

Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (Text with EEA relevance)

COUNCIL DIRECTIVE 2003/85/EC

of 29 September 2003

on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37(3) 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 European Economic and Social Committee⁽³⁾,

Having regard to the Opinion of the Committee of the Regions⁽⁴⁾,

Whereas:

- (1) One of the Community's tasks in the veterinary field is to improve the state of health of livestock, thereby increasing the profitability of livestock farming and facilitating trade in animals and animal products. At the same time the Community is also a Community of values, and its policies to combat animal diseases must not be based purely on commercial interests but must also take genuine account of ethical principles.
- (2) Foot-and-mouth disease is a highly contagious viral disease of biungulates. Although foot-and-mouth disease has no public health importance, due to its exceptional economic importance, it is on the top of list A diseases of the Office International des Epizooties (OIE).
- (3) Foot-and-mouth disease is a compulsorily notifiable disease and outbreaks must be notified by the Member State affected to the Commission and other Member States, in accordance with Council Directive 82/894/EEC of 21 December 1982, on the notification of animal diseases within the Community⁽⁵⁾.
- (4) The Community measures for the control of foot-and-mouth disease are laid down in Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease⁽⁶⁾. That Directive has been significantly amended on many occasions. Now that new amendments are being made to the said

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Directive, it is desirable, in order to clarify matters, that the provisions in question should be recast.

- (5) Following the adoption of Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC, Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine and Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat or meat products from third countries⁽⁷⁾, prophylactic vaccination against foot-and-mouth disease was prohibited throughout the Community as of 1 January 1992.
- (6) Preventive measures are necessary to avoid the incursion of foot-and-mouth disease into the Community and into Community livestock from neighbouring countries or through the introduction into the Community of live animals and products of animal origin. There is no indication that any of the outbreaks of foot-and-mouth disease reported since the prohibition of prophylactic vaccination can be attributed to imports in accordance with Community legislation and subject to veterinary checks at border inspection posts, established in accordance with Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries⁽⁸⁾, and Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries⁽⁹⁾.
- (7) Nevertheless, strict application of the Community rules on imports of animal products aimed at reducing risks should be strongly emphasised, if for no other reason than the increase in trade and movement of persons worldwide. The Member States should ensure that this legislation is implemented in its entirety and make enough personnel and resources available to provide strict controls on the external borders.
- (8) In addition, the European Parliament's Temporary Committee on Foot-and-Mouth Disease found that, in practice, border inspections are failing to prevent significant quantities of meat and meat products from entering the Community illegally.
- (9) Under the conditions of the single market and the overall satisfactory health status of livestock herds, the exchange of animals and animal products has increased substantially and certain regions of the Community have densely populated livestock areas.
- (10) The foot-and-mouth disease epidemic in certain Member States in 2001 demonstrated that due to intensive movement of and trade in animals susceptible to foot-and-mouth disease, an outbreak can quickly take on epizootic proportions, causing disturbances on a scale liable to reduce sharply the profitability of farming of animals of susceptible species and other parts of the rural economy and also requiring substantial financial resources to compensate farmers and the application of control measures.
- (11) During the 2001 foot-and-mouth disease crisis, the Commission reinforced the Community control measures for foot-and-mouth disease laid down in Directive 85/511/EEC by adopting protective measures in accordance with Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable

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- in intra-Community trade in certain live animals and products with a view to the completion of the internal market⁽¹⁰⁾, and Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market⁽¹¹⁾.
- (12) In 2001, the Commission also adopted Decisions on the conditions for the use of emergency vaccination in accordance with Directive 85/511/EEC. Those conditions were laid down taking account of the recommendations contained in the report of the Scientific Committee on Animal Health and Animal Welfare on the strategy for emergency vaccination against foot-and-mouth disease of 1999.
- (13) This Directive should take into account the report of expert groups from Member States on a review of Community legislation on foot-and-mouth disease of 1998, which reflects the experience gained by Member States during the classical swine fever epidemic in 1997, and the conclusions of the International Conference on the Prevention and Control of Foot-and-Mouth Disease held in Brussels in December 2001.
- (14) The Resolution of 17 December 2002 of the European Parliament on the foot-and-mouth disease epidemic in 2001 in the European Union⁽¹²⁾, based on the conclusions of the Temporary Committee on Foot-and-Mouth Disease of the European Parliament should be taken into account in this Directive.
- (15) The recommendations in the Report of the Thirtieth Session of the European Commission for the Control of Foot-and-Mouth Disease of the Food and Agriculture Organisation on minimum standards for laboratories working with foot-and-mouth virus in vitro and in vivo of 1993, should be taken into account.
- (16) This Directive should also take into account the changes made in the Animal Health Code and the Manual of Standards for Diagnostic Tests and Vaccines of the OIE (OIE Manual).
- (17) In order to ensure early detection of any possible outbreak of foot-and-mouth disease, legal provisions are necessary to oblige those in contact with animals of susceptible species to notify any suspect case to the competent authorities. Regular inspections should be introduced in the Member States to ensure that farmers are in fact familiar with and are applying the general rules on disease control and biosecurity.
- (18) It is necessary that action be taken as soon as the presence of the foot-and-mouth disease is suspected so that immediate and effective control measures can be implemented once its presence is confirmed. Such measures should be modulated by the competent authorities depending on the epidemiological situation in the Member State concerned. However, the measures should also be reinforced by specific protection measures established in accordance with Community legislation.
- (19) A rapid and detailed diagnosis of the disease and identification of the relevant virus should be carried out under the auspices of a network of national laboratories in the Member States. Where necessary, cooperation between the national laboratories should be ensured by a Community reference laboratory designated by the Commission in accordance with the procedure of the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002 of the European

Parliament and 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⁽¹³⁾.

- (20) With regard to the differential laboratory diagnosis for foot-and-mouth disease, account should be taken of Commission Decision 2000/428/EC of 4 July 2000 establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease⁽¹⁴⁾.
- (21) Community measures for the control of foot-and-mouth disease should be based first of all on depopulation of the infected herd. The killing of infected and contaminated animals of susceptible species should be carried out without delay in accordance with Council Directive 93/119/EEC of 22 December 1993 on the protection of animals at the time of slaughter or killing⁽¹⁵⁾. Where possible the processing of the carcasses of dead or killed animals should be carried out in accordance with Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption⁽¹⁶⁾.
- (22) It is necessary to integrate public health and environment protection aspects in the event of a foot-and-mouth disease outbreak, in particular by establishing close cooperation between the veterinary health and environment competent authorities. Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control⁽¹⁷⁾ requires an integrated environmental permit for installations for the disposal or recycling of animal carcasses and animal waste with a specified treatment capacity. Unnecessary risks from burning animal carcasses on pyres or burying them at mass burial sites should be avoided.
- (23) It is necessary to prevent any spread of the disease as soon as an outbreak occurs by carefully monitoring movements of animals and the use of products liable to be contaminated, and where appropriate, in particular in densely populated livestock areas, by emergency vaccination.
- (24) The action taken to control the foot-and-mouth disease epidemics which struck certain Member States in 2001 has shown that international and Community rules and the ensuing practices have not taken sufficient account of the possibility offered by the use of emergency vaccination and subsequent tests to detect infected animals in a vaccinated population. Too much importance was attached to the trade-policy aspects, with the result that protective vaccination was not carried out even when it had been authorised.
- (25) Various strategies are available for controlling foot-and-mouth disease. In the event of an epidemic, the choice of strategy to control the disease should likewise take account of which strategy causes the least possible economic damage for non-agricultural sectors of the economy.
- (26) By means of emergency vaccination without subsequent killing of the vaccinated animals the number of animals to be killed for disease control purposes may be reduced significantly. Appropriate testing should thereafter substantiate the absence of infection.

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- (27) Cleansing and disinfection should be an integral part of the Community control policy for foot-and-mouth disease. The use of disinfectants should be in compliance with Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market⁽¹⁸⁾.
- (28) Semen, ova and embryos collected from animals of susceptible species infected with the foot-and-mouth disease virus may contribute to the spread of the disease and should therefore be subject to restrictions in addition to those animal health conditions laid down for intra-Community trade in the following Directives:
- Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species⁽¹⁹⁾;
 - Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importations from third countries of embryos of domestic animals of the bovine species⁽²⁰⁾;
 - Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC⁽²¹⁾.
- (29) In the event of an outbreak it may be necessary to apply control measures not only to infected animals of susceptible species, but also to contaminated animals of species not susceptible to the disease which may be mechanical vectors for the virus. During the 2001 foot-and-mouth disease epidemic, restrictions were also applied on the movement of equidae coming from holdings keeping animals of susceptible species or neighbouring such holdings and specific certification, in addition to the requirements of Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of equidae⁽²²⁾, was required in order to control trade in equidae from Member States affected by foot-and-mouth disease.
- (30) With regard to animal health, the conditions governing placing on the market, trade and imports into the Community of animal products intended for human consumption are laid down in the following Directives:
- Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat⁽²³⁾;
 - Council Directive 77/99/EEC of 21 December 1976 on health problems affecting the intra-Community trade of meat products origin⁽²⁴⁾;
 - Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products⁽²⁵⁾;
 - Council Directive 91/495/EEC of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat⁽²⁶⁾;

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- Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations⁽²⁷⁾,
 - Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption⁽²⁸⁾.
- (31) Those Directives are now in the process of being replaced. In order to ease reference, the treatment of meat and meat products from animals of susceptible species, required to ensure the destruction of possible foot-and-mouth disease virus, is specified in the Annexes VII to IX of this Directive which are based on those Directives and comply with recommendations of the OIE.
- (32) The animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption are laid down in Council Directive 2002/99/EC of 16 December 2002⁽²⁹⁾.
- (33) Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products⁽³⁰⁾ provides for the treatment of milk from animals kept within the perimeters of surveillance zones established in accordance with Community control measures for foot-and-mouth disease. The requirements of that Directive are not sufficient, as they do not provide for treatment of milk from protection zones and from vaccinated animals. In addition, the treatment for milk for human consumption provided for in that Directive exceeds the requirements of the code of the OIE on destruction of foot-and-mouth disease virus in milk and results in logistic problems in the disposal of substantial quantities of milk refused by dairy plants. More detailed provisions on the collection and transport of milk from animals of susceptible species in areas subject to control measures for foot-and-mouth disease should be included in this Directive. The treatment of milk and milk products specified in Annex IX of this Directive complies with recommendations of the OIE for the destruction of possible foot-and-mouth disease virus in milk and milk products. Directive 92/46/EEC should therefore be amended accordingly.
- (34) With regard to products of animal origin account should be taken of Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC⁽³¹⁾. Certain provisions of Directive 92/118/EEC have been included in Regulation (EC) No 1774/2002.
- (35) The application of the principle of regionalisation should allow the implementation of strict control measures, including emergency vaccination, in a defined part of the Community without endangering general Community interests. Dairy and meat products from vaccinated animals may be placed on the market in accordance with the relevant Community legislation and this Directive in particular.

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- (36) Directive 64/432/EEC provides for the definition of regions. Commission Decision 2000/807/EC of 11 December 2000 laying down the codified form and the codes for the notification of animal diseases pursuant to Council Directive 82/894/EEC⁽³²⁾ specifies administrative areas in Member States related to disease control measures and disease notification.
- (37) To guard against emergencies, the Community has, in accordance with Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines⁽³³⁾, established reserves of inactivated foot-and-mouth disease virus antigen stored at designated premises, and the Community antigen and vaccine bank. Transparent and efficient procedures should be established to guarantee access to the antigen without undue delay. In addition, certain Member States have established and maintain national antigen and vaccine banks.
- (38) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products⁽³⁴⁾ requires that, with only minor exceptions, all veterinary medicinal products that are placed on the market within the Community hold a marketing authorisation. In addition, that Directive lays down the criteria for the granting of a marketing authorisation for veterinary medicinal products, including immunological veterinary medicinal products. That Directive authorises Member States to permit release onto their market of a product without a marketing authorisation in the event of a serious epidemic under certain conditions. Foot-and-mouth disease has the potential for a serious epidemic. Given the rapid variation of antigen required to produce an effective protection of animals of susceptible species in case of emergency, vaccines against foot-and-mouth disease qualify for the derogation provided for in that Directive.
- (39) The Community Reference Laboratory should advise the Commission and the Member States on the need for vaccines and antigens, in particular where virus strains are detected against which the vaccines produced on the basis of those antigens stored in the Community antigen and vaccine bank do not provide sufficient protection.
- (40) As a matter of precaution, in relation to the risks of a deliberate release of foot-and-mouth disease virus, it is appropriate to apply specific procedures to the procurement of antigens for the Community antigen and vaccine bank and to the publication of certain details relating to disease control measures.
- (41) The presence of an entirely non-immune population of susceptible livestock in Member States requires permanent disease-awareness and preparedness. The need for detailed contingency plans has been proven once more during the 2001 foot-and-mouth disease epidemic. At present, all Member States have contingency plans approved by Commission Decision 93/455/EEC of 23 July 1993 approving certain contingency plans for the control of foot-and-mouth-disease⁽³⁵⁾. Such contingency plans should be reviewed regularly, among other things, in the light of the results of real-time alert exercises carried out in the Member States, the experience of the 2001 epidemic and in order to include measures to protect the environment. Member States should be encouraged to organise and carry out such exercises in close cooperation and across borders. The Commission should be encouraged, in cooperation with the Member

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States, to make provision for the setting-up of technical assistance which could be made available to Member States affected by an epidemic.

- (42) In order to protect Community livestock and based on risk assessment, provision should be made to assist neighbouring third countries infected by or at risk of foot-and-mouth disease, in particular as regards the emergency supply of antigen or vaccines. However, such provisions should apply without prejudice to agreements concluded between the third country concerned and the Community on access to the Community antigen and vaccine bank.
- (43) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field⁽³⁶⁾, applies in the event of the occurrence of foot-and-mouth disease and provides for Community aid to be granted to reference laboratories and antigen and vaccine banks. Any Community compensation paid to Member States for financial expenditures relating to control measures in the case of outbreaks of foot-and-mouth disease, should be subject to scrutiny regarding compliance with at least the minimum requirements laid down in this Directive.
- (44) In order to ensure close cooperation between the Member States and the Commission in controlling foot-and-mouth disease and taking into account the nature of the disease, the Commission should be empowered to modify and adapt certain technical aspects of the control measures. Where necessary, the Commission should base any such modifications or adaptations on the results of a veterinary inspection mission carried out 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⁽³⁷⁾.
- (45) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.
- (46) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of maintaining and, in the event of an outbreak, of quick recovery of a foot-and-mouth disease and infection-free status of all Member States, to lay down rules on the measures to increase disease preparedness and to control outbreaks as quickly as possible, if necessary by emergency vaccination, and to limit the adverse effects on the production of and trade in livestock and products of animal origin. This Directive does not go beyond what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.
- (47) 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⁽³⁸⁾,

HAS ADOPTED THIS DIRECTIVE:

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- (1) Proposal of 18 December 2002.
- (2) Opinion delivered on 15 May 2003 (not yet published in the Official Journal).
- (3) Opinion delivered on 14 May 2003 (not yet published in the Official Journal).
- (4) Opinion delivered on 2 July 2003 (not yet published in the Official Journal).
- (5) [OJ L 378, 31.12.1982, p. 58](#). Directive as last amended by Commission Decision 2000/556/EC ([OJ L 235, 19.9.2000, p. 27](#)).
- (6) [OJ L 315, 26.11.1985, p. 11](#). Directive as last amended by the 2003 Act of Accession.
- (7) [OJ L 224, 18.8.1990, p. 13](#).
- (8) [OJ L 268, 24.9.1991, p. 56](#). Directive as last amended by Directive 96/43/EC ([OJ L 162, 1.7.1996, p. 1](#)).
- (9) [OJ L 373, 31.12.1990, p. 1](#). Directive as last amended by Directive 96/43/EC ([OJ L 162, 1.7.1996, p. 1](#)).
- (10) [OJ L 224, 18.8.1990, p. 29](#). Directive as last amended by Directive 2002/33/EC of the European Parliament and of the Council ([OJ L 315, 19.11.2002, p. 149](#)).
- (11) [OJ L 395, 30.12.1989, p. 13](#). Directive as last amended by Directive 92/118/EEC ([OJ L 62, 15.3.1993, p. 49](#)).
- (12) [OJ C 21 E, 24.1.2002, p. 339](#).
- (13) [OJ L 31, 1.2.2002, p. 1](#).
- (14) [OJ L 167, 7.7.2000, p. 22](#).
- (15) [OJ L 340, 31.12.1993, p. 21](#).
- (16) [OJ L 273, 10.10.2002, p. 1](#). Regulation as last amended by Commission Regulation (EC) No 808/2003 ([OJ L 117, 13.5.2003, p. 1](#)).
- (17) [OJ L 257, 10.10.1996, p. 26](#).
- (18) [OJ L 123, 24.4.1998, p. 1](#).
- (19) [OJ L 194, 22.7.1988, p. 10](#). Directive as last amended by the 2003 Act of Accession.
- (20) [OJ L 302, 19.10.1989, p. 1](#). Directive as last amended by Commission Decision 94/113/EC ([OJ L 53, 24.2.1994, p. 23](#)).
- (21) [OJ L 268, 14.9.1992, p. 54](#). Directive as last amended by Commission Regulation (EC) No 1282/2002 ([OJ L 187, 16.7.2002, p. 13](#)).
- (22) [OJ L 224, 18.8.1990, p. 42](#). Directive as last amended by Commission Decision 2002/160/EC ([OJ L 53, 23.2.2002, p. 37](#)).
- (23) [OJ 121, 29.7.1964, p. 2012/64](#). Directive as last amended by Directive 95/23/EC ([OJ L 243, 11.10.1995, p. 7](#)).
- (24) [OJ L 26, 31.1.1977, p. 85](#). Directive as last amended by Directive 97/76/EC ([OJ L 10, 16.1.1998, p. 25](#)).
- (25) [OJ L 47, 21.2.1980, p. 4](#). Directive as last amended by the 2003 Act of Accession.
- (26) [OJ L 268, 24.9.1991, p. 41](#). Directive as last amended by Directive 94/65/EC ([OJ L 368, 31.12.1994, p. 10](#)).
- (27) [OJ L 368, 31.12.1994, p. 10](#).
- (28) [OJ L 18, 23.1.2003, p. 11](#). Directive as last amended by the 2003 Act of Accession.
- (29) [OJ L 18, 23.1.2003, p. 11](#).
- (30) [OJ L 268, 14.9.1992, p. 1](#). Directive as last amended by Directive 94/71/EC ([OJ L 368, 31.12.1994, p. 33](#)).
- (31) [OJ L 62, 15.3.1993, p. 49](#). Directive as last amended by Commission Decision 2003/42/EC ([OJ L 13, 18.1.2003, p. 24](#)).

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- (32) [OJ L 326, 22.12.2000, p. 80](#). Decision as last amended by Decision 2002/807/EC ([OJ L 279, 17.10.2002, p. 50](#)).
- (33) [OJ L 368, 21.12.1991, p. 21](#). Decision as last amended by Decision 2001/181/EC ([OJ L 66, 8.3.2001, p. 39](#)).
- (34) [OJ L 311, 28.11.2001, p. 1](#).
- (35) [OJ L 213, 24.8.1993, p. 20](#). Decision as last amended by Decision 2001/96/EC ([OJ L 35, 6.2.2001, p. 52](#)).
- (36) [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](#)).
- (37) [OJ L 38, 12.2.1998, p. 10](#).
- (38) [OJ L 184, 17.7.1999, p. 23](#).