

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

(2001/C 304 E/19)

(Text with EEA relevance)

COM(2001) 452 final — 2001/0177(COD)

(Submitted by the Commission on 1 August 2001)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

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

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

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

Whereas:

- (1) The protection of human health against diseases and infections transmissible directly or indirectly from animals to man (zoonoses) is of paramount importance.
- (2) Zoonoses transmissible through food may cause human suffering, as well as economic losses to food production and food industry.
- (3) Zoonoses transmitted through sources other than food, especially from wild animal and pet animal populations, are also a matter of concern.
- (4) Council Directive 92/117/EEC of 17 December 1992 concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications⁽¹⁾ was adopted in order to establish monitoring systems for certain zoonoses and to establish controls on Salmonella in poultry flocks.

(5) Directive 92/117/EEC required the Member States to submit to the Commission the national measures that they are taking to achieve the objectives of the Directive. Member States were also required to draw up plans for monitoring salmonella in poultry. That requirement was, however, suspended by Council Directive 97/22/EC⁽²⁾ amending Directive 92/117/EEC, pending the review provided for in Article 15a of Directive 92/117/EEC.

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

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

(8) Monitoring and control of certain zoonoses in animal populations has been provided for by other Community legislation, in particular Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine⁽³⁾ as regards bovine tuberculosis and bovine brucellosis and Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals⁽⁴⁾ 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] 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.

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

⁽²⁾ OJ L 113, 30.4.1997, p. 9.

⁽³⁾ OJ L 121, 29.7.1964, p. 1977. Directive as last amended by Directive 2000/20/EC (OJ L 163, 4.7.2000, p. 35).

⁽⁴⁾ 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).

- (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.
- (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].
- (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.
- (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 countries ⁽¹⁾ and Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs ⁽²⁾ 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 States ⁽³⁾ and Commission Decision 98/140/EC of

4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in third countries ⁽⁴⁾.

(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 Commission ⁽⁵⁾, 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],

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;

⁽¹⁾ OJ L 302, 31.12.1972, p. 28. Directive as last amended by Directive 97/79/EC (OJ L 24, 30.1.1998, p. 31).

⁽²⁾ 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).

⁽³⁾ OJ L 38, 12.2.1998, p. 10.

⁽⁴⁾ OJ L 38, 12.2.1998, p. 14.

⁽⁵⁾ OJ L 184, 17.7.1999, p. 23.

- (c) the adoption of specific rules concerning certain control methods applied in the reduction of prevalences of zoonoses and zoonotic agents;
- (d) the adoption of rules concerning intra-Community trade and imports from third countries of certain animals and products thereof.

Article 2

Definitions

For the purposes of this Regulation the 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.

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 ^(e)	Breeding flocks of <i>Gallus gallus</i>	Primary production	31.12.2003	1.1.2005
<i>Salmonella Enteritidis</i> and <i>Salmonella Typhimurium</i>	Laying hens	Primary production	31.12.2004	1.1.2006
All salmonella serotypes with public health significance ^(e)	Broilers	Primary production	31.12.2005	1.1.2007
All salmonella serotypes with public health significance ^(e)	Turkeys	Primary production	31.12.2006	1.1.2008
All salmonella serotypes with public health significance ^(e)	Breeding herds of pigs	Primary production	31.12.2006	1.1.2008

^(e) 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 ZONOSSES AND ZOO NOTIC 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 ^(*)	1. Breeding flocks of <i>Gallus gallus</i>		
	1.1. Rearing flocks	(a) feedingstuffs (b) live animals	(i) Day-old chicks (ii) 4 week old (iii) 2 weeks before moving to laying phase or laying unit
	1.2. Adult breeding flocks	(a) feedingstuffs (b) live animals	(i) every second week during the laying period
<i>Salmonella Enteritidis</i> and <i>Salmonella Typhimurium</i>	2. Commercial layers	(a) feedingstuffs (b) live animals	(i) Day-old chicks (ii) pullets 2 weeks before moving to laying phase or laying unit
	2.2. Laying flocks	(a) feedingstuffs (b) live animals	(i) every 9 weeks during the laying phase
All salmonella serotypes with public health significance ^(*)	3. Broilers	(a) feedingstuffs (b) live animals (c) Ante mortem inspection	(i) Birds leaving for slaughter
All salmonella serotypes with public health significance ^(*)	4. Turkeys	Ante mortem inspection	(i) Birds leaving for slaughter
	5. Pigs	Ante mortem inspection	(i) Animals leaving for slaughter

^(*) 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], 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].

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].

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].

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.
