Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC

DIRECTIVE 2003/99/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 17 November 2003

on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

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

Having regard to the opinion of the European Economic and Social Committee⁽²⁾,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽³⁾,

Whereas:

- (1) Live animals and food of animal origin appear on the list in Annex I to the Treaty. Livestock farming and the placing on the market of food of animal origin constitute an important source of income for farmers. The implementation of veterinary measures aimed at raising the level of public and animal health in the Community assists the rational development of the farming sector.
- (2) The protection of human health against diseases and infections transmissible directly or indirectly between animals and humans (zoonoses) is of paramount importance.
- (3) Zoonoses transmissible through food may cause human suffering, as well as economic losses to food production and the food industry.
- (4) Zoonoses transmitted through sources other than food, especially from wild animal and pet animal populations, are also a matter of concern.
- (5) 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⁽⁴⁾ provided for the establishment of a monitoring system for certain zoonoses both at the level of Member States and at Community level.
- (6) With the assistance of the Community reference laboratory for the epidemiology of zoonoses, the Commission collects the results of monitoring yearly from Member States and compiles them. Publication of the results has taken place yearly since 1995. They provide a basis for the evaluation of the current situation concerning zoonoses and

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zoonotic agents. However, the data collection systems are not harmonised and therefore do not permit comparisons between Member States.

- (7) Other Community legislation provides for the monitoring and control of certain zoonoses in animal populations. In particular, Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine⁽⁵⁾ deals with bovine tuberculosis and bovine brucellosis. Council Directive 91/68/ EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals⁽⁶⁾ deals with ovine and caprine brucellosis. This Directive should not create any unnecessary duplication of those existing requirements.
- (8) Moreover, a future regulation of the European Parliament and of the Council on the hygiene of foodstuffs should cover specific elements necessary for prevention, control and monitoring of zoonoses and zoonotic agents and include specific requirements for the microbiological quality of food.
- (9) Directive 92/117/EEC provides for collection of data on human cases of zoonoses. The aim of Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community⁽⁷⁾ is to reinforce the collection of such data and to contribute to improving the prevention and control, in the Community, of communicable diseases.
- (10) The collection of data on the occurrence of zoonoses and zoonotic agents in animals, food, feed and humans is necessary to determine the trends and sources of zoonoses.
- (11) In its opinion on zoonoses adopted on 12 April 2000, the Scientific Committee on Veterinary Measures relating to Public Health considered that the measures in place at that time to control food-borne zoonotic infections were insufficient. It further considered that the epidemiological data that Member States were collecting were incomplete and not fully comparable. As a consequence, 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.
- (12) It is therefore necessary to improve the existing monitoring and data collection systems established by Directive 92/117/EEC. Simultaneously, Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents⁽⁸⁾ will replace the specific control measures established by Directive 92/117/EEC. Directive 92/117/EEC should therefore be repealed.
- (13) The new framework for scientific advice and scientific support in matters of food safety set up by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽⁹⁾ should be used to collect and analyse the relevant data.

- (14) Where necessary to make data easier to compile and compare, monitoring should take place on a harmonised basis. This would make 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.
- (15) 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 and new strains of zoonotic organisms.
- (16) The alarming emergence of resistance to antimicrobial agents (such as antimicrobial medicinal products and antimicrobial feed additives) is a characteristic that should be monitored. Provision should be made for such monitoring to cover not only zoonotic agents but also, in so far as they present a threat to public health, other agents. In particular, the monitoring of indicator organisms might be appropriate. Such organisms constitute a reservoir of resistance genes, which they can transfer to pathogenic bacteria.
- (17) In addition to general monitoring, specific needs may be recognised which may necessitate the establishment of coordinated monitoring programmes. Attention should be paid in particular to zoonoses listed in Annex I to Regulation (EC) No 2160/2003.
- (18) If thoroughly investigated, food-borne outbreaks of zoonoses 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 close cooperation between the various authorities.
- (19) Transmissible spongiform encephalopathies are covered by Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies⁽¹⁰⁾.
- (20) 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 in the form of reports, which should be forwarded to the European Food Safety Authority and made available to the public in an appropriate way without delay.
- (21) The reports should be submitted on an annual basis. However, additional reports may be appropriate, when warranted by circumstances.
- (22) It may be appropriate to designate national and Community reference laboratories for giving guidance and assistance for analysis and testing in relation to zoonoses and zoonotic agents falling within the scope of this Directive.
- (23) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field⁽¹¹⁾ 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.

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- (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) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee set up by Regulation (EC) No 178/2002.
- (26) Member States cannot, acting alone, collect comparable data to provide a basis for risk assessment of zoonotic organisms of significance at Community level. The collection of such data can better be achieved at Community level. The Community may therefore 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.
- (27) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽¹²⁾,

HAVE ADOPTED THIS DIRECTIVE:

- (1) OJ C 304 E, 30.10.2001, p. 250.
- (**2**) OJ C 94, 18.4.2002, p. 18.
- (3) Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 161), Council common position of 20 February 2003 (OJ C 90 E, 15.4.2003, p. 9) and position of the European Parliament of 19 June 2003 (not yet published in the Official Journal).
- (4) OJ L 62, 15.3.1993, p. 38. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
- (5) OJ 121, 29.7.1964, p. 1977. Directive as last amended by Commission Regulation (EC) No 1226/2002 (OJ L 179, 9.7.2002, p. 13).
- (6) OJ L 46, 19.2.1991, p. 19. Directive as last amended by Commission Decision 2003/708/EC (OJ L 258, 10.10.2003, p. 11).
- (7) OJ L 268, 3.10.1998, p. 1.
- (8) See page 1 of this Official Journal.
- (9) OJ L 31, 1.2.2002, p. 1.
- (10) OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 1494/2002 (OJ L 225, 22.8.2002, p. 3).
- (11) OJ L 224, 18.8.1990, p. 19. Decision as last amended by Decision 2001/572/EC (OJ L 203, 28.7.2001, p. 16).
- (12) OJ L 184, 17.7.1999, p. 23.