

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

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas live animals and products of animal origin appear on the list in Annex II to the Treaty; whereas livestock farming and the placing on the market of products of animal origin constitute an important source of income for the farming population;

Whereas the rational development of this sector and an improvement in its productivity may be achieved by the implementation of veterinary measures aimed at protecting and raising the level of public and animal health in the Community;

Whereas it is necessary to prevent and reduce, by appropriate measures, the appearance of zoonoses which pose a threat to human health in particular, through food of animal origin;

Whereas the Community has already undertaken action for the eradication of certain zoonotic diseases and in particular bovine tuberculosis, bovine brucellosis, brucellosis in sheep and goats, and rabies; whereas it is advisable to collect epidemiological information on those diseases;

Whereas those measures should apply without prejudice to Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (4);

Whereas, in order to assess the priorities for preventive action, it is necessary to collect information in the Member States on the incidence of zoonotic diseases in the human population, in domestic animals, in animal feedingstuffs and wildlife;

Whereas the Commission should follow the development of the epidemiological situation so as to propose the appropriate measures;

Whereas the situation with respect to salmonellosis justifies the adoption of immediate control measures for certain types of farming at risk;

Whereas the harmonization of the essential requirements concerning the protection of public health presupposes prior designation of Community liaison and reference laboratories and the implementation of technical and scientific actions;

Whereas detailed rules governing the Community's financial contribution towards certain actions laid down in this Directive have been laid down by Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field (5);

Whereas it is appropriate to make provision for a procedure establishing close effective cooperation between the Member States and the Commission for the adoption of implementing measures,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive lays down rules for the collection of information on zoonoses and zoonotic agents and the relevant measures to be taken in the Member States and at Community level.

Article 2

For the purposes of this Directive:

1. zoonosis means any disease and/or infection which is likely to be naturally transmitted from animals to man;
2. zoonotic agent means any bacterium, virus or parasite which is likely to cause a zoonosis;
3. approved national laboratory means a laboratory approved or recognized by the competent authority of a Member State to carry out examinations of official samples in order to detect a zoonotic agent;
4. sample means a sample taken by the owner of or person responsible for the establishment or the animals, or taken on his behalf, to be examined for a zoonotic agent;
5. official sample means a sample taken by the competent authority to test for a zoonotic agent. The official sample bears a reference to the species, the type, the amount and the method of collection, and the

identification of the origin of the animal or the product of animal origin; this sample is to be taken without prior warning;

6. competent authority means the central authority or authorities of a Member State which is/are responsible for monitoring provisions concerning public health, animal health or other veterinary matters arising from this Directive, or any other authority to which such responsibility has been delegated by the central authority.

Article 3

1. Each Member State shall ensure that measures taken in accordance with this Directive by the competent authority are coordinated at national and local level, in particular in relation to epidemiological surveys.

2. The competent authority at local level shall be assisted by approved national laboratories.

3. Each Member State shall designate the approved national reference laboratories for the zoonoses and zoonotic agents listed in Annex I, point I, at which the identification of a zoonotic agent or final confirmation of its presence may be carried out.

Article 4

1. Member States shall ensure that:

(a) the operators or managers of establishments approved in accordance with Directives 64/433/EEC (6), 71/118/EEC (7) and 77/99/EEC (8) are obliged to keep for a minimum period to be specified by the competent authority and to communicate to the latter at its request, the results of examinations for the presence of the zoonoses listed in Annex I, point I;

(b) the isolation and identification of zoonotic agents or the establishment of any other evidence of their presence rests with the person responsible for the laboratory or, where the identification is carried out elsewhere than at a laboratory, with the person responsible for the examination;

(c) the diagnosis and identification of a zoonotic agent are reported to the competent authority;

(d) the competent authority collects information on any zoonotic agents the presence of which has been confirmed in the course of the tests or examinations carried out and on any clinical cases in humans or animals of the zoonoses listed in Annex I, point I;

(e) the other Member States are regularly informed within the Standing Veterinary Committee set up by Decision 68/361/EEC (9) of clinical cases recorded in accordance with (d).

2. In accordance with the procedure laid down in Article 16, the provisions of this Article may be extended to cover the zoonoses and zoonotic agents listed in Annex I, points II and III.

Article 5

1. The competent authority shall evaluate the information collected in accordance with Article 4 (1) (d). It shall report to the Commission, by 31 March each year, the trends and sources of the zoonotic infections recorded during the previous year.

2. Paragraph 1 shall not rule out more frequent reporting to the Commission by Member States, or requests from the Commission for additional information, where the circumstances warrant. The Commission shall evaluate the information supplied by Member States and shall report to the Standing Veterinary Committee before 1 October each year.

3. The Commission shall, before 1 January 1996, submit a report to the Council on experience acquired, accompanied by proposals to improve the reporting system, on which the Council will take a decision by a qualified majority.

Article 6

The Commission shall follow the development of the situation in relation to zoonoses in the Community, particularly on the basis of the information collected pursuant to Articles 5 and 8, and:

(a) shall conduct specific studies, in particular in relation to the evaluation of risks from zoonotic agents, diagnostic procedures and control measures, in collaboration with the competent national laboratories, the Community reference laboratories referred to in Article 13 and the Scientific Veterinary Committee set up by Decision 81/651/EEC (10);

(b) shall, in accordance with the procedure laid down in Article 16, establish the methods of collecting samples and carrying out examinations in the national laboratories referred to in Article 3 (2) and (3). In the case of salmonella this shall be done before the date laid down in Article 17;

(c) shall establish guidelines for measures to combat zoonoses.

Article 7

The systems for tracing the movement of farm animals laid down in Commission Decision 89/153/EEC (11) shall be enforced in relation to the measures for zoonoses and zoonotic agents laid down in this Directive.

Article 8

1. Member States shall submit to the Commission before 1 October 1993 the national measures which they are taking to achieve the objectives of this Directive in respect of the zoonoses listed in Annex I, points I and II, with the exception of those already being taken for brucellosis and tuberculosis under plans already approved within the framework of Community legislation.

They may include measures to detect the zoonoses and zoonotic agents listed in Annex I, point III.

Member States which have national plans for the detection of the zoonoses listed in Annex I, point II, may submit them to the Commission as the information required in accordance with the first subparagraph.

Member States shall forward to the Commission, every year, a report on the epidemiological situation for trichinosis.

The Commission shall examine the measures communicated by the Member States to determine whether they are compatible with the objectives of this Directive. It shall inform the Member States, meeting in the Standing Veterinary Committee, of its conclusions.

2. In the case of salmonella in fowls, Member States must forward to the Commission before 1 January 1994 plans drawn up in accordance with the criteria laid down in Annexes II and III. These plans must:

(a) specify as regards salmonella the measures taken to comply with the minimum requirements laid down in Annex III;

(b) take into account the specific situation in each Member State;

(c) indicate the number of approved national laboratories at which examination and identification of salmonella will take place and the approval procedures for those laboratories.

3. In accordance with the procedure laid down in Article 16:

- the plans referred to in paragraph 2, amended if necessary, shall be approved not later than six months after their submission,

- amendments or additions may be made to a plan previously approved in order to take account of developments in the situation in the Member State concerned or in one of its regions.

Article 9

1. Detailed rules governing the Community's financial contribution towards the measures for slaughter and destruction and official sampling imposed pursuant to Annex III, Section I, point V and towards the operation of the laboratories listed in Annex IV shall be laid down in accordance with Decision 90/424/EEC.

As regards the measures provided for in Annex III, the financial contribution provided for in Decision 90/424/EEC must not benefit breeders who have contravened the requirements of this Directive.

50 % of the cost of applying the slaughter and destruction measures referred to in the first subparagraph shall be met from the aforementioned Community financial contribution.

2. In Article 4 of Decision 90/424/EEC the following paragraph 3 shall be added:

'3. The provisions of Article 3, with the exception of the fourth indent of paragraph 2 and the second indent of paragraph 5, shall apply when a zoonosis listed in Directive 92/117/EEC occurs, provided that this occurrence is an immediate risk to human health. This condition will be fulfilled when the decision provided for in Article 3 (3) is taken.'

Article 10

1. Member States shall implement as from 1 January 1994 the minimum measures laid down for salmonella in Annex III, Section I.

Member States must, before 1 January 1994, establish rules specifying the measures to be taken to avoid the introduction of salmonella onto a farm, taking account of the principles set out in Annex II to Directive 90/539/EEC.

The Council, acting by a qualified majority before 1 January 1995 on a proposal from the Commission

drawn up in the light of an opinion from the Scientific Veterinary Committee and on the basis of experience gained at the time this Directive was implemented, shall decide on the measures required to control salmonella in flocks of layers.

Pending the adoption of such measures, Member States may, with due regard for the rules of the Treaty, maintain their national rules in respect of layers.

2. The Council, acting by a qualified majority on a proposal drawn up by the Commission on the basis of the information gathered in accordance with Articles 5 and 6 and Article 8 (1), shall decide whether specific measures to control other zoonoses of comparable seriousness are needed.

Article 11

1. Experts from the Commission may, in so far as is necessary for the uniform application of this Directive and in cooperation with the competent authorities of the Member States, make on-the-spot checks. To do this, they may verify by checking a representative percentage of holdings whether the Member States are ensuring compliance with this Directive. The Commission shall inform the competent authority of the results of the checks made.

The Member State concerned shall take any measures which may prove necessary to take account of the results of the checks. If the Member State does not take such measures, after the situation has been examined by the Standing Veterinary Committee appropriate measures may be decided on under the procedure laid down in Article 16.

2. The detailed rules for implementing this Article, especially as regards the frequency and method of carrying out the checks referred to in the first subparagraph of paragraph 1, shall be adopted under the procedure set out in Article 16.

Article 12

The safeguard measures provided for in Directive 90/425/EEC (12) concerning veterinary checks to be carried out in trade with a view to the completion of the internal market shall apply for the purposes of this Directive.

Article 13

The Community reference laboratories listed in Annex IV shall, in accordance with the tasks and duties described therein, be responsible, for liaison with and coordination of the national reference laboratories referred to in Article 3 (3).

Article 14

1. Admission to, or retention on, the Community list of third countries or parts thereof from which imports are authorized in health terms shall be subject to the submission, by the third country concerned, of a plan giving details of the guarantees afforded by that country as regards inspections for zoonoses and zoonotic agents.

The effect of these guarantees must be no less than that resulting from the guarantees provided for by this Directive.

The Commission shall approve the plans in question in accordance with the procedure provided for in Article 16. Alternative guarantees to those resulting from the application of this Directive may be allowed in accordance with that procedure, provided that they are not more favourable than those applicable to trade.

2. Where no decision pursuant to paragraph 1 has been taken with regard to a given third country by 31 December 1995, entry of that country on the list referred to in paragraph 1 shall be suspended in accordance with the procedure provided for in Article 16.

3. Compliance by the competent authorities of third countries with the execution of the plans shall be verified when the Community experts carry out the checks provided for in Community rules.

Article 15

The Annexes may be amended or supplemented by the Council, acting by a qualified majority on a proposal from the Commission.

In particular, Annex III shall be reviewed under this procedure before 1 January 1996.

Article 16

1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay to the Committee by its chairman, either on his own initiative or at the request of a Member State.
2. Within the Committee the votes of the Member States shall be weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.
3. The Commission representative shall submit a draft of the measures to be taken. The Committee shall deliver its opinion on those measures within a time limit which the chairman may set according to the urgency of the matter submitted. Opinions shall be delivered by a majority of 54 votes.
4. (a) The Commission shall adopt the measures and implement them immediately where they are in accordance with the opinion of the Committee.
(b) Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall forthwith submit to the Council a proposal concerning the measures to be taken. The Council shall adopt the measures by a qualified majority.
If, three months after the proposals were submitted to it, the Council has not adopted any measures, the Commission shall adopt the measures proposed and implement them immediately unless the Council has rejected those measures by a simple majority.

Article 17

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1994.
When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.
2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.

Article 18

This Directive is addressed to the Member States.

Done at Brussels, 17 December 1992.

For the Council

The President

J. GUMMER

ANNEX I

LIST OF THE ZOOSES COVERED BY ARTICLE 4

- I. - Tuberculosis due to *Mycobacterium bovis*
 - Brucellosis and the agents thereof
 - Salmonellosis and the agents thereof
 - Trichinosis.
- II. - *Campylobacteriosis*
 - Echinococcosis
 - Listeriosis
 - Rabies
 - Toxoplasmosis
 - Yersiniosis
 - Other zoonoses and the agents thereof.
- III. Any other zoonosis not found in the Community and the agents of that zoonosis.

ANNEX II

CRITERIA FOR DRAWING UP PLANS FOR MONITORING SALMONELLA IN FOWL FLOCKS

I. The plans must indicate:

- the number and type of samples to be taken,
- the number and type of official samples to be taken,
- the methods of sampling,
- the methods of examination of the samples and identification of the zoonotic agents.

II. The plans must take into account the following criteria for establishing the sampling procedures:

- (a) factors likely to encourage the spread of one or more zoonoses;
- (b) previous history of the zoonosis in question in a country or region, in domestic animals or wildlife;
- (c) the animal population concerned as regards:
 - total size of population,
 - homogeneity of the population group,
 - age of animals,
 - animal production;
- (d) the environment of the farms as regards:
 - regional differences,
 - density of flocks,
 - relations with urban areas,
 - relations with areas populated by wildlife;
- (e) farm production systems including:
 - intensive farming units,
 - extensive farming units,
 - husbandry systems, in particular feeding regimes and animal health care measures;
- (f) problems likely to arise in the light of known precedents and other information;
- (g) the required degree of protection according to the nature and gravity of the zoonosis in question.

ANNEX III

INSPECTION FOR SALMONELLA

Section I

MONITORING AND CONTROL - PRESENCE OF SALMONELLA IN BREEDING FLOCKS

I. Breeding flocks

A breeding flock comprises at least 250 birds (*Gallus gallus*), kept or reared on a single holding for the production of hatching eggs.

II. Monitoring for salmonella in breeding flocks

The owner or the person responsible for hatcheries or for a breeding flock must, at his own expense, have samples taken for analysis for the detection of salmonella either in an approved national laboratory or in a laboratory recognized by the competent authority, with the minimum levels of sampling indicated below being respected.

A. Rearing flocks

1. Samples must be taken from birds being reared for breeding purposes at least when the chicks are one day old, when the birds are four weeks old and two weeks prior to pullets entering the laying phase.

2. The samples to be taken must comprise:

(a) in the case of day-old chicks, samples from the internal linings of the boxes in which the chicks were delivered to a holding and from the carcasses of chicks found to be dead on arrival; and

(b) in the case of pullets at four weeks of age or two weeks prior to entering the laying phase, pooled faeces samples made up of separate samples of fresh faeces each weighing not less than 1 g taken at random from a number of sites in the building in which the birds are kept, or, where the birds have free access to more than one building on a particular holding, from each group of buildings on the holding in which the birds are kept;

(c) the number of sites from which separate faeces samples are to be taken in order to make a pooled sample shall be as follows:

B. Adult breeding flocks

1. All adult breeding flocks must be sampled at least every two weeks during the laying period.

2. Breeding flocks whose eggs are hatched at a hatchery with a total incubator capacity of less than 1 000 eggs must be sampled on the holding and the samples to be taken shall consist of a pooled faeces sample made up of separate faeces samples, each weighing not less than 1 g, collected in accordance with point A (2) (b).

3. Breeding flocks whose eggs are hatched at a hatchery with a total incubator capacity of 1 000 eggs or more must be sampled through the hatchery and the samples to be taken shall consist of:

(a) pooled samples of meconium taken from 250 chicks hatched from eggs supplied to the hatchery from each breeding flock; or

(b) samples of carcasses of 50 chicks which are dead in the shells of eggs or which have been hatched from

eggs supplied to the hatchery from each breeding flock.

4. Such samples must also be taken from breeding flocks comprising less than 250 birds whose eggs are hatched in hatcheries with a total incubator capacity of 1 000 eggs or more.

5. Every eight weeks, the sampling provided for in point B must be replaced by official sampling, which must be conducted in accordance with point 4.

C. Examination of samples for salmonella

The total number of samples taken in each building may be pooled for analysis.

The analyses and tests for salmonella shall be carried out by methods recognized in accordance with the procedure laid down in Article 16 of this Directive, after consultation of the Scientific Veterinary Committee, or, pending recognition, by tried and tested national methods which afford the guarantees laid down in Decision 89/610/EEC (1).

III. Notification of results

Where, as a result of monitoring carried out in accordance with point II, the presence of *Salmonella enteritidis* or *Salmonella typhimurium* is detected in a breeding flock, the person responsible for the laboratory carrying out the examination, the person carrying out the examination or the owner of the flock shall notify the results to the competent authority.

IV. Investigation of flocks declared positive after monitoring

Where the presence of *Salmonella enteritidis* or *Salmonella typhimurium* is notified in accordance with point III, the flock shall be officially sampled in order to confirm the initial results. A sample of birds must be taken at random from within each house of birds on the farm, the size of sample being selected in accordance with the table at point II (A) (2) (c). For the purposes of examination, the birds from each house must be grouped into batches of five and samples of liver, ovary and intestines taken from each bird in the batch must be examined for salmonella using analyses and tests recognized in accordance with the procedures laid down in Article 16 of this Directive or pending such recognition by tried and tested national methods.

V. Measures to be taken in respect of flocks where infection is confirmed

The measures must comply with the following minimum standards.

1. Where, as a result of an investigation carried out in accordance with point IV, the presence of *Salmonella enteritidis* or *Salmonella typhimurium* is confirmed in the birds in a house, the following measures must be taken:

(a) no bird may leave the house concerned unless the competent authority has authorized the slaughter and destruction under supervision or slaughter in a slaughterhouse designated by the competent authority in accordance with (c);

(b) non-incubated eggs produced by the birds in the house in question must be destroyed on the spot or after appropriate marking be taken under supervision to an approved egg-processing establishment to be heat treated in accordance with the requirements of Directive 89/437/EEC (2);

(c) all the birds in the house must be slaughtered in accordance with Annex I, Chapter VI, point 31 (c) of Directive 71/118/EEC, the official veterinarian of the slaughterhouse being informed of the decision to slaughter, in accordance with Annex I, Chapter VI, point 25 (a) of that Directive, or be slaughtered and destroyed so as to reduce as much as possible the risk of spreading salmonella.

2. Once a house occupied by a flock infected with *Salmonella enteritidis* or *Salmonella typhimurium* has been emptied of birds, effective cleansing and disinfection must be carried out, including safe disposal of manure or litter, in accordance with procedures laid down by the local veterinary authority. Restocking must be with chicks satisfying the requirements of point II (A) (1).

3. 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 high risk material in accordance with Directive 90/667/EEC (3).

VI. Under the procedure provided for in Article 16 and following the opinion of the Scientific Veterinary Committee, to be ascertained before 1 October 1993,

(a) surveillance systems based on a serological check at the holding may be recognized if they offer guarantees equivalent to the system of inspection at the hatchery provided for in point II (A) (1), (B) (3) and (4) and (C);

(b) alternative solutions to compulsory slaughter provided for in point V (c), such as antibiotic treatment, may be approved for breeding flocks;

(c) specific rules may be established with a view to safeguarding valuable genetic material.

The checks provided for in this Chapter may, according to the procedure laid down in Article 16, be

reviewed in the light of the development of scientific knowledge.

Section II

INSPECTION FOR SALMONELLA AT THE FINAL PRODUCTION STAGE OF COMPOUND FEEDINGSTUFFS FOR POULTRY

When official samples are being taken on a holding or in cases of justified suspicion, sampling may be carried out on the compound feedingstuffs used to feed poultry.

Where a sample is positive for salmonella, the competent authority shall carry out an investigation in order to:

- (a) identify the source of contamination, in particular by means of official samples taken at different stages of production;
- (b) examine the application of rules and controls concerning the disposal and processing of animal waste and in particular those laid down in Directive 90/667/EEC;
- (c) establish procedures for good manufacturing practices and ensure compliance with recognized procedures.

ANNEX IV

CHAPTER I

LIST OF COMMUNITY REFERENCE LABORATORIES FOR ZONOSSES (1)(0)

I. Epidemiology of zoonoses

Institut fuer Veterinaermedizin

(Robert von Ostertag-Institut)

Postfach 33 00 13

Thielallee 88/92

D-1000 Berlin (Federal Republic of Germany)

II. Salmonella

Rijksinstituut voor de Volksgezondheid

PO Box 1

NL-3720 BA Bilthoven (The Netherlands)

CHAPTER II

DUTIES AND TASKS OF THE COMMUNITY REFERENCE LABORATORY

1. The Community reference laboratories listed in Chapter I shall be responsible for:

- providing national reference laboratories with details of analytical methods and comparative testing,
- coordinating the application by national reference laboratories of the methods referred to in the first indent, in particular by organizing comparative testing,
- coordinating research into new analytical methods and informing national reference laboratories of advances in this field,
- conducting initial and further training courses for the benefit of staff from national reference laboratories,
- providing scientific and technical assistance to the Commission, especially in cases where the results of analyses are contested between Member States.

2. The Community reference laboratories shall ensure that the following operating conditions are maintained:

They must:

- have suitably qualified staff with adequate training in the techniques applied to the detection of zoonoses,
- possess the equipment and substances needed to carry out the tasks provided for in 1,
- have an appropriate administrative infrastructure,
- ensure that their staff respect the confidential nature of certain subjects, results or communications,
- have sufficient knowledge of international standards and practices.

(1)(0) Without prejudice to the reference laboratories for brucellosis, tuberculosis and rabies.