*].

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

- - -

* OJ L".

2. The following Article 29a is inserted:

"Article 29a

Member States may seek from the Community the financial contribution referred to in Article 29(2) for a national plan which was approved on the basis of Directive 92/117/EEC, until the date on which corresponding control programmes have been approved in accordance with Article 6 of Regulation (EC) No/... [*Regulation of the European Parliament and of the Council on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC*]."

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

- Campylobacteriosis
- Cryptosporidiosis
- Listeriosis
- Salmonellosis (zoonotic salmonella)
- Trichinellosis
- Verotoxigenic *Escherichia coli*."

Article 16
Entry into force

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

Article 17
Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

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

A. Zoonoses and zoonotic agents to be included in monitoring

Brucellosis and agents thereof
Campylobacteriosis and agents thereof
Cryptosporidiosis and agents thereof
Echinococcosis and agents thereof
Listeriosis and agents thereof
Salmonellosis and agents thereof
Trichinellosis and agents thereof
Tuberculosis due to *Mycobacterium bovis*
Verotoxigenic *Escherichia coli*

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

1. Viral zoonoses

Calicivirus
Hepatitis A virus
Influenzavirus
Rabies
Tick borne viruses

2. Bacterial zoonoses

Borreliosis and agents thereof
Botulism and agents thereof
Leptospirosis and agents thereof
Psittacosis and agents thereof
Tuberculosis other than in Point A
Vibriosis and agents thereof
Yersiniosis and agents thereof

3. Parasitic zoonoses
Anisakiasis and agents thereof
Cysticercosis and agents thereof
Toxoplasmosis and agents thereof
4. Other zoonoses and zoonotic agents

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

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

- their occurrence in animal and human populations, feed and food
- their gravity in humans,
- their economic consequences for health care and food businesses,
- epidemiological trends in animal and human populations, feed and food.

ANNEX II

Requirements for monitoring of antimicrobial resistance pursuant to Article 5

A. General requirements

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

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

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

1. animal species included in monitoring
2. bacterial species and/or strains included in monitoring
3. sampling strategy used in monitoring
4. antimicrobials included in monitoring
5. laboratory methodology used for the detection of resistance
6. laboratory methodology used for the identification of microbial isolates
7. methods used for the collection of the data

B. Specific requirements

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

- Antibigrams for a representative number of isolates of *Salmonella* spp., *Campylobacter jejuni* and *Campylobacter coli* from cattle, pigs and poultry.

ANNEX III

Co-ordinated monitoring programmes as referred to in Article 6

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

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

ANNEX IV

Requirements for the reports to be submitted pursuant to Article 9

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

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

- a) Monitoring systems (sampling strategies, frequency of sampling, kind of specimen, case definition, diagnostic methods used)
- b) Vaccination policy and other preventive actions
- c) Control programmes
- d) Measures in case of positive findings or single cases
- e) Notification systems in place
- f) History of the disease and/or infection in the country

B. Each year shall be reported:

- a) Relevant susceptible animal population (and date the figures are related to)
 - Number of herds or flocks
 - Total number of animals
- b) Laboratories and institutions involved in reporting

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

- a) Changes in the systems already described
- b) Changes in previously described methods
- c) Results of the investigations and of further typing or other method of characterization 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 EU level on the basis of the recent situation

D. Reporting of results of examinations

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

E. For food-borne outbreak data:

- a) Total number of outbreaks over a year.
- b) Number of ill and dead persons in these outbreaks.
- c) The causative agents of the outbreaks, including, where possible, serotype or other definitive description of the agent. Where the identification of the causative agent is not possible, the reason for that should be stated.
- d) Foodstuffs implicated in the outbreak and other potential vehicles.
- e) Identification of the type of place where the foodstuff incriminated was produced / purchased / acquired/ consumed.
- f) Contributory factors, for example, deficiencies in food processing hygiene.

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**

(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 Commission³¹,

Having regard to the opinion of the Economic and Social Committee³²,

Having regard to the opinion of the Committee of the Regions³³,

Acting in accordance with the procedure laid down in Article 251 of the Treaty³⁴,

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 intoxications³⁵ was adopted in order to establish monitoring systems for certain zoonoses and to establish controls on Salmonella in poultry flocks.

³¹ OJ C ...

³² OJ C ...

³³ OJ C ...

³⁴ OJ C ...

³⁵ 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/EC³⁶ 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 swine³⁷ 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 animals³⁸ 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]³⁹ 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 comparison 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.

³⁶ OJ L 113, 30.4.1997, p. 9.

³⁷ OJ 121, 29.7.1964, p. 1977. Directive as last amended by Directive 2000/20/EC (OJ L 163, 4.7.2000, p. 35).

³⁸ OJ L 46, 19.2.1991 p. 19. Directive as last amended by Commission Decision 94/953/EC (OJ L 371, 31.12.1994, p. 14).

³⁹ 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. 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*]⁴⁰.
- (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 zoonoses and zoonotic agents it is necessary to lay down specific requirements for controls.
- (17) Those specific requirements should be based on targets for the reduction of the prevalence of zoonoses and zoonotic agents.
- (18) The targets should be established for zoonoses and zoonotic agents in animal population taking into account in particular their incidence and epidemiological trend 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. Targets may also be established in respect of other parts of the food chain, where necessary.
- (19) To ensure the achievement of the targets in good time, the Member States should set up specific control programmes, which should be approved by the Community.
- (20) The main responsibility for the safety of food should lie with food businesses. Member States should, therefore, encourage the creation of business-wide control programmes.
- (21) Within their control programmes Member States or food businesses may wish to use specific control methods. However, certain methods may not be acceptable, in particular if they hamper the achievement of the 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.

⁴⁰

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 zoonoses and zoonotic agents. The Commission should, therefore, have the authority to approve the use of such methods at Community level.
- (23) It will be 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. Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine, 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 countries⁴¹ 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 eggs⁴² 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 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.
- (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 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 States⁴³ 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 countries⁴⁴.

⁴¹ OJ L 302, 31.12.1972, p. 28. Directive as last amended by Directive No 97/79/EC (OJ L 24, 30.1.1998, p. 31).

⁴² OJ L 303, 31.10.1990, p. 6. Directive as last amended by Commission Decision 2000/505/EC (OJ L 201, 9.8.2000, p. 8).

⁴³ OJ L 38, 12.2.1998, p. 10.

⁴⁴ OJ L 38, 12.2.1998, p. 14.

- (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) Since the said measures are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁴⁵, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision. The Commission should be assisted by the Committee on Food Safety and Animal Health set up by Regulation (EC) No .../... of the European Parliament and of the Council of ... [*laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food*]⁴⁶,

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 salmonella and other 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 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;
 - b) the approval of specific control programmes established by Member States and food business operators;
 - c) the adoption of specific rules concerning certain control methods applied in the reduction of prevalences of zoonoses and zoonotic agents;
 - d) the adoption of rules concerning intra-Community trade and imports from third countries of certain animals and products thereof.

⁴⁵ OJ L 184, 17.7.1999, p. 23.

⁴⁶ OJ L ...

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

1. "zoonosis" means any disease and/or infection which is naturally transmissible directly or indirectly from animals to humans;
2. "zoonotic agent" means any virus, bacterium, fungus, parasite or other biological entity which is likely to cause a zoonosis;
3. "food business" means a business as defined in Article 2 of Regulation (EC) No .../... *[on the hygiene of foodstuffs]*;
4. "food business operator" means the person or persons responsible for ensuring that the requirements of this Regulation are met within the food business under his/her or their supervision;
5. "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;
6. "herd" means an animal or group of animals as defined in Article 2(2)(a) of Directive 64/432/EEC;
7. "flock" means an animal or group of animals as defined in Article 2(2)(7) of Directive 90/539/EEC;
8. "primary production" means production as defined in Article 2 of Regulation (EC) No .../... *[on the hygiene of foodstuffs]*.

Article 3

Competent authorities

1. Each Member State shall designate its competent authority for the purpose of this Regulation and notify the Commission thereof.
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 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 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 zoonoses and zoonotic agents

1. Community targets shall be established for the reduction of prevalences of 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 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 criteria laid down in Annex I, Part B.

When necessary, in accordance with the procedure laid down in Article 14(2), Annex I may be amended and it may be decided that Community targets shall be established for other stages in the food-chain.

2. Community targets shall at least include the details set out in Annex I, Part C.
3. Community targets shall be established for the first time before the respective dates indicated in Annex I, Part A, Column 4. The targets, as well as any amendments to them, shall be established in accordance with the procedure referred to in Article 14(2), and after consultation of the European Food Authority.
4. Without prejudice to Community rules on animal nutrition, animal health, or food hygiene, the reduction of prevalences of 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 zoonoses in their territory, establish national control programmes for each 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 zoonoses and zoonotic agents in accordance with the requirements and minimum sampling rules laid down in Annex II;
 - b) define the responsibilities of 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 zoonoses and zoonotic agents, in particular to protect public health, including implementation of the specific measures 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 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 despatched within the national territory, as part of the official controls provided for in Annex II, Part A, point 1.6.
6. The requirements and minimum sampling rules laid down in Annex II may be amended in accordance with the procedure referred to in Article 14(2).
7. Within 6 months after 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 after submission of a national control programme, establish whether it complies with the relevant rules including this Regulation in particular. The Commission may ask Member States to modify or supplement programmes to bring them into conformity. When the Commission has established the conformity of the programmes, they shall be approved in accordance with the procedure referred to in Article 14(2).

2. Amendments to a 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 food business operators

1. Member States shall encourage 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.

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

2. 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 shall approve the control programmes submitted pursuant to paragraph 2 only if they are 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 food business operators or their representative organisations.

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

5. 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 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 for the reduction of prevalence of 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 methods referred to in (a);
 - c) detailed rules concerning necessary documents and procedures as well as minimum requirements for the methods referred to in (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 methods using substances or techniques covered by 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 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, as laid down in Directive 64/432/EEC or Directive 90/539/EEC.
2. Without prejudice to the specific requirements concerning the control of salmonella in certain flocks, as laid down in Annex II, the 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 results of the tests to be referred to in the relevant health certificates for consignments of animals and hatching eggs subject to testing in the Member State of dispatch, fulfil the same criteria as those laid down under its national programme, in accordance with Article 5(5), for consignments despatched within its territory.

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

3. Without prejudice to Article 5(6), specific rules concerning the setting by Member States of the criteria referred to in Article 5(5) and in paragraph 2 above, 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 a programme equivalent to those provided for under Article 5. The programme shall give details of the guarantees offered by that country as regards inspections and controls for zoonoses and zoonotic agents. Those guarantees must be at least equivalent to the guarantees provided for by this Regulation.
2. These programmes shall be approved in accordance with the procedure referred to in Article 14(2), provided that the equivalence of the measures 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 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 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 import certificates, for which the models laid down by Community legislation shall be amended accordingly.
5. The Member State of final destination may be authorised, in accordance with the procedure referred to in Article 14(2), to require for a transitional period that the results of the testing referred to in Paragraph 4 fulfil the same criteria as those laid down under its national programme, in accordance with Article 5(5). The authorisation may be withdrawn and, without prejudice to Article 5(6), specific rules concerning such criteria may be laid down, in accordance with the procedure referred to in Article 14(2).

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 zoonoses and zoonotic agents listed in Annex I 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 zoonotic agents referred to in Annex I. The names and addresses of 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 at which samples are analysed for the testing of the presence of zoonoses and zoonotic agents referred to in Annex I shall be approved by the competent authority.
2. At the latest from 1 January 2005, each Member State shall ensure that laboratories referred to in paragraph 1 apply quality assurance systems which conform to the requirements of Standard EN/ISO 17025.

Laboratories shall regularly participate in collaborative testing organised or co-ordinated by the national reference laboratory.

3. Testing for the presence of zoonoses and zoonotic agents referred to in Annex I 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.

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

Where appropriate after consultation of the European Food Authority, 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).

Article 14

Committee

1. The Commission shall be assisted by the Committee on Food Safety and Animal Health instituted by Regulation (EC) No .../... of the European Parliament and of the Council [*laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food*].
2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Council Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.
3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Chapter VIII

General and final provisions

Article 15

Community controls

The Commission 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.

Article 16
Amendment of Directive 64/432/EEC

In Article 3(2) of Directive 64/432/EEC, the following point (f) is added:

"f) they have been subject, where relevant, to controls in accordance with the requirements of Regulation (EC) No/.... of the European Parliament and of the Council* [*this Regulation*],

* OJ L ...".

Article 17
Amendment of Directive 72/462/EEC

In Article 6 of Directive 72/462/EEC, the following paragraph 7 is added:

"7. Live animals must originate from third countries with rules equivalent to the requirements on the control of zoonoses and zoonotic agents set out in Regulation (EC) No .../... of the European Parliament and of the Council* [*this Regulation*]

* OJ L".

Article 18
Amendment of Directive 90/539/EEC

Directive 90/539/EEC is amended as follows:

1. In Article 6(1), the following point (d) is added:

"d) they have been subject to controls in accordance with the requirements of Regulation (EC)/.... of the European Parliament and of the Council [*this Regulation*]*

* OJ L ...".

2. In Article 10, the following point (e) is added:

"e) which has been subject to controls in accordance with the requirements of Regulation (EC)/.... of the European Parliament and of the Council [*this Regulation*]."

3. In Article 21(2), the following point (h) is added:

"h) compliance with Community rules on the control of zoonoses and zoonotic agents".

Article 19
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

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

1. 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 <i>Gallus gallus</i>	Primary production	31.12.2003	1.1.2005
<i>Salmonella</i> Enteritidis and <i>Salmonella</i> Typhimurium	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	Breeding herds of pigs	Primary production	31.12.2006	1.1.2008

^a Serotypes shall be defined when the target is established.

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 zoonoses and zoonotic agents listed in Annex I

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
 - 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 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 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 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 zoonosis or zoonotic agents listed in Annex I, with the minimum scope of sampling indicated below being respected.

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 <i>Gallus gallus</i> 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 iii) 2 weeks before moving to laying phase or laying unit i) every second week during the laying period
<i>Salmonella</i> Enteritidis and <i>Salmonella</i> Typhimurium	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 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. Turkey 5. Pigs	Ante mortem inspection Ante mortem inspection	i) Birds leaving for slaughter i) Animals leaving for slaughter

^a Serotypes shall be defined when the 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.1, 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 below, 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*]⁴⁷, 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*]⁴⁸.

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*]⁴⁹.

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 Point 2 in the Table of Part B.1 and subsequently found non contaminated.

The eggs originating from flocks with unknown status, suspected to be 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, in accordance with Regulation (EC) No .../... [*on the hygiene of foodstuffs*]:.

Without prejudice to the requirements under Part E below, all the birds 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*] 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*].

⁴⁷ OJ L ...

⁴⁸ OJ L ...

⁴⁹ OJ L ...

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"

These requirements may be revised in accordance with the procedure referred to in Article 14(2) and after consulting the appropriate Scientific Committee.

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 field⁵⁰, 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.

⁵⁰ 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							
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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
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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

☒ 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 ⁵¹

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.

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.

⁵¹ For further information see a separate guidance paper .

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 : <i>of which for construction and maintenance of computerised management systems</i>							
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)⁵²

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)
<u>Action 1</u> - Measure 1 - Measure 2 <u>Action 2</u> - 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		<i>If necessary, a fuller description of the tasks may be annexed.</i>
Other human resources					
Total					

⁵² 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	0.216	2*0.108
Temporary staff	0.216	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.

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES(SMEs)

Title of proposal

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

Document reference number

The proposal

1. Taking account of the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims?

The aim of the proposals is to increase the protection of public health by enhancing the monitoring and control of zoonoses (diseases transmissible from animals to man). Since zoonoses may spread from one Member State to another directly or indirectly through food or other sources, action at the Community level is necessary. The control of zoonoses may also have an impact on trade with third countries.

The impact on business

2. Who will be affected by the proposal?
 - which sectors of business: The specific rules on the control of zoonoses will cover
 - breeders of *Gallus gallus* as from 2004,
 - producers of laying hens as from 2005,
 - producers of broilers as from 2006,
 - producers of turkeys as from 2007, and
 - producers of breeding pigs as from 2007.
 - which sizes of business (what is the concentration of small and medium-sized firms): the proposals will affect all farms irrespective of their size
 - are there particular geographical areas of the Community where these businesses are found: the production of animals referred above takes place in all Member States.

3. What will business have to do to comply with the proposal?

The businesses have to comply with the requirements of the respective national control programmes (including sampling of flocks or herds) and the specific requirements laid down in the Regulation. The businesses may create their own control programmes.

4. What economic effects is the proposal likely to have?

- on employment: neutral
- on investment and the creation of new businesses: the needs for enhanced control of zoonoses at the primary production may necessitate new investments on farming buildings. Control programmes, which include sampling and testing regimes, would increase the demand of appropriate test systems and laboratories.
- on the competitiveness of businesses: the control programmes envisaged in the proposal would create additional costs to the businesses. The amount of these costs will be defined when specific Commission Decisions based on the proposal will be made. On the other hand, the aim of the proposal is to increase the consumer health protection and therefore it can be stated that the businesses can benefit from the increased consumer reliance on the products concerned.

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms (reduced or different requirements etc)?

It is the purpose of the national control programmes, that they take account of the size of enterprises in the sector.

Consultation

6. List the organisations which have been consulted about the proposal and outline their main views.

Farming, food production and consumer organisations, in particular in the framework of the Advisory Committee on Livestock Products. The representatives of food businesses have been anxious about the potentially high costs incurred due to the control programmes foreseen.