



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13.12.2002
COM(2002) 736 final

2002/0299 (CNS)

Proposal for a

COUNCIL DIRECTIVE

**on Community measures for the control of foot-and-mouth disease and amending
Directive 92/46/EEC**

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. INTRODUCTION

- 1.1. Foot-and-mouth disease is a highly contagious viral disease of predominantly cloven-hoofed animals, which was for the first time described in Italy in the 16th century. Due to its exceptional economic importance, foot-and-mouth disease is listed at the top of the list A diseases of the Office International des Epizooties (OIE).
- 1.2. Foot-and-mouth disease is not dangerous for humans but may in exceptionally rare cases affect them, causing light and transitional clinical symptoms.

2. GLOBAL FOOT-AND-MOUTH DISEASE SITUATION

- 2.1. Foot-and-mouth disease continues to be endemic in third countries neighbouring the Member States or candidate countries. Acute outbreaks of foot-and-mouth disease were reported in certain Balkan countries in 1996, Transcaucasia since 1997 and certain Maghreb states in 1999. The Community supplied vaccine and vaccination equipment to these countries to quickly eradicate the disease. New topotypes and exotic strains of foot-and-mouth disease virus continue to emerge in Turkey due to virus introduction from areas further east.
- 2.2. A substantial part of these activities has been carried out in close co-operation with international institutions, first of all the European Commission for the Control of Foot and Mouth Disease (EUFMD), a statutory body of the Food and Agriculture Organization (FAO) of the United Nations (UN). By adopting Decision 2001/300/EC the Commission formalised its long-standing co-operation with the EUFMD and signed an Implementing Agreement on the use of the Trust Fund for permanent activities of that organisation, maintained by EUFMD and replenished by the Commission for many years.
- 2.3. In 2000 and 2001 outbreaks have also been reported in countries previously free of foot-and-mouth disease infection. Where the disease affected third countries exporting fresh meat to the Community, such imports were suspended until the health situation improved and appropriate Community measures were adopted to allow such imports to continue under reinforced conditions which prevented the introduction of virus onto Community territory through such imports.
- 2.4. The global foot-and-mouth disease situation calls for a permanent disease awareness and prophylactic and preventive measures are necessary to avoid the incursion of foot-and-mouth disease virus onto community territory and into Community livestock herds from adjacent countries or through imports of live animals or products of animal origin.

3. HISTORY OF CONTROL MEASURES IN MEMBER STATES

- 3.1. The Community measures for the control of foot-and-mouth disease are laid down in Directive 85/511/EEC¹, as last amended by the Act of Accession of Austria, Finland and Sweden². The prohibition of prophylactic vaccination introduced by Council Directive 90/423/EEC³ effectively facilitated the improvement of the health status of the Community livestock and thereby contributed to free trade in susceptible live animals and products derived from such animals.
- 3.2. Since the establishment of the single market and due to an overall satisfactory health status in livestock herds in the Member States, the movement and exchange of animals and animal products has increased substantially and certain regions of the EU developed into densely populated livestock areas. Under these conditions an outbreak of foot-and-mouth disease can quickly take on epizootic proportions, causing disturbances on a scale liable to reduce sharply the profitability of farming of susceptible domestic animals as a whole, and in particular pigs and ruminants, and possibly requiring substantial financial resources for compensation of affected farmers and application of control measures.
- 3.3. Since 1 January 1992, the date prophylactic vaccination was prohibited throughout the Community, outbreaks of foot-and-mouth disease have been reported in Italy in 1993 and Greece in 1994, 1996 and 2000 due to incursion from third countries, which were successfully controlled by applying the measures provided for in Directive 85/511/EEC, including stamping out of infected or contaminated herds and strict enforcement of movement controls.
- 3.4. In 2001 a major foot-and-mouth disease epidemic occurred in the United Kingdom. More than 2000 holdings in the United Kingdom were affected. Related to the movement of sheep prior to the detection of the first outbreak in the United Kingdom, a limited number of holdings in France, Ireland and the Netherlands were also infected. A large number of animals had to be slaughtered and destroyed in all affected Member States and the economic losses affected not only the farming, but also the whole rural community in the affected parts of the Community. For the first time since 1991 a Member State, the Netherlands, had recourse to emergency vaccination carried out in accordance with Directive 85/511/EEC. However, for reasons of international trade restrictions the vaccinated animals were subsequently killed in order to re-establish the health status of the country without delay.

¹ OJ L 315, 26.11.1985, p. 11.

² OJ L 1, 1.1.1995, p. 1.

³ OJ L 224, 18.8.1990, p. 13.

3.5. During the past decade the Community experienced outbreaks and in some cases epidemics of classical swine fever, a contagious viral disease in domestic and feral pigs. This disease and in particular the epidemic in 1997/1998 led to heavy economic losses for the Community, the Member States concerned and the farming community due to the killing and destruction of large numbers of animals, as well as in some cases long lasting restrictions on trade in porcine animals and products. However, the overall economic, social and animal welfare implications were far exceeded by the 2001 foot-and-mouth disease epidemic, notably because foot-and-mouth disease affects more than one species, in particular bovine animals, and is far more contagious and easily spread by wind and fomites.

4. PREPARATION OF A REVIEW OF CONTROL MEASURES FOR FOOT-AND-MOUTH DISEASE

4.1. Already in the light of the experience gained with classical swine fever, the measures provided for in Directive 85/511/EEC were considered incomplete. For this reason the Commission together with laboratory experts, epidemiologists and representatives of the veterinary administrations of all Member States commenced in 1998 an in-depth review of the measures provided for by that Directive and implementing Decisions based on the Directive. In addition a special working group of the Scientific Veterinary Committee produced a report on emergency vaccination against foot-and-mouth disease in 1999.

4.2. Those working groups unanimously supported the Commission's view that there is a need to modify some of the measures so far adopted to take account of the most recent scientific development in this field, the experience gained in eradicating important contagious diseases and the technical developments in laboratory diagnosis and in particular with regard to vaccination.

4.3. Based on expert advice, a draft proposal for a new Council Directive on control measures for foot-and-mouth disease had been prepared by the Commission services when on 20 February 2001 the first outbreak was notified of what should become one of Europe's most severe foot-and-mouth disease epidemics.

4.4. During that epidemic, which lasted about one year until the foot-and-mouth disease free status of the Community was re-established by the OIE, the Community as a whole and not only the affected Member States experienced severe restrictions on internal and international trade and movement of susceptible animals and products derived from such animals.

4.5. The classical swine fever epidemic and the recent foot-and-mouth epidemic also revealed that a disease control policy based entirely on stamping out of infected and contaminated animals is questionable from an ethical and environmental point of view and is publicly less and less accepted.

- 4.6. The 2001 FMD crisis was managed in close co-operation between the Commission and the Member States by adopting and continuously adapting protective measures reinforcing and supplementing the provisions of Council Directive 85/511/EEC. These protective measures took full account of the measures agreed previously in expert groups established in 1998 to review the current Community control measures for foot-and-mouth disease. Thereby additional and valid experience has been gained in the Member States in application of certain measures included in the present draft proposal.
- 4.7. When the crisis came to an end, an International Conference on the Prevention and Control of Foot-and-Mouth Disease was organised jointly by the Belgian Presidency of the Council and the Commission in December 2001 in order to draw the first conclusions from the 2001 outbreak. The conference called upon the Commission to submit suitable legislative proposals to prevent such outbreaks in future and, if they would occur, to minimise the adverse economic effects. Amongst other things it was requested that emergency vaccination should become a viable option of disease control, taking into account technical developments in laboratory diagnosis. It was also requested that the international trade standards should be reviewed so as to limit the economic consequences affecting adversely countries which had recourse to emergency vaccination.
- 4.8. During 2001 and in particular following the conference, a series of activities has started in Member States, in the Commission and within the framework of international organisations, to review the adopted approach in relation to this disease and to improve the instruments to prevent and where necessary to control the disease.
- 4.9. During the year 2001 important modifications have been made to international animal health standards, notably the description of tests for the detection of antibodies against non-structural proteins in the 4th Edition of Manual of Standards for Diagnostic Tests and Vaccines of the OIE , published in August 2001.
- 4.10. The second important modification are the amendment to the OIE Animal Health Code adopted at the 70th General Session in 2002. These amendments require to describe the health status of a country not only on the basis of absence of clinical signs but also on substantiated by laboratory testing evidence of absence of foot-and-mouth disease infection. Under the condition of previous vaccination, such laboratory testing should include the detection of antibodies against non-structural proteins, thereby integrating the tests described in the Manual of Standards into the Animal Health Code. Consequently, the foot-and-mouth disease and infection free status of a country that had recourse to emergency vaccination in combination with stamping out of infected herds and post-vaccination serological surveillance using tests for the detection of antibodies against non-structural proteins in vaccinated animals would be re-established six months after the last outbreak or after the completion of vaccination what ever event occurs latest. Thereby emergency vaccination would become an option to control foot-and-mouth disease.
- 4.11. In 2002 a Temporary Committee on Foot-and-Mouth Disease has been established by the European Parliament to look into the 2001 foot-and-mouth disease crisis and to draw general conclusions on the future control strategies. The conclusions of that Committee will have to be considered in the text of the new Directive to be adopted finally.

- 4.12. The Commission considers that the internationally recognised status of “Free from foot and-mouth disease without vaccination” applied by the OIE to all Member States is an achievement which has facilitated the establishment of the single market and opens trade opportunities for all Member States.

For technical and economical reasons the Commission and the Member States decided not to divert from the current policy banning prophylactic vaccination. The most important of these reasons being that foot-and-mouth disease is not endemic on Community territory and therefore an exotic disease as many other animal diseases prevalent elsewhere in the world. If virus was accidentally introduced onto Community territory, it might originate from various endemic regions in the world. Given the nature of the virus and in particular its antigenical diversity this situation would render any prophylactic vaccination with a set of vaccine strains chosen in advance a costly and eventually ineffective measure and hence increase the risks of undetected spread of infection in an inadequately vaccinated population.

Neither the above mentioned international conference, nor the Temporary Committee of the European Parliament suggested to revert to a policy of prophylactic vaccination, while at the same time requesting to move emergency vaccination from a measure of last resort more to the forefront of control strategies in conjunction with measures to prevent virus introduction onto Community territory and into susceptible livestock and to enhance the capacity of Member States to respond to a possible outbreak.

5. GENERAL FEATURES OF THE PROPOSAL

- 5.1. The present proposal, although its preparation started well before the events of 2001, is therefore also a consequence of the lessons learned during this crisis. However, due to the nature of the disease, there is no perfect solution which could fully accommodate all of the economic, environmental and the ethical desires of civil society and therefore this proposal can only present the best currently available compromise.
- 5.2. The structure of the proposal tries to follow the sequence of events should an outbreak occur and contains in its final part the measures to be taken in order to prepare for an outbreak.
- 5.3. As soon as the presence of the disease is suspected rapid action must be taken so that immediate and effective control measures can be implemented once its presence is confirmed. Such measures must be modulated by the competent authorities and in some cases extended to large geographic and administrative areas depending on the epidemiological situation in the Member State concerned. It must also be possible to apply a preventive stamping out programme to reduce the number of susceptible animals in the vicinity of an outbreak.

- 5.4. Rapid and detailed diagnosis of the disease and identification of the relevant virus are of paramount importance and should be carried out under the auspices of responsible laboratories which must be networked between themselves and the co-ordination of which should be ensured by a reference laboratory designated by the Commission after consultation of the Member States in the Standing Committee on the Food Chain and Animal Health. Contrary to previous expert advice and in line with policy pursued by the Commission over the past decade, the 2001 outbreak confirmed that laboratory capacity, expertise and sound scientific competition in the field of foot-and-mouth disease diagnosis must be maintained in as many Member States as possible.
- 5.5. 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 exceptional severe cases, particularly in densely populated livestock areas, by vaccination. At the same time, it should be acknowledged that there are sufficiently effective tools to prevent the spread of virus when healthy animals from herds outside the restricted areas are slaughtered or their milk is processed in establishments situated within zones restricted for disease reasons.
- 5.6. Applying the principles of regionalisation with regard to the control measures allows the implementation of strict control measures in a certain part of the Community without endangering general Community interests.
- 5.7. Although the silent form of foot-and-mouth disease in sheep has been well documented for a long time, the extent to which this species was involved in and contributed to the spread of foot-and-mouth disease in the United Kingdom in 2001 was unexpected and overwhelmed those in charge of controlling the disease. The involvement of sheep in the epidemic necessitated the elaboration of principles for serological surveillance prior to releasing restrictions imposed on holdings situated in certain zones and for the re-establishment of the disease and infection free status of a country.
- 5.8. To guard against emergencies, the Community has established reserves of inactivated foot-and-mouth disease virus antigen stored at designated antigen banks. Transparent and efficient procedures must be established to guarantee access to the antigen without undue delay. In addition, certain Member States have established and maintain national vaccine and antigen banks. In order to protect Community livestock and based on risk assessment, provision must be made to assist adjacent third countries infected by or at risk of foot-and-mouth disease, in particular as regards the emergency supply of antigen or vaccines. However, following recent political developments and in particular the events of 11 September 2001, more consideration must be given to aspects of agro-terrorism which requires a higher degree of confidentiality as far as details of antigen stocks are concerned. Consequently provisions must be made to derogate from certain Commission procurement procedures and to limit access to essential information.

- 5.9. In accordance with Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products⁴ foot-and-mouth disease vaccines have been subject to marketing authorisation granted by Member States.
- 5.10. Article 8 of Directive 2001/82/EEC provides for emergency situations, where the administration to animals of susceptible species of vaccines against foot-and-mouth disease may be authorized, even if this vaccine was not granted marketing authorisation in the Member State concerned. Given the rapid variation of antigen required to produce an effective protection of animals of susceptible species in case of emergency, it appears appropriate to maintain that emergency clause.
- 5.11. However, in close co-operation between the European Agency for the Evaluation of Medicinal Products (EMEA), the OIE, the Research Group of the European Commission for the Control of Foot and Mouth Disease (EUFMD) of the Food and Agriculture Organization (FAO) of the United Nations (UN) and the European Commission, the foot-and-mouth disease monograph of the European Pharmacopoeia is being modified so as to lay down standards for vaccines against foot-and-mouth disease which would incorporate essential requirements for the purity of such vaccines necessary to perform a test for the identification of infected animals within a vaccinated animal population.
- 5.12. The presence of an entirely non-vaccinated population of susceptible livestock in Member States requires permanent disease awareness and preparedness. Detailed contingency plans have proven to be an effective tool to counteract the occurrence of the disease. Such contingency plans have to be reviewed regularly in the light of the results of real-time alert exercises in the Member States, and close co-operation between Member States in such exercises should be encouraged. Such contingency plans, when reviewed in the light of this Directive, must however include provisions on the use of emergency vaccination. Furthermore contingency plans are crucial in ensuring that environmental protection considerations are integrated in case of an outbreak. Those plans shall establish a well-structured and organised collaboration that will apply between veterinary and environmental competent authorities so that actions to address veterinary and environmental safety issues are appropriately co-ordinated.
- 5.13. In order to ensure close co-operation 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 by the procedure of the Standing Committee on the Food Chain and Animal Health in accordance with the procedures for the exercise of implementing powers conferred on the Commission laid down in Council Decision 1999/468/EC⁵.

⁴ OJ L 311, 28.11.2001, p. 1.

⁵ OJ L 184, 28.6.1999, p. 23.

- 5.14. Articles 11, 12, 13, 14 and 15 of Council Decision 90/424/EEC of 26 June on expenditure in the veterinary field⁶, as last amended by Council Regulation (EC) No 1258/1999⁷, apply in the event of the occurrence of foot-and-mouth disease and for the Community aid to be granted to liaison and reference laboratories and antigen and vaccine banks. Any Community compensation to Member States for financial expenditures relating to control measures in case of outbreaks of foot-and-mouth disease should be subject to scrutiny with regard to application of at least the minimum requirements laid down in this Directive.

⁶ OJ L 224, 18.8.1990, p. 19.

⁷ OJ L 160, 26.6.1999, p. 103.

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**on Community measures for the control of foot-and-mouth disease 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 Commission¹,

Having regard to the opinion of the European Parliament²,

Having regard to the opinion of the European Economic and Social Committee³,

Having regard to the opinion of the Committee of the Regions⁴,

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.
- (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 Community⁵.

¹ OJ C ..., ..., p.

² OJ C ..., ..., p.

³ OJ C ..., ..., p.

⁴ OJ C ..., ..., p.

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).

- (4) The Community measures for the control of foot-and-mouth disease are laid down in Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease⁶.
- (5) Following the adoption of Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease, 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 countries⁷ 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 onto Community territory 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 organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC⁸, and Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries⁹.
- (7) 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.
- (8) 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.

⁶ OJ L 315, 26.11.1985, p. 11. Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

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).

- (9) 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 in intra-Community trade in certain live animals and products with a view to the completion of the internal market¹⁰, 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 market¹¹.
- (10) 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 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 1999¹².
- (11) 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 1998¹³, 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 2001¹⁴.
- (12) The resolution of the European Parliament on the foot-and-mouth disease epidemic in 2001 in the European Union¹⁵, and the conclusions of the Temporary Committee on Foot-and-Mouth Disease of the European Parliament should be taken into account in this Directive.
- (13) 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 1993,¹⁶ should be taken into account.
- (14) 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.
- (15) 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, such measures should also be reinforced by specific protection measures established in accordance with Community legislation.

¹⁰ OJ L 224, 18.8.1990, p. 29. Directive as last amended by Directive 92/118/EEC (OJ L 62, 15.3.1993, p. 49).

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 http://europa.eu.int/comm/food/fs/sc/scah/out22_en.pdf.

¹³ Working Document VI/6319/98 Rev. 1.

¹⁴ <http://www.cmlag.fgov.be/eng/conference.html>].

¹⁵ OJ C 21 E, 24.1.2002, p 339.

¹⁶ Working Document VI/6684/96.

- (16) 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, co-operation 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 safety¹⁷.
- (17) With regard to the differential laboratory diagnosis for foot-and-mouth disease account must 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 disease¹⁸.
- (18) 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 the provisions of Council Directive 93/119/EEC of 22 December 1993 on the protection of animals at the time of slaughter or killing¹⁹.
- (19) It is necessary to integrate environment protection aspects in the event of a foot-and-mouth disease outbreak, in particular by establishing close co-operation between the veterinary and environment competent authorities. Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control²⁰ requires an integrated environmental permit for installations for the disposal or recycling of animal carcasses and animal waste with a specified treatment capacity.
- (20) 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.
- (21) Cleansing and disinfection should be an integral part of the Community control policy for foot-and-mouth disease. The use of disinfectants must be in compliance with the provisions of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market²¹.

¹⁷ OJ L 31, 1.2.2002, p. 1.

¹⁸ OJ L 167, 7.7.2000, p. 22.

¹⁹ OJ L 340, 31.12.1993, p. 21.

²⁰ OJ L 257, 10.10.1996, p.26.

²¹ OJ L 123, 24.4.1998, p. 1.

- (22) 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 species²²;

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 species²³;

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/EEC²⁴.

- (23) In the event of an outbreak it may be necessary to apply control measures not only to infected animals of susceptible species, but also contaminated animals of species not susceptible to the disease, notably poultry, 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 equidae²⁵, was required in order to control trade in equidae from Member States affected by foot-and-mouth disease.

- (24) 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 conditions for the production and marketing of fresh meat²⁶;

Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat²⁷;

²² OJ L 194, 22.7.1988, p. 10. Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

²³ 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).

²⁴ OJ L 268, 14.9.1992, p. 54. Directive as last amended by Commission Regulation (EC) No 1282 (OJ L 187, 16.7.2002, p.13).

²⁵ 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).

²⁶ OJ L 121, 29.7.1964, p. 2012/64. Directive as last amended by Directive 95/23/EC (OJ L 243, 11.10.1995, p. 7).

²⁷ OJ L 302, 31.12.1972, p. 24. Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

Council Directive 77/99/EEC of 21 December 1976 on health problems affecting the production and marketing of meat products and certain other products of animal origin²⁸;

Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products²⁹;

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 meat³⁰;

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 preparations³¹;

- (25) Those Directives are 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 which are based on the provisions of the those Directives and comply with recommendations of the OIE.
- (26) 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 products³² 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 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. Council Directive 92/46/EEC should be amended accordingly.

²⁸ 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).

²⁹ OJ L 47, 21.2.1980, p. 4. Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

³⁰ 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).

³¹ OJ L 368, 31.12.1994, p. 10.

³² OJ L 268, 14.9.1992, p. 1. Directive as last amended by Directive 96/23/EC (OJ L 125, 23.5.1996, p. 10).

- (27) 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/EEC³³. Certain provisions of Council Directive 92/118/EEC have been included in Regulation (EC) No 1774/2002 of the European Parliament and the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption³⁴.
- (28) The application of the principles 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.
- (29) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine³⁵ 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 and repealing Decisions 84/90/EEC and 90/442/EEC³⁶ specifies administrative areas in Member States related to disease control measures and disease notification.
- (30) 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 vaccines³⁷, 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.
- (31) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products³⁸ 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.

³³ OJ L 62, 15.3.1993, p. 49. Directive as last amended by Commission Decision 2001/7/EC (OJ L 2, 5.1.2001, p. 27.)

³⁴ OJ L 273, 10.10.2002, p. 1.

³⁵ OJ 121, 29.7.1964, p. 1977/64. Directive as last amended by Commission Regulation (EC) No 1226/2002 (OJ L 179, 9.7.2002, p. 13).

³⁶ OJ L 326, 22.12.2000, p. 80.

³⁷ 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).

³⁸ OJ L 311, 28.11.2001, p. 1.

- (32) 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.
- (33) 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.
- (34) 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 disease³⁹. 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 co-operation and across borders.
- (35) 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.
- (36) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field⁴⁰, 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.
- (37) In order to ensure close co-operation 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 amendments 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 States⁴¹.

³⁹ 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).

⁴⁰ 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).

⁴¹ OJ L 38, 12.2.1998, p. 10.

- (38) 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 Commission⁴².
- (39) 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.
- (40) 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 if they occur 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.

HAS ADOPTED THIS DIRECTIVE:

Chapter I

Subject matter, scope and definitions

Article 1

SUBJECT MATTER AND SCOPE

1. This Directive sets out:
 - (a) the minimum control measures to be applied in the event of an outbreak of foot-and-mouth disease of whatever type of virus;
 - (b) certain preventative measures aimed at increasing awareness and preparedness of the competent authorities and the farming community for foot-and-mouth disease.
2. Member States shall remain free to take more stringent action in the field covered by this Directive, and in particular with regard to Articles 35 and 43.

⁴² OJ L 184, 17.7.1999, p. 23.

Article 2

DEFINITIONS

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

- (a) “*animal of a susceptible species*” means any domestic or wild animal of the suborders *Ruminantia*, *Suina*, and *Tylopoda* of the order *Artiodactyla* present on a holding;
- (b) “*holding*” means any agricultural or other premises located in the national territory of a Member State where animals of susceptible species are being bred or kept on a permanent or temporary basis. However, this definition does not include living areas for humans on such premises, slaughterhouses, means of transport, border inspection posts or fenced areas where animals of susceptible species are kept and may be hunted, if such fenced areas are of a size which makes the measures provided for in Article 10 inapplicable.
- (c) “*herd*” means an animal or group of animals kept on a holding as an epidemiological unit; if more than one herd is kept on a holding, each of these herds shall form a distinct unit and shall have the same health status;
- (d) “*owner*” means any person or persons, either natural or legal, having ownership of an animal of a susceptible species, or charged with keeping such animals, whether or not for financial reward;
- (e) “*competent authority*” means the authority of a Member State competent to carry out veterinary or zootechnical checks or any authority to which it has delegated that competence;
- (f) “*official veterinarian*” means the veterinarian designated by the competent authority of the Member State;
- (g) “*authorisation*” means a written authorisation given by the competent authorities, of which the necessary copies must be available for subsequent inspections in accordance with the appropriate legislation in the Member State concerned;
- (h) “*incubation period*” means the length of the time between infection and the occurrence of clinical signs of foot-and-mouth disease, namely for the purposes of this Directive, 14 days for bovine and porcine animals, and 21 days for ovine and caprine animals and any other animal of susceptible species;
- (i) “*animal suspected of being infected*” means any animal of a susceptible species or carcass exhibiting clinical symptoms or showing post-mortem lesions or reactions to laboratory tests which are such that the presence of foot-and-mouth disease may reasonably be suspected;
- (j) “*animal suspected of being contaminated*” means any animal of a susceptible species which, according to the epidemiological information collected, may have been directly or indirectly exposed to the foot-and-mouth disease virus;

- (k) “*case of foot-and-mouth disease*” or “*animal infected with foot-and-mouth disease*” means any animal of a susceptible species or carcass of such animal in which
- clinical symptoms or post-mortem lesions consistent with foot-and-mouth disease have been officially confirmed, or
 - the presence of the foot-and- mouth disease has been officially confirmed as the result of a laboratory examination carried out in accordance with Annexes XIII and XIV.
- (l) “*outbreak of foot-and-mouth disease*” means a holding where animals of susceptible species are kept which meets one or more of the criteria set out in Annex I.
- (m) “*primary outbreak*” means the outbreak within the meaning of Article 2 (d) of Directive 82/894/EEC;
- (n) “*killing*” means the killing of animals within the meaning of Article 2 (6) of Directive 93/119/EEC;
- (o) “*slaughter*” means the slaughter within the meaning of Article 2 (7) of Directive 93/119/EEC of animals which on the basis of epidemiological data or clinical diagnosis or results of laboratory testing are not considered infected or contaminated with foot-and mouth disease virus, including slaughter for reasons of animal welfare;
- (p) “*processing*” means one of the treatments for high risk material laid down in Regulation EC No 1774/2002 of the European Parliament and the Council laying down health rules concerning animal by-products not intended for human consumption, applied in such a way as to avoid the risk of spread of foot-and-mouth disease virus;
- (q) “*regionalisation*” means the delimitation of a *restricted zone* in which restrictions are applied on the movements of or trade in certain animals or animal products as provided for in Article 45 in order to prevent the spread of foot-and-mouth disease into the *free zone* where no restrictions are applied in accordance with this Directive;
- (r) “*region*” means an area as defined in Article 2 (2) (p) of Directive 64/432/EEC;
- (s) “*sub-region*” means an area specified in the Annex to Decision 2000/807/EC;
- (t) “*Community antigen and vaccine bank*” means appropriate premises designated in accordance with this Directive for the storage of Community reserves of both concentrated inactivated antigen of the foot and mouth disease virus for the production of foot-and-mouth disease vaccines and veterinary immunological products (vaccines) reconstituted from such antigens and authorised in accordance with Directive 2001/82/EC;
- (u) “*emergency vaccination*” means vaccination in accordance with Article 50 (1);
- (v) “*protective vaccination*” means emergency vaccination carried out on holdings in a designated area in order to protect animals of susceptible species within this area against airborne spread or spread through fomites of foot-and-mouth disease virus and where the animals are intended to be kept alive following vaccination;

- (w) “*suppressive vaccination*” means emergency vaccination which is carried out exclusively in conjunction with a stamping-out policy in a holding or area where there is an urgent need to reduce the amount of foot-and-mouth disease virus circulating and to reduce the risk of it spreading beyond the perimeters of the holding or the area and where the animals are intended to be destroyed following vaccination;
- (x) “*catering waste*” means all waste food originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

Chapter II

Control of outbreaks of foot-and-mouth disease

SECTION 1

NOTIFICATION OF FOOT-AND-MOUTH DISEASE

Article 3

FOOT-AND-MOUTH DISEASE NOTIFICATION

1. Member States shall ensure that:
 - (a) foot-and-mouth disease is listed by the competent authority as a compulsorily notifiable disease;
 - (b) the owner and any person attending animals, accompanying animals during transport or looking after animals shall be obliged to notify without delay to the competent authorities or the official veterinarian the presence or suspected presence of foot-and-mouth disease and keep animals infected with foot-and-mouth disease or animals suspected of being infected, away from places where other animals of susceptible species are at risk of being infected or contaminated with the foot-and-mouth disease virus;
 - (c) veterinary practitioners, official veterinarians, senior staff of veterinary or other official or private laboratories and any person with a occupational relation to animals of susceptible species or products derived from such animals shall be obliged to notify without delay to the competent authorities any knowledge of the presence or suspected presence of foot-and-mouth disease they have obtained prior to official intervention within the framework of this Directive.
2. Without prejudice to existing Community provisions on notification of outbreaks of animal disease, the Member State on whose territory an outbreak of foot-and-mouth disease is confirmed shall give notification of the disease and provide information and written reports to the Commission and the other Member States in accordance with Annex II.

SECTION 2
MEASURES IN CASE OF SUSPICION OF AN OUTBREAK OF FOOT-AND-MOUTH DISEASE

Article 4

MEASURES IN CASE OF SUSPICION OF AN OUTBREAK OF FOOT-AND-MOUTH DISEASE

1. Member States shall ensure that the measures provided for in paragraphs 2 to 6 are carried out where a holding contains one or more animals suspected of being infected or of being contaminated.
2. The official veterinarian shall immediately activate official investigation arrangements under his supervision to confirm or rule out the presence of the foot-and-mouth disease and, in particular, take the necessary samples, or have them taken, for laboratory examination in accordance with Annex III.
3. The competent authority shall place the holding referred to in paragraph 1 under official surveillance as soon as the suspected infection is notified and shall in particular ensure that:
 - (a) a census is made of all categories of animals of susceptible species on the holding and that, in respect of each of these categories, the number of animals that are already dead and the animals suspected of being infected or of being contaminated, is recorded;
 - (b) the census as referred to in point (a) is kept up to date to take account of those animals of susceptible species born or dying during the period of suspicion and such information is produced on request by the owner and checked at each visit by the competent authorities;
 - (c) all stocks of milk, milk products, meat, meat products, carcasses, hides and skins, wool, semen, embryos, ova, slurry, manure as well as animal feed and litter on the holding are recorded and those records are maintained;
 - (d) no animals of susceptible species enter or leave the holding, except in cases of holdings consisting of different epidemiological production units referred to in Article 18, and that all animals of susceptible species on the holding are kept in their living quarters or another place where they can be isolated;
 - (e) appropriate means of disinfection are used at the entrances and exits of buildings or places housing animals of susceptible species and of the holding itself;
 - (f) an epidemiological inquiry is carried out in accordance with Article 13.

Article 5

MOVEMENTS ONTO AND OFF A HOLDING IN CASE OF SUSPICION OF AN OUTBREAK OF FOOT-AND-MOUTH DISEASE

1. Member States shall ensure that in addition to the measures provided for in Article 4, all movement onto and off a holding where there is a suspicion of an outbreak of foot-and-mouth disease is prohibited. That prohibition shall apply in particular to:
 - (a) movement from the holding of meat or carcasses, milk or milk products, semen, ova or embryos of animals of susceptible species or of animal feed, utensils, objects or other substance, such as wool, hides and skins, bristles or animal waste, slurry, manure or anything liable to transmit foot-and-mouth disease virus;
 - (b) movement of animals of species not susceptible to foot-and-mouth disease;
 - (c) movement of persons onto or out of the holding;
 - (d) movement of vehicles onto or out of the holding.
2. By way of derogation from the prohibition in point (a) of paragraph 1, the competent authorities may in the event of difficulties in storing the milk on the holding either order that the milk shall be destroyed on the holding, or authorise the milk to be transported under veterinary supervision and only by means of transport suitably equipped to ensure no risk of spreading foot-and-mouth disease virus from the holding to the nearest possible place for disposal or treatment ensuring destruction of the foot-and-mouth disease virus.
3. By way of derogation from the prohibitions provided for in points (b), (c) and (d) of paragraph 1, the competent authority may authorise such movements onto and off the holding subject to all conditions considered necessary in order to avoid the spread of foot-and-mouth disease virus.

Article 6

EXTENSION OF MEASURES TO OTHER HOLDINGS

The competent authority shall extend the measures provided for in Articles 4 and 5 to other holdings where their location, their construction and layout, or contacts with animals from the holding referred to in Article 4, give reason to suspect possible contamination.

Article 7

TEMPORARY CONTROL ZONE

1. The Competent Authority shall establish a temporary control zone, where required by the epidemiological situation, and in particular when that situation involves a high density of animals of susceptible species, intensive movement of animals or persons in contact with animals of susceptible species, delays in suspect status notifications, or insufficient information on the possible origin and ways of introduction of the foot-and-mouth disease virus.
2. The measures provided for in Articles 4 and 5 shall be applied to holdings in the temporary control zone where animals of susceptible species are kept.
3. The measures applied in the temporary control zone may be supplemented by a temporary ban on movements of all animals in a larger area or on the whole of the territory of a Member State for up to 72 hours.

Article 8

PREVENTIVE ERADICATION PROGRAMME

The competent authority may, where epidemiological information or other evidence indicates, implement a preventive eradication programme, including preventive depopulation of holdings of animals of susceptible species likely to be contaminated and, if considered necessary, of epidemiologically linked production units or adjoining holdings.

In that event, the taking of samples and clinical examinations of animals of susceptible species shall be carried out in accordance with Annex III.

The Competent Authority shall notify the Commission prior to the implementation of the measures provided for in this Article.

Article 9

MAINTENANCE OF MEASURES

Member States shall not withdraw the measures provided for in Articles 4 to 7 until the suspicion of foot-and-mouth disease has been officially ruled out.

SECTION 3
MEASURES IN CASE OF CONFIRMATION OF AN OUTBREAK OF
FOOT-AND-MOUTH DISEASE

Article 10

MEASURES IN CASE OF CONFIRMATION OF AN OUTBREAK OF FOOT-AND-MOUTH DISEASE

1. As soon as an outbreak of foot-and-mouth disease is confirmed, Member States shall ensure that, in addition to the measures provided for in Articles 4 to 6 the following measures are also applied without delay on the holding:

- (a) All animals of susceptible species on the holding shall be killed on-the-spot.

In exceptional circumstances the animals of susceptible species may be killed at the nearest suitable place for that purpose under official supervision and in such a way as to avoid the risk of spreading foot-and-mouth disease virus during transport and killing. The Member State concerned shall notify the Commission about the existence of such exceptional circumstances, and the action taken.

- (b) The official veterinarian shall ensure that before or during the killing of the animals of susceptible species all appropriate samples needed for the epidemiological inquiry referred to in Article 13 have been taken in accordance with Annex III, and in sufficient numbers.

The competent authority may decide that Article 4 (2) shall not apply in cases of appearance of a secondary source which is epidemiologically linked with a primary source for which samples have already been taken in accordance that Article, provided that appropriate and sufficient numbers of samples needed for the epidemiological inquiry referred to in Article 13 have been taken.

- (c) The carcasses of animals of susceptible species which have died on the holding and the carcasses of animals which have been killed in accordance with point (a) shall be processed without undue delay under official supervision in such a way that there is no risk of spreading foot-and-mouth disease virus. The disposal of the carcasses shall be carried out preferably by rendering in facilities approved for that purpose. Where particular circumstances require the carcasses to be buried or burned, on site or off site, such operations shall be carried out in conformity with the instructions prepared in advance in the framework of the contingency plans referred to in Article 72, and in particular in compliance with Community and National environmental and public health legislation.
 - (d) All products and substances referred to in Article 4 (3) (c) shall be treated in accordance with the instructions of the official veterinarian in such a way as to ensure the destruction of any foot-and-mouth disease virus, and disposed of in compliance with Community legislation on waste.

2. After the killing and processing of the animals of susceptible species and the destruction of the substances referred to in Article 4 (3) (c), Member States shall ensure that:
 - (a) the buildings used for housing the killed animals, their surroundings and the vehicles used for their transportation, as well as all other buildings likely to be contaminated shall be cleaned and disinfected in accordance with Article 11;
 - (b) in addition, where there is a reasonable suspicion that the living area for humans or the office area of the holding are contaminated with the foot-and-mouth disease virus, these areas shall also be disinfected by appropriate means;
 - (c) restocking of animals is carried out in accordance with Annex V.

Article 11

CLEANSING AND DISINFECTION

1. Member States shall ensure that cleansing and disinfection operations, as integral parts of the measures provided for in this Directive, are adequately documented and are carried out under official supervision and in accordance with the instructions given by the official veterinarian, using disinfectants and working concentrations of such disinfectants officially approved by the competent authority as veterinary hygiene biocidal products in accordance with Directive 98/8/EC, in order to ensure destruction of the foot-and-mouth disease virus.
2. Member States shall ensure that cleansing and disinfection operations are carried out in a way to reduce as much as possible any adverse environmental impact that may arise from such operations.
3. Member States shall endeavour to ensure that any disinfectants used, in addition to being able to disinfect effectively, also have the lowest possible adverse impacts on the environment and public health in accordance with best available technology.
4. Member States shall ensure that cleansing and disinfection operations are carried out in accordance with Annex IV.

Article 12

TRACING AND TREATMENT OF PRODUCTS AND SUBSTANCES DERIVED FROM OR HAVING BEEN IN CONTACT WITH ANIMALS OF AN OUTBREAK OF FOOT-AND-MOUTH DISEASE

Member States shall ensure that the products and substances referred to in Article 4 (3) (c) of animals of susceptible species collected from an holding where an outbreak of foot-and-mouth disease has been confirmed and semen, ova and embryos collected from animals of susceptible species present on that holding, during the period between the probable introduction of the disease to the holding and the implementation of official measures, shall be traced and processed or, in the case of substances other than semen, ova and embryos, be treated under official supervision and in such a way as to ensure destruction of foot-and-mouth disease virus and to avoid any risk of it spreading further.

Article 13

EPIDEMIOLOGICAL INQUIRY

1. Member States shall ensure that epidemiological inquiries in relation to outbreaks of foot-and-mouth disease are carried out by specifically trained veterinarians on the basis of questionnaires, prepared within the framework of the contingency plans provided for in Article 72, to ensure standardised, speedy and targeted inquiries. Such inquiries shall deal at least with:
 - (a) the length of time during which the foot-and-mouth disease may have been present on a holding before being suspected or notified;
 - (b) the possible origin of the foot-and-mouth disease virus on a holding and the identification of other holdings where there are animals suspected of being infected or animals suspected of being contaminated from the same source;
 - (c) the possible extent to which animals of susceptible species other than bovine and porcine animals may have been infected or contaminated;
 - (d) the movement of persons, vehicles and the substances referred to in Article 4 (3) (c) likely to have carried the foot-and-mouth disease virus to or from the holdings in question.
2. Member States shall inform and regularly update the Commission and the other Member States about the epidemiology and spread of the foot-and-mouth disease virus.

Article 14

ADDITIONAL MEASURES IN CASE OF CONFIRMATION OF OUTBREAKS OF FOOT-AND-MOUTH DISEASE

1. The competent authority may order that, besides the animals of susceptible species, other animals on the holding where an outbreak of foot-and-mouth disease has been confirmed shall also be killed and disposed of in such a way as to avoid any risk of spreading the foot-and-mouth disease virus and any harm to the environment.

However, the provisions of the first subparagraph shall not apply to animals of species not susceptible to foot-and-mouth disease, in particular equidae and dogs, which may be isolated, effectively cleansed and disinfected, provided that they are individually identified, in the case of equidae in accordance with Community legislation, so as to allow the control of their movement.

2. The competent authority may apply the measures provided for in Article 10 (1) (a) on epidemiologically linked production units or adjoining holdings, where epidemiological information or other evidence give reason to suspect a possible contamination of those holdings. The intention to make use of those provisions shall be notified to the Commission, where possible, prior to implementation. In this event, the measures regarding taking of samples and clinical examinations of animals shall be carried out as set out in Annex III.
3. The competent authority shall immediately upon the confirmation of the first outbreak of foot-and-mouth disease prepare all arrangements deemed necessary for emergency vaccination in an area of at least the size of the surveillance zone established in accordance with Article 21.

SECTION 4 MEASURES TO BE APPLIED IN SPECIAL CASES

Article 15

MEASURES TO BE APPLIED IN CASE OF AN OUTBREAK OF FOOT-AND-MOUTH DISEASE IN THE VICINITY OR WITHIN CERTAIN NON-FARMING PREMISES

1. Where an outbreak of foot-and-mouth disease threatens to infect animals of susceptible species in a laboratory, zoo, wildlife park, and fenced area or in bodies, institutes or centres approved in accordance with Article 13 (2) of Directive 92/65/EEC and where animals are kept for scientific purposes or purposes related to conservation of species or rare breeds, the Member State concerned shall ensure that all appropriate bio-security measures are taken to protect such animals from infection. Those measures may include restricting access to public institutions or making such access subject to special conditions.

2. Where an outbreak of foot-and-mouth disease is confirmed in one of the premises referred to in paragraph 1, the Member State concerned may decide to derogate from Article 10 (1) (a), provided that basic Community interests, and in particular the animal health status of other Member States, are not endangered and that all necessary measures are in place to prevent any risk of spreading foot-and-mouth disease virus. That decision shall immediately be notified to the Commission.

Article 16

MEASURES TO BE APPLIED IN SLAUGHTERHOUSES, BORDER INSPECTION POSTS AND MEANS OF TRANSPORTATION

1. Where an outbreak of foot-and-mouth disease is confirmed in a slaughterhouse, a border inspection post established in accordance with Directive 91/496/EEC or in a means of transport, the competent authority shall ensure that the following measures are carried out in relation to the affected premises or means of transport:
 - (a) all animals of susceptible species in such premises or means of transport are killed without delay;
 - (b) the carcasses of possibly infected and contaminated animals are disposed of under official supervision in such a way as to avoid the risk of foot-and-mouth disease virus spreading and any risk to the environment;
 - (c) other animal waste, including offal, of possibly infected and contaminated animals are disposed of under official supervision in such a way as to avoid the risk of foot-and-mouth disease virus spreading and in accordance with Community legislation on waste;
 - (d) cleansing and disinfection of buildings and equipment, including vehicles or means of transport, takes place under the supervision of the official veterinarian in accordance with Article 11 and with the instructions laid down by the competent authority;
 - (e) an epidemiological inquiry is carried out in accordance with Article 13.
2. Member States shall ensure that the measures provided for in Article 19 are applied in contact holdings.
3. Member States shall ensure that no animals are reintroduced for slaughter, inspection or transport in the premises or means of transport referred to in paragraph 1 until at least 24 hours after completion of the cleansing and disinfection operations referred to in paragraph 1 (d).

Article 17

REVIEW OF MEASURES

The Commission shall review the situation regarding the special cases referred to in Article 15 in the Standing Committee on the Food Chain and Animal Health at the earliest possible opportunity. The necessary measures to prevent the spread of the foot-and-mouth disease virus, in particular in relation to regionalisation in accordance with Article 45, and to emergency vaccination in accordance with Article 52, shall be adopted in accordance with the procedure referred to in Article 89 (3).

SECTION 5

HOLDINGS CONSISTING OF DIFFERENT EPIDEMIOLOGICAL UNITS AND CONTACT HOLDING

Article 18

HOLDINGS CONSISTING OF DIFFERENT EPIDEMIOLOGICAL PRODUCTION UNITS

1. In the case of holdings which consist of two or more separate production units, the competent authority may in exceptional cases, and after considering the risks, derogate from Article 10 (1) (a) as regards healthy production units of such holdings.
2. The derogation provided for in paragraph 1 shall only be granted after the official veterinarian has confirmed at the time of the official investigation referred to in Article 4 (2), that the following conditions to prevent the spread of foot-and-mouth disease virus between the production units referred to in paragraph 1, have been in place for at least two incubation periods prior to the date the outbreak of foot-and-mouth disease was identified on the holding:
 - (a) the structure and size of the premises allow a complete separation of housing and keeping for the animals of susceptible species, including separate air space;
 - (b) the operations on the different production units, and in particular stable and pasture management, feeding, removal of dung or manure are completely separated and carried out by different personnel;
 - (c) the machinery, equipment, installations, instruments and disinfection facilities used in the production units are completely separate.
3. In relation to milk, a derogation from Article 10 (1) (d), may be granted to a holding producing milk provided that:
 - (a) such holding complies with the conditions set out in paragraph 2;
 - (b) milking in each unit is carried out separately;

- (c) depending on the intended use, the milk is subject to at least one of the treatments described in Part A or Part B of Annex IX.
4. Where a derogation is granted in accordance with paragraph 1, Member States shall lay down in advance detailed rules for applying such derogation. The Member States shall notify the Commission of the derogation and provide details of the measures taken.

Article 19

CONTACT HOLDINGS

1. Holdings shall be recognized as contact holdings where the official veterinarian finds, or considers on the basis of confirmed data, that the foot-and-mouth disease virus may have been introduced as a result of the movement of persons, animals, products of animal origin, vehicles or in any other way either from other holdings onto a holding referred to in Articles 4 (1) or 10 (1) or from a holding referred to in Articles 4(1) or 10 (1) to other holdings.
2. Contact holdings shall be placed under official surveillance in accordance with Article 4 (3) and this surveillance shall be maintained until the suspected presence of foot-and-mouth disease virus on these contact holdings has been officially ruled out in accordance with the survey requirements provided for in Annex III.
3. The competent authority shall prohibit the removal of animals of susceptible species from contact holdings during a period corresponding to the incubation period specified for the species concerned in Article 2 (h). However, the competent authority may by way of derogation from Article 4 (3) (d) authorise the transport of animals of susceptible species under official supervision directly to a slaughterhouse for the purpose of emergency slaughter.

Prior to granting such derogation, the official veterinarian shall at least carry out the clinical examinations provided for in point 1 of Annex III.

4. Where the competent authority considers that the epidemiological situation permits, it may limit the recognition as a contact holding provided for in paragraph 1, to one identified epidemiological production unit of the holding and to the animals contained therein, provided that the epidemiological production unit complies with Article 18.
5. Where an epidemiological link between an outbreak of foot-and-mouth disease and certain non-farming premises, slaughterhouses, border inspection posts or means of transportation cannot be excluded, Member States shall ensure that the measures provided for in Articles 15 and 16 shall apply to such non-farming premises, slaughterhouses, border inspection posts or means of transportation.

Article 20

CO-ORDINATION OF MEASURES

The Commission may review the situation regarding the holdings referred to in Articles 18 and 19 in the Standing Committee on the Food Chain and Animal Health with a view to the adoption in accordance with the procedure referred to in Article 89 (3) of the necessary measures to ensure co-ordination of the measures implemented by the Member States pursuant to Articles 18 and 19.

SECTION 6

PROTECTION AND SURVEILLANCE ZONES

Article 21

ESTABLISHMENT OF PROTECTION AND SURVEILLANCE ZONES

1. Member States shall ensure that at least the measures laid down in paragraphs 2, 3 and 4 are taken immediately after an outbreak of foot-and-mouth disease is confirmed.
2. The competent authority shall establish a protection zone based on a minimum radius of 3 km and a surveillance zone based on a minimum radius of 10 km centred on the outbreak of foot-and-mouth disease referred to in paragraph 1. The geographical delimitation of those zones shall take account of administrative boundaries, natural barriers, supervision facilities and technological progress which makes it possible to predict the probable dispersion of the foot-and-mouth disease virus by air or any other means. That delimitation shall be reviewed, if necessary, in the light of such elements.
3. The competent authority shall ensure that the protection and surveillance zones are marked by posting signs of sufficient size on roads entering the zones.
4. In order to ensure full co-ordination of all measures necessary to eradicate foot-and-mouth disease as quickly as possible, national and local disease control centres as referred to in Articles 74 and 76 shall be established. For the purpose of carrying out the epidemiological inquiry as provided for in Article 13, those centres shall be assisted by an expert group as provided for in Article 78.
5. Member States shall collaborate in tracing fresh meat, meat products, raw milk and raw milk products derived from animals of susceptible species originating in the protection zone and produced between the date of estimated introduction of the foot-and-mouth disease virus until the date the measures provided for in paragraph 2 come into force. Such fresh meat, meat products, raw milk and raw milk products shall be treated in accordance with Articles 25, 26 and 27 respectively or detained until possible contamination with the foot-and-mouth disease virus is officially ruled out.

Article 22

MEASURES TO BE APPLIED TO HOLDINGS IN THE PROTECTION ZONE

1. Member States shall ensure that at least the following measures are applied in the protection zone:
 - (a) the registration of all holdings with animals of susceptible species and the establishment of a census of all animals present on these holdings shall be carried out and kept up to date;
 - (b) all holdings with animals of susceptible species shall periodically undergo a veterinary inspection, carried out in such a way as to avoid the spread of foot-and-mouth disease virus possibly present on the holdings, which shall include the inspection of general hygiene and measures to prevent the introduction or escape of foot-and-mouth disease virus ;
 - (c) animals of susceptible species shall not be removed from the holding on which they are kept.
2. By way of derogation from paragraph 1 (c), animals of susceptible species may be transported directly under official supervision for the purpose of emergency slaughter to a slaughterhouse situated inside the same protection zone or, if that zone has no slaughterhouse to a slaughterhouse outside the zone designated by the competent authority.

Movement shall be authorised by the competent authority only after an examination by the official veterinarian of all the animals of susceptible species present on the holding has ruled out the presence of animals suspected of being infected or animals suspected of being contaminated. The meat of such animals shall be subject to the measures provided for in Article 25.

Article 23

GATHERINGS AND MOVEMENT IN THE PROTECTION ZONE

Member States shall ensure that the following activities are prohibited within the protection zone:

- (a) fairs, markets, shows and other gatherings of animals of susceptible species, including collection and distribution;
- (b) itinerant service for breeding of animals of susceptible species;
- (c) artificial insemination of animals of susceptible species except the artificial insemination carried out by a farmer with semen from animals on his holding.

Article 24

TRANSPORT OF ANIMALS IN THE PROTECTION ZONE

1. Member States shall ensure that in the protection zone, the transport of animals of susceptible species shall be prohibited. The competent authority may extend such prohibition to:
 - (a) transport of animals of non-susceptible species out of or into the protection zone, taking into account the restrictions on the transport of equidae set out in point 4 of Annex VI;
 - (b) transit of animals of all species through the protection zone;
 - (c) events with gatherings of people with possible contact with animals of susceptible species, where there is a risk of spreading the foot-and-mouth disease virus.
2. The competent authorities may derogate from the prohibitions in paragraph 1 for:
 - (a) transit of animals of all species through the protection zone undertaken exclusively via major highways or mainline railways;
 - (b) animals of susceptible species which have been certified by the official veterinarian as coming from holdings outside the restricted zones and transported on designated routes directly to designated slaughterhouses for immediate slaughter, provided that the means of transport are cleansed and disinfected after delivery under veterinary supervision at the slaughterhouse and such decontamination of transport is recorded in the logbook of the means of transport.

Article 25

MEASURES IN RELATION TO FRESH MEAT PRODUCED IN THE PROTECTION ZONE

1. Member States shall ensure that the placing on the market of fresh meat, minced meat and meat preparations, derived from animals of susceptible species originating in the protection zone shall be prohibited.
2. Member States shall ensure that the placing on the market of fresh meat, minced meat and meat preparations from animals of susceptible species produced in the protection zone shall be prohibited.
3. Member States shall ensure that fresh meat, minced meat and meat preparations as referred to in paragraph 1, shall be marked in accordance with Article 5a of Council Directive 72/461/EEC (cross-stamp) and subsequently transported in sealed containers to an establishment designated by the competent authorities for transformation into meat products treated in accordance with Annex VII.

4. By way of derogation, the prohibition provided for in paragraph 1 shall not apply to fresh meat, minced meat and meat preparations which were produced on a date at least 21 days before the estimated date of infection on the holding recorded as the primary outbreak and which since production have been stored and transported separately from such meats produced after that date. Such meats must be readily distinguished from meats not eligible for dispatch outside the protection zone by means of clear mark established in conformity with Community law.
5. By way of derogation, the prohibition provided for in paragraph 2, shall not apply to fresh meat, minced meat or meat preparations obtained from establishments situated in the protection zone under the following conditions:
 - (a) the establishment shall be operated under strict veterinary control;
 - (b) only fresh meat, minced meat or meat preparations as described in paragraph 4, or fresh meat, minced meat or meat preparations obtained from animals reared and slaughtered outside the protection zone shall be processed in the establishment;
 - (c) all such fresh meat, minced meat or meat preparations must bear the health mark in accordance with Chapter XI of Annex I to Directive 64/433/EEC or in the case of meat from other biungulates the health mark provided for in Chapter III of Annex I to Directive 91/495/EEC, or in the case of minced meat and meat preparations the health mark as provided for in Chapter VI of Annex I to Directive 95/65/EC;
 - (d) all such fresh meat, minced meat or meat preparations must be clearly identified, and transported and stored separately from fresh meat, minced meat or meat preparations which are not eligible for dispatch outside the protection zone in accordance with this Directive.
6. Compliance with the conditions in paragraph 5 shall be certified by the competent authority for fresh meat, minced meat and meat preparations intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authority and in the case of intra-Community trade communicate to other Member States and the Commission a list of those establishments which it has approved for the purpose of such certification.

Article 26

MEASURES IN RELATION TO MEAT PRODUCTS PRODUCED IN THE PROTECTION ZONE

Member States shall ensure that the placing on the market of meat products produced from meat derived from animals of susceptible species originating in the protection zone shall be prohibited.

By way of derogation, this prohibition shall not apply to meat products which have undergone one of the treatments as set out in Annex VII.

Article 27

MEASURES IN RELATION TO MILK AND MILK PRODUCTS PRODUCED IN THE PROTECTION ZONE

1. Member States shall ensure that the placing on the market of milk derived from animals of susceptible species originating in the protection zone and of milk products produced from such milk shall be prohibited.
2. Member States shall ensure that the placing on the market of milk and milk products from animals of susceptible species produced in the protection zone shall be prohibited.
3. By way of derogation, the prohibition provided for in paragraph 1 shall not apply to milk derived from animals of susceptible species originating in the protection zone and milk products produced from such milk which have undergone one of the treatments as set out in Parts A or B of Annex IX depending on the use of the milk or milk products. The treatment shall be carried out under the conditions set out in paragraph 5 in establishments referred to in paragraph 4 or, if there is no establishment situated in the protection zone, in establishments in the surveillance zone designated by the competent authorities.
4. By way of derogation, the prohibition provided for in paragraph 2 shall not apply to milk and milk products which have been prepared in establishments situated in the protection zone under the conditions set out in paragraph 5.
5. Establishments referred to in paragraphs 3 and 4 shall comply with the following conditions:
 - (a) the establishment shall be operated under strict veterinary control;
 - (b) all milk used in the establishment shall either comply with paragraph 3 or be obtained from animals outside the protection zone;
 - (c) the milk shall be clearly identified and transported and stored separately from milk and milk products which are not destined for dispatch outside the protection zone;
 - (d) transport of raw milk from holdings situated outside the protection zone to the establishments shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, and which have had no subsequent contact with holdings in the protection zone keeping animals of susceptible species.
6. Compliance with the conditions in paragraph 5 shall be certified by the competent authority for milk intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authority and in the case of intra-Community trade communicate to other Member States and the Commission a list of those establishments which it has approved for the purpose of such certification.

Article 28

MEASURES IN RELATION TO SEMEN, OVA AND EMBRYOS COLLECTED FROM ANIMALS OF SUSCEPTIBLE SPECIES IN THE PROTECTION ZONE

1. Member States shall ensure that the placing on the market of semen, ova and embryos derived from animals of susceptible species originating in the protection zone shall be prohibited.
2. By way of derogation, the prohibition provided for in paragraph 1 shall not apply to frozen semen, ova and embryos collected and stored at least 14 days before the estimated date of infection with the foot-and-mouth disease virus on the holding referred to in Article 10 (1), taking into account the length of the incubation period.
3. Frozen semen collected in accordance with Community legislation after the date of infection referred to in paragraph 2, shall be stored separately and shall only be released after:
 - (a) all the measures relating to the outbreak of foot-and-mouth disease have been removed in accordance with Article 36, and
 - (b) all animals accommodated in the semen collection centre have undergone a clinical examination and, in the case of animals of susceptible species other than bovine and porcine animals, a serological test to substantiate the absence of infection in the semen collection centre concerned.

Article 29

TRANSPORT AND DISTRIBUTION OF DUNG AND MANURE OF ANIMALS OF SUSCEPTIBLE SPECIES PRODUCED IN THE PROTECTION ZONE

Member States shall ensure that the transport and distribution of dung or manure from holdings situated in the protection zone where animals of susceptible species are kept, shall be prohibited within the protection zone.

Article 30

MEASURES IN RELATION TO HIDES AND SKINS FROM ANIMALS OF SUSCEPTIBLE SPECIES IN THE PROTECTION ZONE

1. Member States shall ensure that the placing on the market of hides and skins of animals of susceptible species originating in the protection zone shall be prohibited.

2. By way of derogation, the prohibition as provided for in paragraph 1 shall not apply to hides and skins which either:
 - (a) were produced at least 14 days before the estimated date of infection on the holding referred to in Article 10 (1), taking into account the length of the incubation period and that have been stored separately from hides and skins produced after that date; or
 - (b) comply with the requirements laid down in paragraph 2 (c) or (d) of Chapter VI of Annex VIII to Regulation (EC) No 1774/2002.

Article 31

MEASURES IN RELATION TO SHEEP WOOL, RUMINANT HAIR AND PIG BRISTLS PRODUCED IN THE PROTECTION ZONE

1. Member States shall ensure that the placing on the market of sheep wool, ruminant hair and pigs bristles originating in the protection zone shall be prohibited.
2. By way of derogation, the prohibition as provided for in paragraph 1 shall not apply to untreated wool, hair and bristles which:
 - (a) were produced at least 14 days before the estimated date of infection on the holding referred to in Article 10 (1), taking into account the length of incubation period and have been stored separately from wool, hair and bristles produced after that date; or
 - (b) have undergone factory washing or have been obtained from tanning and are securely enclosed and dry.

Article 32

MEASURES IN RELATION TO OTHER ANIMAL PRODUCTS PRODUCED IN THE PROTECTION ZONE

1. Member States shall ensure that the placing on the market of animal products of the bovine, ovine, caprine and porcine species and other biungulates not referred to in Articles 25 to 31 shall be prohibited.
2. By way of derogation, the prohibitions provided for in paragraph 1 shall not apply to:
 - (a) animal products referred to in paragraph 1 which have undergone:
 - (i) a heat treatment in a hermetically sealed container with a Fo value of 3,00 or more; or
 - (ii) a heat treatment in which the centre temperature is raised to at least 70 °C for at least 60 minutes;

- (b) blood and blood products of animals of susceptible species used for technical purposes, including pharmaceuticals, *in vitro* diagnostics and laboratory reagents which have undergone at least one of the treatments referred to in point B (3) (e) (ii) of Chapter IV of Annex VIII to Regulation (EC) No 1774/2002.
- (c) lard and rendered fats which have undergone the heat treatment referred to in point B (2) (d) (iv) of Chapter IV of Annex VII to Regulation (EC) No 1774/2002;
- (d) petfood and dogchews which comply with the requirements of points B (2), (3) or (4) of Chapter II of Annex VIII to Regulation (EC) No 1774/2002;
- (e) game trophies of ungulates having undergone a complete taxidermy treatment ensuring their preservation at ambient temperatures;
- (f) animal casings which in accordance with Chapter 2 of Annex I to Directive 92/118/EEC have been cleaned, scraped and either salted with sodium-chloride for 30 days or bleached or dried after scraping and were protected from re-contamination after treatment;
- (g) composite products which are not subject to further treatment containing products of animal origin which either have undergone a treatment ensuring destruction of possible foot-and-mouth disease virus or have been obtained from animals not subject to restrictions under the provisions of this Directive;
- (h) packed products intended for use as in-vitro diagnostic or laboratory reagents.

Article 33

MEASURES IN RELATION TO FEED, FORAGE, HAY AND STRAW PRODUCED IN THE PROTECTION ZONE

1. Member State shall ensure that the placing on the market of feed, forage, hay and straw originating in the protection zone shall be prohibited.
2. By way of derogation, the prohibition provided for in paragraph 1 shall not apply to feed, forage, hay and straw:
 - (a) produced at least 14 days before the estimated date of infection on the holding referred to in Article 10 (1), taking into account the length of the incubation period, and stored and transported separately from feed, forage, hay and straw produced after that date; or
 - (b) intended for use within the protection zone, subject to authorisation by the competent authorities.

3. By way of derogation, the prohibition provided for in paragraph 1 shall not apply to forage and straw, if
 - (a) it has undergone the action of steam in a closed chamber for at least 10 minutes and at a minimum temperature of 80°C, or
 - (b) it has undergone the action of formalin fumes (formaldehyde gas) produced in a chamber kept closed for at least 8 hours and at a minimum temperature of 19°C, using commercial-type solutions at 35-40% concentration, or
 - (c) it has been stored in package or bales under shelter at premises situated not closer than 2 km to the nearest outbreak of foot-and-mouth disease and is not released from the protection zone before at least three months have elapsed following the completion of cleansing and disinfection measures provided for in Article 11.

Article 34

GRANTING OF DEROGATIONS AND ADDITIONAL CERTIFICATION

Any derogation from the prohibitions provided for in Articles 25 to 33 shall be granted by a specific decision of the competent authority only after it has satisfied itself that all relevant requirements have been met for a sufficient period before the products leave the protection zone, and that there is no risk of spreading the foot-and-mouth disease virus.

Any derogation from the prohibitions provided for in Articles 25 to 33 requires in the case of intra-Community trade additional certification by the competent authority.

Article 35

ADDITIONAL MEASURES APPLIED BY MEMBER STATES IN THE PROTECTION ZONE

In addition to the measures applicable in the protection zone in accordance with this Directive, Member States may take additional national measures which are deemed necessary and proportionate to contain the foot-and-mouth disease virus taking into account the particular epidemiological, animal husbandry, commercial and social conditions prevailing in the affected area.

Article 36

REMOVAL OF MEASURES IN THE PROTECTION ZONE

1. Member states shall ensure that the measures applied in the protection zone are maintained until the following requirements have been met:
 - (a) at least 15 days have elapsed since the killing and safe disposal of all the animals of susceptible species from the holding referred to in Article 10 (1) and the completion of the preliminary cleansing and disinfection on that holding, carried out in accordance with Article 11,

- (b) a survey has been concluded with negative results in all holdings keeping animals of susceptible species and situated within the protection zone,
2. After the removal of the measures specific to the protection zone, the measures applied in the surveillance zone as provided for in Articles 37 to 42, shall continue to apply for at least 15 days until those measures are removed in accordance with Article 44.
3. The survey referred to in paragraph 1 (b) shall be carried out in compliance with the criteria of point 1 of Annex III and may, where required by the epidemiological situation and based on the criteria set out in point 2.1 of Annex III, include the measures provided for in point 2.3 of Annex III.

Article 37

MEASURES TO BE APPLIED TO HOLDINGS IN THE SURVEILLANCE ZONE

1. Member States shall ensure that the measures provided for in Article 22 (1) are applied in the surveillance zone.
2. By way of derogation from the prohibition provided for in Article 22 (1) (c), the competent authorities may authorize the removal from the surveillance zone of animals of susceptible species for transporting them directly and under official supervision for the purpose of emergency slaughter to a slaughterhouse located outside the surveillance zone and designated by the competent authority. Such slaughterhouse to be located as near to the surveillance zone as possible, and this derogation shall only be used where there is no or insufficient slaughter capacity available within the surveillance zone. The meat produced from such animals shall be subject to the treatment specified in Article 39.

Article 38

MOVEMENT OF ANIMALS OF SUSCEPTIBLE SPECIES WITHIN THE SURVEILLANCE ZONE

1. Member States shall ensure that animals of susceptible species shall not move within the surveillance zone.
2. By way of derogation, the prohibition provided for in paragraph 1 shall not apply to movement of animals for one of the following purposes:
 - (a) for leading them to pasture not earlier than 15 days after the last outbreak of foot-and-mouth disease has been recorded in the protection zone;
 - (b) for transporting them directly and under official supervision for the purpose of emergency slaughter either to a slaughterhouse located inside the same zone , or in accordance with Article 37 (2).

3. Movements of animals provided for in paragraph 2 (a) and (b) shall be authorised by the competent authority only after an examination by an official veterinarian of all the animals of susceptible species on the holding has ruled out the presence of animals suspected of being infected or animals suspected of being contaminated.

Article 39

MEASURES TO BE APPLIED TO FRESH MEAT OF ANIMALS OF SUSCEPTIBLE SPECIES ORIGINATING IN THE SURVEILLANCE ZONE AND MEAT PRODUCTS PRODUCED FROM SUCH MEAT

1. Member States shall prohibit the placing on the market of fresh meat, minced meat and meat preparations derived from animals of susceptible species originating in the surveillance zone and of meat products produced from such meats unless:
 - (a) the fresh meat complies with Annex VIII and minced meat and meat preparations are produced from fresh meat complying with Annex VIII;
 - (b) the meat products comply with Annex VII.
2. Derogation from the prohibition provided for in paragraph 1 may be granted subject to specific conditions adopted in accordance with the procedure referred to in Article 89 (3), in particular with regard to the health marking of meat produced from animals of susceptible species originating in surveillance zones maintained for more than 30 days.

Article 40

MEASURES TO BE APPLIED TO MILK AND MILK PRODUCTS OF ANIMALS OF SUSCEPTIBLE SPECIES PRODUCED IN THE SURVEILLANCE ZONE

1. Member States shall ensure that placing on the market of milk derived from animals of susceptible species originating in the surveillance zone and of milk products produced from such milk shall be prohibited.
2. Member States shall ensure that the placing on the market of milk and milk products from animals of susceptible species produced in the surveillance zone shall be prohibited.
3. By way of derogation, the prohibition provided for in paragraph 1 shall not apply to milk derived from animals of susceptible species originating in the surveillance zone and milk products produced from such milk which have undergone one of the treatments as set out in Parts A or B of Annex IX depending on the use of the milk or milk products. The treatment shall be carried out under the condition set out in paragraph 5 in establishments referred to in paragraph 4 or, if there is no establishment situated in the surveillance zone, in establishments designated by the competent authorities and situated outside the protection and surveillance zone.
4. By way of derogation, the prohibition provided for in paragraph 2 shall not apply to milk and milk products which have been prepared in establishments situated in the surveillance zone under the conditions set out in paragraph 5.

5. Establishments referred to in paragraphs 3 and 4 shall comply with the following conditions:
 - (a) the establishment shall be operated under strict veterinary control;
 - (b) all milk used in the establishment shall either comply with paragraph 3 or be obtained from animals outside the surveillance and protection zone;
 - (c) the milk shall be clearly identified and transported and stored separately from milk and milk products which are not destined for dispatch outside the surveillance zone;
 - (d) transport of raw milk from holdings situated outside the protection and surveillance zone to the establishments shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, and which have had no subsequent contact with holdings in the protection and surveillance zone keeping animals of susceptible species.
6. Compliance with the conditions in paragraph 5 shall be certified by the competent authority for milk intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authority and in the case of intra-Community trade communicate to other Member States and the Commission a list of those establishments which it has approved for the purpose of such certification.

Article 41

TRANSPORT AND DISTRIBUTION OF DUNG AND MANURE OF ANIMALS OF SUSCEPTIBLE SPECIES PRODUCED IN THE SURVEILLANCE ZONE

1. Member States shall ensure that the transport and distribution of dung or manure from holdings situated in the surveillance zone where animals of susceptible species are kept shall be prohibited within that zone.
2. By way of derogation from the prohibition provided for in paragraph 1 the competent authorities may in exceptional circumstances authorise the transport of dung or manure for distribution in designated areas within the surveillance zone and preferably at sufficient distance to holdings where animals of susceptible species are kept under the following conditions:
 - (a) an examination by an official veterinarian of all the animals of susceptible species on the holding has ruled out the presence of animals suspected of being infected or animals suspected of being contaminated with the foot-and-mouth disease virus;
 - (b) the manure is distributed close to the ground to avoid the generation of aerosols;
 - (c) the dung or manure is immediately ploughed into the ground;
 - (d) the means of transport used are thoroughly cleansed and disinfected prior to and after use.

Article 42

MEASURES IN RELATION TO OTHER ANIMAL PRODUCTS PRODUCED IN THE SURVEILLANCE ZONE

Member State shall ensure that the placing on the market of products of animal origin other than those referred to in Articles 39 to 41 shall be subject to the conditions provided for in Articles 30 to 32.

Article 43

ADDITIONAL MEASURES APPLIED BY MEMBER STATES IN THE SURVEILLANCE ZONE

In addition to the measures provided for in Articles 37 to 42, Member States may take additional national measures which are deemed necessary and proportionate to contain foot-and-mouth disease virus taking into account the particular epidemiological, animal husbandry, commercial and social conditions prevailing in the affected area. Where specific measures to restrict the movement of equidae are considered necessary, such measures shall not exceed those provided for in Annex VI.

Article 44

REMOVAL OF MEASURES IN THE SURVEILLANCE ZONE

1. Member states shall ensure that the measures applied in the surveillance zone are maintained until the following requirements have been met:
 - (a) at least 30 days have elapsed since the killing and safe disposal of all animals of susceptible species from the holding referred to in Article 10 (1) and the completion of the preliminary cleansing and disinfection on that holding, carried out in accordance with Article 11;
 - (b) the requirements provided for in Article 36 have been met in the protection zone,
 - (c) a clinical and a serological survey have been concluded with negative results.
2. The surveys referred to in paragraph 1 (c) shall be carried out in compliance with the criteria of point 1 of Annex III and may, where required by the epidemiological situation and based on the criteria of point 2.1. of Annex III, include the measures provided for in point 2.4 of Annex III.

SECTION 7
REGIONALISATION, MOVEMENT CONTROL AND IDENTIFICATION

Article 45

REGIONALISATION

1. Without prejudice to Directive 90/425/EC, and in particular Article 10 thereof, where the foot-and-mouth disease virus appears to be spreading despite the measures taken in accordance with this Directive and the epizootic becomes extensive and in any case when emergency vaccination is implemented, Member States shall ensure that their territory is regionalised into one or more restricted zones and a free zone.
2. Member States shall notify to the Commission without delay the details of the measures implemented in the restricted zone and the Commission shall review, where necessary amend, and endorse the measures in accordance with the procedure referred to in Article 89 (3).
3. Without prejudice to the obligation of Member States to regionalise referred to in paragraph 1, regionalisation, and the measures to be applied within the restricted zone, may be decided in accordance with the procedure referred to in Article 89 (3). This decision may extent its effects to neighbouring Member States not infected at the time the measures are taken.
4. Prior to the delimitation of the restricted zone, a thorough epidemiological assessment of the situation shall be carried out, especially with respect to the possible time and probable location of introduction, the possible spread and the probable period of time necessary to eradicate the foot-and-mouth disease virus.
5. For the purpose of delimitation the restricted zone shall as far as possible be delimited on the basis of administrative boundaries rather than geographical barriers. Regionalisation shall take as its starting point larger administrative units rather than regions. The restricted zone may be reduced in the light of the results of the epidemiological inquiry provided for in Article 13, to an area of the size not less than a sub-region, and where necessary the surrounding sub-regions. In the event of the foot-and-mouth disease virus spreading, additional regions or sub-regions shall be included.

Article 46

MEASURES APPLIED IN A RESTRICTED ZONE OF A MEMBER STATE

1. Where regionalisation is applied, Member States shall ensure that at least the following measures are taken:
 - (a) control within the restricted zone of trade and movement of animals, animal products and goods and of the movement of means of transport as potential carriers of foot-and-mouth disease virus;

- (b) tracing and marking in accordance with Community legislation of all products in stock not eligible for dispatch outside the restricted zone;
 - (c) specific certification of animals of susceptible species and products derived from such animals and health marking in accordance with Community legislation of products for human consumption intended and eligible for dispatch outside the restricted zone.
2. Where regionalisation is applied, Member States shall ensure that movements of animals of susceptible species dispatched from the restricted zone during the time between the date of estimated introduction of the foot-and-mouth disease virus until the date regionalisation is implemented shall be traced, and such animals shall be isolated under official veterinary control until possible infection or contamination is officially ruled out.
 3. Member States shall collaborate in tracing fresh meat and raw milk and raw milk products derived from animals of susceptible species produced in the restricted zone between the date of estimated introduction of the foot-and-mouth disease virus until the date regionalisation comes into force. Such fresh meat, raw milk and milk products shall be treated in accordance with Annexes VII and IX or detained until possible contamination with the foot-and-mouth disease virus is officially ruled out.

Article 47

IDENTIFICATION OF ANIMALS OF SUSCEPTIBLE SPECIES

1. Without prejudice to Community legislation on identification of domestic bovine, ovine and caprine animals and swine, Member States shall ensure that in the event of an outbreak of foot-and-mouth disease on their territory animals of susceptible species shall only leave the holding on which they are kept, if they are identified in such a way as to enable the competent authorities to trace rapidly their movements and their holding of origin, or any holding from which they have come. However, for special cases referred to in Article 15 (1) and Article 16 (1), the competent authority may, in certain circumstances and having regard to the health situation, authorise other ways of rapidly tracing the movement of those animals and of their holding of origin, or of any holding from which they have come. The arrangements for identifying such animals or for tracing their holdings of origin shall be determined by the competent authority and notified to the Commission.
2. The measures taken by Member States on additional identification or marking of animals for the particular purpose of control of the foot-and-mouth disease, and in particular in case of vaccination carried out in accordance with Articles 52 and 53, may be modified in accordance with the procedure referred to in Article 89 (3).

Article 48

MOVEMENT CONTROL IN CASE OF AN OUTBREAK OF FOOT-AND-MOUTH DISEASE

Member States shall ensure that in the event of an outbreak of foot-and-mouth disease on their territory the following measures to control movement of animals of susceptible species are applied:

- (a) owners shall supply the competent authority, on request of that authority, with appropriate information concerning animals entering or leaving their holding. That information shall include at least the details required by Article 14 of Directive 64/432/EEC;
- (b) persons engaged in the transport or marketing of animals of susceptible species shall supply the competent authority, on request of that authority, with appropriate information concerning the movements of such animals which they have transported or marketed. That information shall include at least the details required by Articles 12 (2) and 13 (1) (b) of Directive 64/432/EEC.

**SECTION 8
VACCINATION**

Article 49

USE, MANUFACTURE, SALES AND CONTROLS OF FOOT-AND-MOUTH DISEASE VACCINES

Member States shall ensure that:

- (a) the use of foot-and-mouth disease vaccines is prohibited on their territory except as provided for in this Directive;
- (b) the production, storage, supply, distribution and sale of foot-and-mouth disease vaccines on their territory are carried out under official control;
- (c) the marketing of foot-and-mouth disease vaccines is under the supervision of the competent authorities in accordance with Community legislation;
- (d) the use of foot-and-mouth disease vaccines for purposes other than to induce active immunity in animals of susceptible species, notably laboratory investigations, is authorized by the competent authorities and carried out under appropriate bio-security conditions.

Article 50

DECISION ON INTRODUCING EMERGENCY VACCINATION

1. It may be decided to introduce emergency vaccination where at least one of the following conditions applies:
 - (a) outbreaks of foot-and-mouth disease have been confirmed and threaten to become widespread in the Member State where such outbreaks have been confirmed;
 - (b) other Member States are at risk due to the geographical situation of or the prevailing meteorological conditions in relation to reported outbreaks of foot-and-mouth disease in a Member State;
 - (c) other Member States are at risk due to epidemiologically relevant contacts between holdings on their territories and holdings keeping animals of susceptible species in a Member States where there are outbreaks of foot-and-mouth disease;
 - (d) Member States are at risk due to the geographical situation or the prevailing meteorological conditions in a neighbouring third country where there are outbreaks of foot-and-mouth disease;
2. When deciding on the introduction of emergency vaccination, consideration shall be given to the measures provided for in Article 15 and to the criteria listed in Annex X.
3. The decision to introduce emergency vaccination shall be adopted in accordance with the procedure referred to in Article 89 (3), either on request of the Member State directly affected or at risk, or on the Commission's own initiative.
4. By way of derogation from paragraph 3, the decision to introduce emergency vaccination may be taken by the Member State concerned and implemented in accordance with this Directive, after a written notification to the Commission which shall include the specifications provided for in Article 51.
5. If a Member State introduces emergency vaccination in accordance with paragraph 4, that decision shall be immediately reviewed in the Standing Committee on the Food Chain and Animal Health and Community measures shall be adopted in accordance with the procedure referred to in Article 89 (3).

Article 51

CONDITIONS FOR EMERGENCY VACCINATION

1. The decision to introduce emergency vaccination in accordance with Article 50 (3) and (4) shall specify the conditions under which such vaccination shall be carried out and these conditions must specify at least:
 - (a) the delimitation in accordance with Article 45 of the geographical area in which emergency vaccination is to be carried out;
 - (b) the species and the age of the animals to be vaccinated;
 - (c) the duration of the vaccination campaign;
 - (d) a specific prohibition on movements of vaccinated and non-vaccinated animals of susceptible species and their products;
 - (e) the special identification and special registration of the vaccinated animals pursuant to Article 47;
 - (f) other matters appropriate to the emergency situation.
2. The conditions for emergency vaccination as provided for in paragraph 1, shall ensure that such vaccination is carried out in accordance with Article 52, irrespective of whether the vaccinated animals are subsequently killed and disposed of or stay alive.

Article 52

PROTECTIVE VACCINATION

1. Member States applying protective vaccination shall ensure that:
 - (a) the vaccination zone shall be regionalised in accordance with Article 45, and where necessary in close co-operation with neighbouring Member States;
 - (b) vaccination shall be carried out swiftly and in conformity with principle rules of hygiene and bio-security so as to avoid possible spread of foot-and-mouth disease virus;
 - (c) all measures applied in the vaccination zone shall be carried out without prejudice to the measures provided for in Section 7;

- (d) where the vaccination zone includes parts of or the entire protection or surveillance zone:
 - (i) the measures applicable for the protection zone or surveillance zone in accordance with this Directive shall be maintained within that part of the vaccination zone until such measures have been removed in accordance with Article 36 or Article 44;
 - (ii) after the measures applied in the protection zone and surveillance zone have been removed, the measures applicable for the vaccination zone as provided for in Articles 54 to 58 shall continue to apply.
2. Member States applying protective vaccination shall ensure that the vaccination zone is surrounded by a surveillance area (surveillance zone as defined by the Office International des Epizooties) of at least 10 km width from the perimeters of the vaccination zone
- (a) in which vaccination is prohibited;
 - (b) in which intensified surveillance is carried out;
 - (c) in which the movement of animals of susceptible species is subject to controls by the competent authorities;
 - (d) which remains in place until the foot-and-mouth disease and infection free status is recovered in accordance with Article 61.

Article 53

SUPPRESSIVE VACCINATION

1. Member States shall notify the Commission if they decide to introduce suppressive vaccination and shall provide details of the control measures to be taken which shall include at least those provided for in Article 21.
2. Member States shall ensure that suppressive vaccination is carried out as follows:
 - (a) only within a protection zone;
 - (b) only on clearly identified holdings subject to the measures provided for in Article 10 (1).

However, for logistical reasons and by way of derogation from Article 10 (1) (a), the killing of all animals on such holdings may be delayed as long as necessary to comply with Directive 93/119/EEC and the provisions of Article 10 (1) (c) of this Directive;

Article 54

MEASURES APPLICABLE IN THE VACCINATION ZONE DURING THE PERIOD FROM THE BEGINNING OF EMERGENCY VACCINATION UNTIL AT LEAST 30 DAYS HAVE ELAPSED FOLLOWING THE COMPLETION OF SUCH VACCINATION (PHASE 1)

1. Member States shall ensure that the measures provided for in paragraphs 2 to 6 are applied in the vaccination zone during the period from the beginning of the emergency vaccination until at least 30 days have elapsed following the completion of such vaccination.
2. Movement of live animals of susceptible species shall be prohibited within and out of the vaccination zone.

By way of derogation from the prohibition provided for in the first subparagraph, and after clinical inspection of such live animals and the herds of origin or dispatch of those animals, the competent authorities may authorise their direct transport for immediate slaughter in a slaughterhouse designated by the competent authority and situated within the vaccination zone or in exceptional cases close to that zone.

3. Fresh meat produced from vaccinated animals slaughtered during the period referred to in paragraph 1 shall:
 - (a) bear the cross stamp provided for in Article 5a of Directive 72/461/EEC;
 - (b) be stored and transported separately from meat not bearing a cross stamp referred to in point (a), and shall subsequently be transported in sealed containers to an establishment designated by the competent authorities for treatment in accordance with Annex VII.
4. Milk and milk products produced from vaccinated animals may be placed on the market within or outside the vaccination zone, provided that such milk and milk products have undergone at least one of the treatments specified in Parts A or B of Annex IX depending on the intended use.
5. The collection of semen for artificial insemination from male animals kept in semen collection centres situated within the vaccination zone shall be suspended.

By way of derogation from the prohibition provided for in the first subparagraph, the competent authorities may authorise the collection of semen at semen collection centres within the vaccination zone for the production of frozen semen, subject to the following conditions:

- (a) it is ensured that the semen collected during the period referred to in paragraph 1 is stored separately for at least 30 days;
- (b) prior to dispatch of the semen:
 - (i) the donor males have been vaccinated following a negative test for antibodies against foot-and-mouth disease virus carried out prior to vaccination;

- (ii) a negative result has been achieved in a virus isolation test or an approved test for the detection of antibody against non-structural proteins, carried out at the end of the quarantine period for the semen on samples taken from all animals of susceptible species present at that time on the semen collection centre;
 - (iii) the semen complies with the conditions of Article 4 (3) of Chapter II of Directive 88/407/EEC.
6. Collection of ova and embryos from donor females shall be prohibited.

Article 55

MEASURES APPLICABLE IN THE VACCINATION ZONE DURING THE PERIOD FROM EMERGENCY VACCINATION UNTIL THE SURVEY AND THE CLASSIFICATION OF HOLDINGS ARE COMPLETED (PHASE 2)

1. Member States shall ensure that the measures provided for in paragraphs 2 to 5 are applied in the vaccination zone during a period starting not earlier than 30 days from the date of completion of emergency vaccination and terminating with the completion of the measures provided for in Articles 56 and 57.
2. Movement of animals of susceptible species within and out of the vaccination zone shall be prohibited.
3. By way of derogation from the prohibition provided for in paragraph 2, the competent authorities may authorise direct transport for immediate slaughter of animals of susceptible species from holdings referred to in Article 57 (4) to a slaughterhouse situated within or out of the vaccination zone on the following conditions:
 - (a) during transport those animals shall not come into contact with other animals of susceptible species;
 - (b) the animals shall be accompanied by an official document certifying that all animals of susceptible species on the holding of origin or dispatch have undergone a survey as provided for in Article 56 (2);
 - (c) the transport vehicles shall be cleansed and disinfected before loading and after the animals have been delivered, with the date and time of the cleaning and disinfection being recorded in the logbook of the means of transport;
 - (d) the animals shall have passed the ante-mortem health inspection at the slaughterhouse during the 24 hours before slaughter and have in particular undergone examination for mouth and feet disease and not shown signs of that disease.
4. Fresh meat, excluding offal, produced from vaccinated large and small ruminants during the period referred to in paragraph 1, may be placed on the market within and outside the vaccination zone under the following conditions:

- (a) the establishment shall be operated under strict veterinary control;
 - (b) only fresh meat, excluding offal, which was subjected to the treatment described in Annex VIII or fresh meat obtained from animals reared and slaughtered outside the vaccination zone shall be processed in the establishment;
 - (c) all such fresh meat shall bear the health mark in accordance with Chapter XI of Annex I to Directive 64/433/EEC or in the case of meat from other biungulates the health mark provided for in Chapter III of Annex I of Directive 91/495/EEC, or in the case of minced meat and meat preparations the health mark provided for in Chapter VI of Annex I of Directive 94/65/EC;
 - (d) the fresh meat shall be clearly identified, and transported and stored separately from meat which is not eligible for dispatch outside the zone in accordance with this Directive.
5. Compliance with the conditions in paragraph 4 shall be certified by the competent authority for fresh meat intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authorities and in the case of intra-Community trade communicate to other Member States and the Commission a list of those establishments which it has approved for the purpose of such certification.
6. Fresh meat produced from vaccinated porcine animals slaughtered during the period referred to in paragraph 1 shall bear the stamp provided for in Article 5a of Directive 72/461/EEC (cross stamp) and shall be stored and transported separately from meat not bearing that stamp and subsequently be transported in sealed containers to an establishment designated by the competent authorities for treatment in accordance with Annex VII.
7. Milk and milk products produced from vaccinated animals may be placed on the market within or outside the vaccination zone, provided that depending on the final use for either human consumption or non-human consumption it has undergone at least one of the treatments referred to in Parts A and B of Annex IX. Such treatment shall have been undergone, in an establishment located in the vaccination zone or, in exceptional cases and subject to authorisation by the competent authorities, close to that zone. The competent authorities shall certify such treatment.
8. The placing on the market of products of animal origin other than those referred to in paragraphs 5 and 6 shall be subject to the conditions provided for in Articles 30, 31, 32 and 41.

Article 56

CLINICAL AND SEROLOGICAL SURVEY IN THE VACCINATION ZONE (PHASE 2-A)

1. Member States shall ensure that the measures provided for in paragraphs 2 and 3 are applied in the vaccination zone during a period starting not earlier than 30 days from the date of completion of emergency vaccination and terminating with the completion of a clinical and serological survey.

2. A survey shall be carried out with the aim to identify herds of animals of susceptible species that had contact with the foot-and-mouth disease virus without showing overt clinical signs of the foot-and-mouth disease. That survey shall include a clinical inspection of all animals of susceptible species in all herds in the vaccination zone, and laboratory testing in accordance with paragraph 3.
3. Laboratory testing shall be carried out by use of tests complying with the criteria for diagnostic tests as set out in Annex XIII and approved in accordance with the procedure referred to in Article 89 (2), and shall comply with one of the following conditions:
 - (a) testing for infection with the foot-and-mouth disease virus, either by an assay for antibodies against non-structural proteins of the foot-and-mouth disease virus, or by another approved method, shall meet criteria for sampling on holdings set out in point 2.2 of Annex III and, where the competent authorities use sentinel animals, the conditions for restocking of infected holdings in Annex V shall be taken into account;
 - (b) testing for antibodies against non-structural proteins of the foot-and-mouth disease virus shall be carried out on samples taken from all vaccinated animals of susceptible species and their non-vaccinated offspring in all herds in the vaccination zone.

Article 57

CLASSIFICATION OF HERDS IN THE VACCINATION ZONE (PHASE 2-B)

1. Member States shall ensure that the holdings containing animals of susceptible species:
 - (a) are classified according to the outcome of the survey referred to in Article 56 (2) and the criteria set out in Annex I;
 - (b) comply with the measures set out in paragraphs 2 to 4.
2. Holdings containing at least one animal suspected of being infected and where the presence of foot-and-mouth disease virus is confirmed in accordance with the criteria laid down in Annex I shall be subject to Articles 10 and 21.
3. Holdings containing at least one animal of susceptible species infected through previous contact with the foot-and-mouth disease virus but where the absence of circulating foot-and-mouth disease virus is confirmed shall be subject to at least the following measures:
 - (a) killing and processing of carcasses of the animals positive to at least one of the approved tests referred to in Article 56 (3);
 - (b) slaughter of the remaining animals of susceptible species of the herd of the animals referred to at point (a), under conditions authorised by the competent authorities;
 - (c) cleansing and disinfection of the holdings in accordance with Article 11;

- (d) restocking of animals in accordance with Annex V;
 - (e) products derived from animals of susceptible species during the period referred to in Article 56 (1) shall be traced and treated in accordance with the Article 12;
 - (f) fresh meat produced from the animals referred to in point (b) shall be subject to Article 55 (4) and (6);
 - (g) milk and milk products produced from the animals referred to in point (b) shall undergo at least one of the treatments specified in Parts A and B of Annex IX depending on the intended use.
4. Animals of susceptible species on holdings where the presence of previous or present infection with the foot-and-mouth disease virus has been officially ruled out in accordance with Article 56 (3) may be subject to the measures provided for in Article 58.

Article 58

MEASURES APPLICABLE IN THE VACCINATION ZONE AFTER THE COMPLETION OF THE SURVEY AND THE CLASSIFICATION OF HOLDINGS UNTIL THE FOOT-AND-MOUTH DISEASE AND INFECTION FREE STATUS IS RECOVERED (PHASE 3)

1. Member States shall ensure that the measures provided for in paragraphs 2 to 6 are applied in the vaccination zone after the completion of the measures laid down in Article 57 and until the foot-and-mouth disease and infection free status has been recovered in accordance with Article 59.
2. Movement of animals of susceptible species out of the vaccination zone shall be prohibited. By way of derogation from this prohibition, the competent authorities may authorise direct transport to a slaughterhouse for immediate slaughter of animals of susceptible species under the conditions provided for in Article 55 (3).
3. Non-vaccinated offspring of vaccinated dams shall be prohibited from leaving the holding of origin unless being transported to:
 - (a) a holding within the vaccination zone of the same health status as the holding of origin;
 - (b) a slaughterhouse for immediate slaughter;
 - (c) a holding designated by the competent authority, from which the offspring are to be sent directly to the slaughterhouse;
 - (d) any holding, after having obtained a negative result in a serological test for the detection of antibody against the foot-and-mouth disease virus carried out on a sample of blood taken prior to dispatch from the holding of origin.

4. Fresh meat produced from vaccinated large and small ruminants may be placed on the market within and outside the vaccination zone under the following conditions:
 - (a) the establishment shall be operated under strict veterinary control;
 - (b) only fresh meat which has undergone a treatment set out in Annex VIII or fresh meat obtained from animals reared and slaughtered outside the vaccination zone are processed in the establishment;
 - (c) all such fresh meat shall bear the health mark in accordance with Chapter XI of Annex I to Directive 64/433/EEC or in the case of meat from other biungulates the health mark provided for in Chapter III of Annex I of Directive 91/495/EEC, or in the case of minced meat and meat preparations the health mark provided for in Chapter VI of Annex I of Directive 94/65/EC;
 - (d) the fresh meat shall be clearly identified, and transported and stored separately from meat which is not eligible for dispatch outside the vaccination zone in accordance with this Directive.
5. Compliance with the conditions provided for in paragraph 4 shall be certified by the competent authority for fresh meat intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authorities and shall in the case of intra-Community trade communicate to other Member States and the Commission a list of those establishments which they have approved for such certification.
6. Fresh meat produced from vaccinated porcine animals may be placed on the market within and outside the vaccination zone without restrictions.
7. Milk and milk products produced from vaccinated animals may be placed on the market within and outside the vaccination zone, provided that depending on the final use for either human consumption or non-human consumption it has undergone at least one of the treatments referred to in Parts A and B of Annex IX. Such treatment shall have been undergone in an establishment located in the vaccination zone or, in exceptional cases and subject to authorisation by the competent authorities, close to that zone. Such treatment shall be certified by the competent authority.
8. The placing on the market of products of animal origin other than those referred to in paragraphs 4, 6 and 7 shall be subject to the conditions provided for in Articles 30, 31, 32 and 42.

SECTION 9

RECOVERY OF THE FOOT-AND-MOUTH DISEASE AND INFECTION FREE STATUS

Article 59

RECOVERY OF THE FOOT-AND-MOUTH DISEASE AND INFECTION FREE STATUS

The foot-and-mouth disease and infection free status of a Member State or a region thereof shall be re-established in accordance with the procedure referred to in Article 89 (3), taking into account the conditions referred to in Articles 60 and 61.

Article 60

RECOVERY OF STATUS FOLLOWING ERADICATION OF FOOT-AND-MOUTH DISEASE WITHOUT EMERGENCY VACCINATION

1. A Member State or region of a Member State regionalised in accordance with Article 45 shall regain its previous foot-and-mouth disease and infection free status following the control and eradication of one or more outbreaks of foot-and-mouth disease without vaccination under the following conditions:
 - (a) all the measures provided for in Articles 36 and 44 have been completed, and
 - (b) at least one of the following conditions applies:
 - (i) the relevant recommendations of the Animal Health Code of the OIE are met;
 - (ii) at least three months have elapsed after the last recorded outbreak of foot-and-mouth disease and clinical and laboratory surveillance carried out in accordance with Annex III has confirmed the absence of infection with the foot-and-mouth disease virus in the Member State or region concerned.
2. A decision on regaining a foot-and-mouth disease and infection free status shall be adopted in accordance with the procedure referred to Article 89 (3).

Article 61

RECOVERY OF STATUS FOLLOWING ERADICATION OF FOOT-AND-MOUTH DISEASE WITH VACCINATION

1. A Member State or region of a Member State regionalised in accordance with Article 45 shall regain its previous foot-and-mouth disease and infection free status following the control and eradication of one or more outbreaks of foot-and-mouth disease with vaccination under the following conditions:
 - (a) all the measures provided for in Articles 36, 44, 54, 55, 56 and 57 have been completed, and

- (b) at least one of the following conditions applies:
 - (i) the relevant recommendations of the Animal Health Code of the OIE are met;
 - (ii) at least three months have elapsed since the slaughter of the last vaccinated animal and serological surveillance has been carried out in accordance with the guidelines of the OIE;
 - (iii) at least six months have elapsed since the last outbreak of foot-and-mouth disease or the completion of emergency vaccination, what ever event occurred later, and in accordance with the guidelines of the OIE a serological survey based on the detection of antibodies against non-structural proteins of the foot-and-mouth disease virus has demonstrated the absence of infection in vaccinated animals.
- 2. A decision on regaining a foot-and-mouth and infection free status shall be adopted in accordance with the procedure referred to Article 89 (3).

Article 62

MODIFICATIONS OF MEASURES TO RECOVER THE FOOT-AND-MOUTH DISEASE AND INFECTION FREE STATUS

- 1. By way of derogation from Article 60 it may be decided in accordance with the procedure referred to in Article 89 (3), to withdraw the restrictions applied in accordance with this Directive after the requirements provided for in Articles 36 and 44 have been met and the clinical and serological survey has been completed with satisfactory results.
- 2. By way of derogation from Article 61 it may be decided in accordance with the procedure referred to in Article 89 (3), to withdraw the restrictions applied in accordance with this Directive after the clinical and serological survey provided for in Article 56 and the measures provided for in Article 57 have been completed with satisfactory results.
- 3. Without prejudice to paragraphs 1 and 2 it may be decided in accordance with the procedure referred to in Article 89 (3) that no animals of a susceptible species shall be removed from the territory or region of the Member State where the outbreak of foot-and-mouth disease has occurred to another Member State until the foot-and-mouth disease and infection free status is recovered in accordance with the conditions of the Animal Health Code of the OIE, unless such animals:
 - (a) have not been vaccinated and are consigned directly to a slaughter house for immediate slaughter; or
 - (b) have been isolated for at least 30 days immediately prior to loading and have undergone a serological test for the detection of antibody against foot-and-mouth disease virus structural proteins, carried out with negative results on samples taken during the 10 days prior to loading.

4. Without prejudice to paragraph 2 it may be decided in accordance with the procedure referred to in Article 89 (3) that until the foot-and-mouth disease and infection free status is recovered in accordance with the conditions of the Animal Health Code of the OIE the radius of the surveillance area around the vaccination zone referred to in Article 52 (2) shall be reduced after the completion with satisfactory results of the measures provided for in Article 57.

Article 63

CERTIFICATION OF ANIMALS OF SUSCEPTIBLE SPECIES AND PRODUCTS DERIVED FROM SUCH ANIMALS FOR INTRA-COMMUNITY TRADE

Member States shall ensure that additional certification for intra-Community trade in animals of susceptible species or products derived from such animals required in accordance with this Directive shall be continued until the foot-and-mouth disease and infection free status of the Member State or part of the territory of a Member State has been recovered in accordance with Articles 60 and 61.

Article 64

MOVEMENT OF VACCINATED ANIMALS OF SUSCEPTIBLE SPECIES AFTER THE RECOVERY OF THE FOOT-AND-MOUTH DISEASE AND INFECTION FREE STATUS

The dispatch from one Member State to another Member State of animals of susceptible species vaccinated against foot-and-mouth disease shall be prohibited.

**CHAPTER III
Preventative Measures**

**SECTION 10
LABORATORIES AND ESTABLISHMENTS HANDLING
FOOT-AND-MOUTH DISEASE VIRUS**

Article 65

LABORATORIES AND ESTABLISHMENTS HANDLING LIVE FOOT-AND-MOUTH DISEASE VIRUS

Member States shall ensure that:

- (a) laboratories and establishments in which live foot-and-mouth disease virus, its genome, antigens or vaccines produced from such antigens are handled for research, diagnosis or manufacture are strictly controlled by the competent authorities;
- (b) the handling of live foot-and-mouth disease virus for research and diagnosis is carried out only in approved laboratories listed in Part A of Annex XI;

- (c) the handling of live foot-and-mouth disease virus for the manufacturing of either inactivated antigens for the production of vaccines or vaccines and related research is carried out only in the approved establishments and laboratories listed in Part B of Annex XI;
- (d) the laboratories and establishments referred to in points (b) and (c) are operated at least according to the bio-security standards set out in Annex XII.

Article 66

CHECKS OF LABORATORIES AND ESTABLISHMENTS HANDLING LIVE FOOT-AND-MOUTH DISEASE VIRUS

Veterinary experts from the Commission, in collaboration with the competent authorities of the Member States, shall carry out spot-checks to ascertain whether the security systems applied in the establishments and laboratories referred to in Parts A and B of Annex XI comply with the bio-security standards set out in Annex XII.

Article 67

MODIFICATION OF THE LIST OF APPROVED LABORATORIES AND ESTABLISHMENTS HANDLING LIVE FOOT-AND-MOUTH DISEASE VIRUS

1. The list of establishments and laboratories in Part A and B of Annex XI may be amended in accordance with the procedure referred to in Article 89 (3), in the light of the spot-checks provided for in Article 66.
2. The list of establishments and laboratories in Part A and B of Annex XI shall be regularly updated based on written information submitted by the Member States, in accordance with the procedure referred to in Article 89 (2).

Article 68

NATIONAL LABORATORIES

1. Member States shall ensure that:
 - (a) laboratory testing for foot-and-mouth disease is carried out in laboratories authorised for such testing by the competent authorities;
 - (b) laboratory testing to confirm the presence of foot-and-mouth disease virus or other vesicular disease viruses is carried out in accordance with Article 71 by one of the laboratories listed in Part A of Annex XI;
 - (c) one of the laboratories listed in Part A of Annex XI shall be designated as the national reference laboratory for the Member State on whose territory it is situated, and it shall be responsible for co-ordinating standards and methods of diagnosis in that Member State;

- (d) the national reference laboratory carries out at least the functions and duties set out in Annex XV;
 - (e) the national reference laboratory referred to in point (c) liaises with the Community Reference Laboratory provided for in Article 69 and in particular ensures the sending of appropriate samples to the Community Reference Laboratory.
2. The national reference laboratory referred to in paragraph 1 (c) of one Member State may provide the services of a national reference laboratory to one or more other Member States. Member States which have no national reference laboratory situated on their territory may use the services of the national reference laboratory in one or more other Member States.

That co-operation shall be formalised in a mutual agreement between the competent authorities of the Member States concerned, which shall be notified to the Commission. Such co-operation shall be listed in the special column in the table in Part A of Annex XI.

3. Member States shall ensure that laboratory investigations provided for in this Directive are first of all carried out to confirm or rule out foot-and-mouth disease and to exclude other vesicular diseases.

Where an outbreak of foot-and-mouth disease has been confirmed and the serotype of the virus was identified, that virus shall be antigenically characterised in relation to the reference vaccine strains, where necessary with the assistance of the Community Reference Laboratory.

Samples from domestic livestock showing signs of vesicular disease which are negative for foot-and-mouth disease virus and, where relevant, Swine Vesicular Disease virus shall be sent to the Community Reference Laboratory for further investigation.

4. Member States shall ensure that the national reference laboratory on their territory is adequately equipped and staffed with the appropriate numbers of trained personnel to carry out the laboratory investigations required in accordance with this Directive.

Article 69

COMMUNITY REFERENCE LABORATORY

1. The Community Reference Laboratory shall be designated in agreement with the laboratory concerned and in accordance with the procedure referred to in Article 89 (2), for a period to be determined under that procedure.
2. When designating a Community Reference Laboratory, the technical and scientific competence of the laboratory as well as the expertise and excellence of the scientific and technical staff employed shall firstly be taken into account.

3. The Commission shall review the designation of the Community Reference Laboratory by the end of the designated period of operation or earlier in the light of its compliance with the functions and duties of the Community Reference Laboratory specified in Annex XVI.

Article 70

SECURITY STANDARDS AND CODE OF CONDUCT FOR APPROVED LABORATORIES AND ESTABLISHMENTS HANDLING LIVE FOOT-AND-MOUTH DISEASE VIRUS

1. An Operational Manual for Minimum Standards for Laboratories working with the foot-and-mouth disease virus in vitro and in vivo may be adopted in accordance with the procedure referred to in Article 89 (2).
2. A uniform code of good conduct for the security systems applied in the establishments and laboratories listed in Parts A and B of Annex XI may be adopted in accordance with the procedure referred to in Article 89 (2).

**SECTION 11
DIAGNOSIS OF FOOT-AND-MOUTH DISEASE**

Article 71

STANDARDS AND TESTS FOR THE DIAGNOSIS OF FOOT-AND-MOUTH DISEASE AND FOR THE DIFFERENTIAL DIAGNOSIS OF OTHER VESICULAR DISEASES

1. Member States shall ensure that the national laboratories use the tests and standards for diagnosis set out in Annexes XIII and XIV.
2. A decision regarding the suitable arrangements for the purchase, storage and supply to national laboratories of sufficient quantities of specific reagents or diagnostic tests in case of an emergency, in particular with regard to the measures provided for in Article 56 (3) may be adopted in accordance with the procedure referred to in Article 89 (2).
3. An Operational Manual for the diagnosis of foot-and-mouth disease and the differential diagnosis of vesicular diseases other than swine vesicular disease may be adopted in accordance with the procedure referred to in Article 89 (2).

SECTION 12

CONTINGENCY PLANS AND REAL TIME ALERT EXERCISES

Article 72

CONTINGENCY PLANS

1. Member States shall draw up a contingency plan specifying the national measures required to maintain a high level of foot-and-mouth disease awareness and preparedness, and environmental protection and to be implemented in the event of an outbreak of foot-and-mouth disease.
2. The contingency plan shall provide for the access to all facilities, equipment, personnel and other appropriate materials necessary for the rapid and efficient eradication of an outbreak of foot-and-mouth disease and shall ensure co-ordination with neighbouring Member States.
3. The contingency plan shall provide for measures to be implemented in the event of a worst case scenario as referred to in point 12 of Annex XVII and shall give precise indications of:
 - (a) the vaccine requirements considered necessary in the event of emergency vaccination, and
 - (b) the regions containing densely populated livestock areas.
4. The contingency plan shall ensure that all necessary arrangements are made to prevent any avoidable damage to the environment in the event of an outbreak, while ensuring at the same time the highest disease control level, and minimise any damage caused as a result of an outbreak, in particular if it is necessary to bury or burn the carcasses of dead or killed animals on site.
5. The criteria and requirements for drawing up the contingency plan shall be those set out in Annex XVII. Those criteria and requirements may be amended taking into account the specific nature of foot-and-mouth disease and progress made in the development of disease control and environmental protection measures in accordance with the procedure referred to in Article 89 (2).
6. The Commission shall examine the contingency plans in order to determine whether they permit the objective provided for in paragraph 1 to be attained and shall suggest to the Member State concerned any amendments required, in particular to ensure that such plans are compatible with those of the other Member States.
7. The contingency plans shall be approved in accordance with the procedure referred to in Article 89 (2).
8. Member States shall ensure that significant modifications in their approved contingency plans are notified to the Commission without delay.

9. The revised contingency plans may subsequently be approved in accordance with the procedure referred to in Article 89 (2), to take into account developments in the situation.
10. In any case, every five years each Member State shall update its contingency plan in particular in the light of real-time alert exercises referred to in Article 73, and submit it to the Commission for approval in accordance with the procedure referred to in Article 89 (2).

Article 73

REAL-TIME ALERT EXERCISES

1. Member States shall ensure that real-time alert exercises are carried out in accordance with their approved contingency plan and Annex XVI.
2. Member States shall ensure that where possible and practical real-time alert exercises are carried out in close collaboration with the competent authorities of neighbouring Member States or third countries.
3. Member States shall inform the Commission about the main results of real-time alert exercises. That information shall be submitted to the Commission as part of the information required in Article 8 of Directive 64/432/EEC.

SECTION 13 CONTROL CENTRES AND EXPERT GROUPS

Article 74

NATIONAL DISEASE CONTROL CENTRES – FUNCTIONS AND DUTIES

1. Member States shall ensure that a fully functional national disease control centre may be immediately established in the event of foot-and-mouth disease outbreaks.
2. The national disease control centre shall first of all direct and monitor the operations of local disease control centres as provided for in Article 76. Certain functions originally attributed to the national disease control centre may subsequently be transferred to the local disease control centre operated at the administrative level provided for in Article 2 (2) (p) of Directive 64/432/EEC or higher provided that the tasks of the national disease control centre are not compromised.
3. The national disease control centre shall be at least responsible for:
 - (a) designing the necessary control measures;
 - (b) ensuring the prompt and efficient implementation of those measures by the local disease control centres;
 - (c) deploying staff and other resources to local disease control centres;

- (d) providing information to the Commission, to the competent authorities of other Member States and other national authorities including competent environmental authorities and bodies, as well as veterinary, agricultural and trading organisations and bodies;
- (e) organising an emergency vaccination campaign and also the delimitation of vaccination zones;
- (f) liaising with diagnostic laboratories;
- (g) liaising with competent environmental authorities to co-ordinate the actions on veterinary and environmental safety;
- (h) liaising with the press and other media;
- (i) liaising with the police authorities to ensure specific legal measures.

Article 75

NATIONAL DISEASE CONTROL CENTRES – TECHNICAL REQUIREMENTS

1. Member States shall ensure that the national disease control centres have all the necessary means including staff, facilities and equipment, to manage an efficient eradication campaign.
2. The means referred to in paragraph 1 shall include at least the following:
 - (a) a herd identifier and animal location system, preferably computerised;
 - (b) all suitable means of communication including telephones, fax and if possible facilities for communication with the press;
 - (c) a communication system allowing exchange of information with the local disease control centres, the laboratories and other relevant organisations, preferably computerised;
 - (d) maps and other sources of information that can be used in directing control measures;
 - (e) a shared daily journal which shall be maintained to record in chronological order all the events associated with an outbreak of foot-and-mouth disease and allowing different activities to be linked and co-ordinated;
 - (f) lists of national and international organisations and laboratories that are interested in an outbreak of foot-and-mouth and shall be contacted in such an event;
 - (g) lists of staff and other persons who may be called upon immediately to serve at local disease control centres or in expert groups provided for in Article 78 in the event of an outbreak of foot-and-mouth disease;

- (h) lists of competent environmental protection authorities and bodies to contact in the event of an outbreak of foot-and-mouth disease;
- (i) maps identifying appropriate disposal site areas;
- (j) lists of treatment and disposal undertakings authorised to treat or dispose of animal carcasses and animal waste that could be commissioned in the event of an outbreak of foot-and-mouth disease, in particular, indicating their capacity, address and other contact details;
- (k) lists of measures to monitor and control disinfectant run-off as well as body tissue and fluid displacement into the surrounding environment as a result of carcass decomposition, particularly into surface waters and groundwaters.

Article 76

LOCAL DISEASE CONTROL CENTRES – FUNCTIONS AND DUTIES

1. Member States shall ensure that fully functional local disease control centres may be established immediately in the event of outbreaks of foot-and-mouth disease.
2. Member States shall ensure that within the framework of their contingency plans provisions are made for likely locations of local disease control centres, their organisation, staff, accommodation, facilities and equipment, management systems, communication lines as well as information channels.
3. Member States shall ensure the local disease control centres have the necessary organisation to ensure the prompt implementation of the measures provided for in this Directive to be applied in the event of an outbreak of foot-and-mouth disease.

Article 77

LOCAL DISEASE CONTROL CENTRES – TECHNICAL REQUIREMENTS

1. Member States shall ensure that the local disease control centres have staff, facilities and equipment as required, and a clear management structure and effective management to ensure the prompt implementation of the legislation relating to the epidemiological inquiry, environmental protection, disposal of carcasses from infected herds, official surveillance of the zones, tracing, welfare and emergency slaughter, cleansing and disinfection and others measures of sanitation, emergency vaccination, and all other policy decisions.
2. The local disease control centres shall have at least:
 - (a) one telephone line reserved for communication with the national disease control centre;
 - (b) field staff equipped with necessary tools for communication and effective management of all necessary data;

- (c) a record system, preferably computer-based, connected to the national disease control centre and to all necessary databases, laboratories and other organisations;
- (d) a shared daily journal which shall be maintained to record in chronological order all the events associated with an outbreak of foot-and-mouth and allowing different activities to be linked and co-ordinated;
- (e) up-to-date lists of persons and local organisations in each region who shall be contacted and may be involved in the event of an outbreak of foot-and-mouth disease;
- (f) up-to-date lists of holdings to which the provisions of Article 18 may be applied in the case of an outbreak of foot-and-mouth disease;
- (g) up-to-date inventories of possible burning or burial places for animals killed in accordance with this Directive and to be destroyed in accordance with Community and national legislation on the protection of the environment;
- (h) up-to-date list of competent environmental authorities in each region, as well as other environmental bodies who must be contacted and are to be involved in the event of an outbreak of foot-and-mouth disease;
- (i) maps identifying suitable disposal sites for burial of carcasses that will not present a risk of harm to the environment, in particular to surface waters or groundwaters;
- (j) list of treatment and disposal undertakings authorised to treat or dispose of animal carcasses and animal waste;
- (k) list of measures to monitor and control disinfectant run-off as well as body tissue and fluid displacement into the surrounding environment as a result of carcass decomposition, particularly into surface waters and groundwaters.

Article 78

EXPERT GROUP

1. Member States shall create a permanently operational expert group to maintain expertise in order to assist the competent authority in ensuring preparedness against an outbreak of foot-and-mouth disease.
2. In case of a suspicion of an outbreak of foot-and-mouth disease the expert group shall at least:
 - (a) evaluate the clinical picture and the epidemiological situation;
 - (b) give advice regarding the sampling and analyses needed for diagnosing the foot-and-mouth disease together with the additional actions and measures to be taken.

3. In case of an outbreak of foot-and-mouth the expert group shall at least:
 - (a) conduct at least in the index case and if necessary on the spot, an evaluation of the clinical picture and an analysis of the epidemiological inquiry in order to collect the necessary data for determining the following:
 - (i) the origin of the infection;
 - (ii) the date of introduction of the infectious agent;
 - (iii) the possible spread of the disease.
 - (b) report to the Chief Veterinary Officer and the national disease control centre;
 - (c) give advice on screening, sampling, test procedures, control and the other measures to be applied and on the strategy to be implemented;
 - (d) follow up and guide the epidemiological inquiry;
 - (e) amplify the epidemiological data with geographical, meteorological and other necessary information;
 - (f) analyse the epidemiological information and perform risk assessments at regular intervals;
 - (g) assist in ensuring that the disposal of animal carcasses and animal waste is done without causing any harm to the environment.

SECTION 14

ANTIGEN AND VACCINE BANKS

Article 79

NATIONAL ANTIGEN AND VACCINE BANKS

1. Member States shall be authorised by the Commission within the framework of the contingency plan, to establish or maintain national antigen and vaccine banks for the storage of reserves for emergency vaccination of antigens or vaccines authorised in accordance with Directive 2001/82/EC of the European Parliament and of the Council⁴³.
2. Member States shall be authorised by the Commission to retain establishments for the packaging and storage of vaccines in the case of emergency vaccination.
3. Member States shall ensure that the antigen and formulated vaccine in the national antigen and vaccine banks comply with the minimum standards laid down for the Community antigen and vaccines bank with respect to safety, innocuity and content of non-structural proteins.

⁴³ OJ L 311, 28.11.2001, p.1.

4. Member States maintaining a national antigen and vaccine bank shall inform the Commission about the antigen and vaccine stocks kept. Such information shall be submitted to the Commission every 12 months as part of the information required by Article 8 of Directive 64/432/EEC.

Article 80

COMMUNITY ANTIGEN AND VACCINE BANK

1. A Community antigen and vaccine bank shall be established in accordance with the procedure referred to in Article 89 (2).
2. The Commission shall ensure that Community reserves of concentrated inactivated antigens for the production of foot-and-mouth disease vaccines are maintained on the premises of the Community antigen and vaccine bank. For that purpose, the number of doses and the diversity of strains and subtypes of antigen of foot-and-mouth disease virus and, if necessary, of authorised vaccines stored in the Community antigen and vaccine bank shall be decided in accordance with the procedure referred to in Article 89 (2), taking into account the needs as estimated in the context of the contingency plans provided for in Article 72 and the epidemiological situation, where appropriate after consultation with the Community Reference Laboratory.
3. The information on quantities and subtypes of antigens or authorised vaccines stored in the Community antigen and vaccine bank shall be treated as classified information and in particular shall not be published.
4. The conditions for the establishment and maintenance of Community reserves of antigen and authorised vaccines at the premises of preferably at least two manufacturing establishments shall be laid down in contracts concluded between the Commission and the manufacturing establishments. Such contracts shall include at least:
 - (a) conditions for supply of quantities and subtypes of concentrated inactivated antigen;
 - (b) conditions for secure storage of antigen and authorised vaccines;
 - (c) guarantees and conditions of rapid formulation, production, bottling, labelling and distribution of vaccines.
5. The conditions and guarantees referred to in paragraph 4 (a) to (c) may be amended in accordance with the procedure referred to in Article 89 (3).

Article 81

SUPPLY AND STORAGE OF CONCENTRATED INACTIVATED ANTIGEN

1. The Commission shall ensure that the contracted manufacturer of the concentrated inactivated antigen supplied to the Community antigen and vaccine bank, guarantees that:
 - (a) each antigen consists of a single homogeneous batch;
 - (b) each batch is split in order to permit it to be stored at two separate geographical sites under the responsibility of the designated premises of the Community antigen and vaccine bank;
 - (c) the antigen meets at least the requirements of the European Pharmacopoeia and the relevant provisions of the Manual of Standards for Diagnostic Tests and Vaccines of the OIE;
 - (d) if not otherwise specified in the standards referred to in point (c), the antigen is purified from non-structural proteins of the foot-and-mouth disease virus. The purification shall at least ensure that the residual content of non-structural proteins in vaccines reconstituted from such antigen does not induce detectable levels of antibody against non-structural proteins in animals which had received one initial and one subsequent booster vaccination.
2. The provisions in paragraph 1 may be amended in accordance with the procedure referred to in Article 89 (3).

Article 82

FORMULATION, PRODUCTION, BOTTLING, LABELLING AND DISTRIBUTION OF VACCINE

1. The Commission shall ensure that the contracted manufacturer of the concentrated inactivated antigen supplied to the Community antigen and vaccine bank guarantees:
 - (a) rapid formulation into vaccine of the antigen referred to in Article 81;
 - (b) production of a safe, innocuous and efficient vaccine with a potency of at least 6 PD_{50} in accordance with the tests prescribed by the European Pharmacopoeia, and suitable for use in case of emergency vaccination of ruminants and pigs,
 - (c) a capacity to formulate from concentrated inactivated antigen in stock
 - (i) up to one million doses of vaccine within four days of instruction from the Commission;
 - (ii) additionally, up to four million doses of vaccine within 10 days of instruction from the Commission;
 - (d) rapid bottling, labelling and distribution of the vaccine according to the specific needs of the area where vaccination is to be carried out.

2. In case of emergency and with due regard to the epidemiological situation, the Commission shall be authorised to arrange for the immediate production, bottling, labelling, temporary storage and distribution of necessary quantities of vaccines reconstituted from any suitable antigen.

Article 83

ACCESS TO THE COMMUNITY ANTIGEN AND VACCINE BANK

1. Member States shall have access to the Community antigen and vaccine bank following a request to the Commission.

The Commission shall, within the limits of the Community reserves of antigens and vaccines, immediately arrange for the formulation, production, bottling, labelling and distribution of the required quantities and subtypes of vaccines, in particular in application of Article 51.

2. Member States that maintain a national antigen and vaccine bank or Member States that are associated to an international antigen and vaccine bank shall have the same rights and obligations to the Community antigen and vaccine bank as other Member States without such reserves.
3. Where it is in the interest of the Community, the Commission may supply or lend to third countries antigens from the Community reserves or vaccines reconstituted from such antigens.

Without prejudice to agreements concluded between the Community and third countries, access of third countries to the Community antigen and vaccine bank shall be authorised in accordance with the procedure referred to in Article 89 (2), subject to detailed arrangements between the Commission and the third country concerned on the financial and technical co-operation to be adopted under that procedure.

4. Following the use of the antigen or formulated vaccine from the Community reserves, the Commission shall ensure that the used antigen or vaccine is replaced as soon as possible and according to the epidemiological situation.

Article 84

TESTING OF FOOT-AND-MOUTH DISEASE VACCINES

1. The Commission shall be responsible for arranging independent testing for potency and innocuity of vaccines reconstituted from antigen stored in the Community antigen and vaccine bank, and of vaccines reconstituted from other antigens and intended for use within the framework of Community assistance to control measures against foot-and-mouth disease in third countries in accordance with Articles 82 (2) and 83 (3).
2. For the purpose of the testing referred to in paragraph 1 the Commission may employ the services of an independent Community Co-ordinating Institute.

If necessary, the Community Co-ordinating Institute shall be designated and detailed rules on its functions, responsibilities and Community financial contributions shall be adopted in accordance with the procedure referred to in Article 89 (2).

3. Without prejudice to the standards for potency, safety and production procedures provided for in Community legislation, vaccines reconstituted from antigen stored within the Community antigen and vaccine bank shall meet at least the minimum standards for potency, safety and production procedures laid down in the European Pharmacopoeia and the relevant provisions of the Manual of Standards for Diagnostic Tests and Vaccines of the OIE.

SECTION 15

USE OF CATERING WASTE

Article 85

USE OF CATERING WASTE

1. Member States shall ensure that:
 - (a) the feeding of catering waste to animals of susceptible species is prohibited;
 - (b) the information on the application of the provisions of point (a) and the relevant checks carried out by Member States shall be transmitted to the Commission by 31 May each year at the latest, and for the first time in 2004. The Commission shall submit this information to the Standing Committee on the Food Chain and Animal Health.
2. Detailed rules for the control measures to be applied and the information to be supplied by Member States as provided for in paragraph 1, and, in particular point (b), may be adopted in accordance with the procedure referred to in Article 89 (2).
3. The provisions laid down in paragraphs 1 and 2 shall apply until the date of application of Community legislation on the use of catering waste for feeding to animals of susceptible species in the framework of the rules on animal by-products not intended for human consumption or on animal nutrition.

Chapter IV

Implementing measures

Article 86

PENALTIES

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by the date specified in Article 93 (1) at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 87

PROCEDURES FOR AMENDING SPECIFIC ARTICLES, THE ANNEXES AND FOR THE ADOPTION OF FURTHER DETAILED RULES FOR THE IMPLEMENTATION OF THIS DIRECTIVE

1. The technical requirements for the inactivation of the foot-and-mouth disease virus in products and substances referred to in Articles 30 to 33 may be amended in accordance with the procedure referred to in Article 89 (3), after consultation of the appropriate scientific committee or in the light of modifications made to relevant provisions in other Community legislation.
2. The Annexes may be amended in accordance with the procedure referred to in Article 89 (2) or, in the case of Annex XI, in accordance with the procedure referred to in Article 89 (3).
3. Any detailed rules necessary for the implementation of this Directive may be adopted in accordance with the procedure referred to in Article 89 (2).

Article 88

PROCEDURE FOR THE ADOPTION OF AD HOC EPIDEMIOLOGICAL MEASURES

Where, in implementing the measures provided for by this Directive, a Member State determines that a measure is not adapted to the epidemiological situation, or where the foot-and-mouth disease virus appears to be spreading despite the measures taken in accordance with this Directive, a Decision may be adopted on an ad hoc basis in accordance with the procedure referred to in Article 89 (3) to authorise that Member State to implement alternative measures with equivalent epidemiological effect for a limited period of time appropriate to the epidemiological situation.

Article 89

REGULATORY PROCEDURE

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002 of the European Parliament and of the Council.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply and the period referred to in Article 5 (6) of that Decision shall be three months.
3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply and the period referred to in Article 5 (6) of that Decision shall be 15 days.

Chapter V Transitory and Final provisions

Article 90

AMENDMENT TO DIRECTIVE 92/46/EEC

In point 4 (b) of Chapter I of Annex A to Council Directive 92/46/EEC, the second subparagraph is deleted.

Article 91

REPEALS

1. Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC adopted in implementation thereof are repealed.
2. Directive 85/511/EEC shall be repealed without prejudice to the obligations of the Member States concerning the time-limits for transposition and application set out in Part B of Annex XVIII.
3. References to Directive 85/511/EEC shall be construed as references to this Directive and shall be read in accordance with the correlation table set out in Annex XIX.

Article 92

TRANSITIONAL PROVISIONS

1. Transitional provisions may be adopted in accordance with the procedure referred to in Article 89 (2) for a period of five years from the date of entry into force of this Directive.

2. Within six months after the date referred to in Article 94, Member States shall submit to the Commission amended contingency plans to take into account the provisions of Article 72.

The Commission shall examine those contingency plans against the objectives of this Directive and shall suggest to the Member States concerned any amendments it deems necessary, in particular to ensure that such plans are compatible with those of the other Member States.

Those amended contingency plans shall be approved in accordance with the procedure referred to in Article 89 (2).

Article 93

TRANSPOSITION INTO NATIONAL LEGISLATION, APPLICATION AND ENTRY INTO FORCE

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 2003 at the latest. They shall forthwith inform the Commission thereof.

They shall apply these provisions as from 1 July 2003.

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

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

Article 94

ENTRY INTO FORCE

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

Article 95

ADDRESSEES

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX I

DEFINITION OF OUTBREAK

An outbreak shall be declared where a holding meets one or more of the following criteria:

1. foot-and-mouth disease virus has been isolated from an animal, any product derived from that animal, or its environment;
2. clinical signs consistent with foot-and-mouth disease are observed in an animal of a susceptible species, and the viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of foot-and-mouth disease virus has been detected and identified in samples collected from the animal or its cohorts;
3. clinical signs consistent with foot-and-mouth disease are observed in an animal of a susceptible species and the animal or its cohorts are positive for antibody to foot-and-mouth disease virus structural or non-structural proteins, provided that previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity;
4. viral antigen or viral RNA specific to one or more of the serotypes of foot-and-mouth disease virus has been detected and identified in samples collected from animals of susceptible species and the animals are positive for antibody to foot-and-mouth disease virus structural or non-structural proteins, provided that in the case of antibodies to structural proteins previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity;
5. an epidemiological link has been established to a confirmed foot-and-mouth disease outbreak and at least one of the following conditions applies:
 - (a) one or more animals are positive for antibody to foot-and-mouth disease virus structural or non-structural proteins, provided that previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity;
 - (b) viral antigen or viral RNA specific to one or more of the serotypes of foot-and-mouth disease virus has been detected and identified in samples collected from one or more animals of susceptible species;
 - (c) serological evidence of active infection with foot-and-mouth disease by detection of seroconversion from negative to positive for antibody to foot-and-mouth disease virus structural or non-structural proteins has been established in one or more animals of susceptible species, and previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity.

Where a previously seronegative status cannot be reasonably expected, this detection of seroconversion is to be carried out in paired samples collected from the same animals on two or more occasions at least 5 days apart, in the case of structural proteins, and at least 21 days apart, in the case of non-structural proteins.

ANNEX II

Notification of disease and further epidemiological information to be provided by the Member State where foot and mouth disease has been confirmed

1. Within 24 hours from the confirmation of each primary outbreak or case in a slaughterhouse or means of transport, the Member State concerned must notify by means of the Animal Disease Notification System established in accordance with Article 5 of Council Directive 82/894/EEC:
 - (a) Date of dispatch;
 - (b) Time of dispatch;
 - (c) Country of origin;
 - (d) Name of disease and type of virus, where appropriate;
 - (e) Serial number of outbreak;
 - (f) Type of outbreak;
 - (g) Reference number of outbreak linked to this outbreak;
 - (h) Region and geographical location of the holding;
 - (i) Other region affected by restrictions;
 - (j) Date of confirmation and method used for confirmation;
 - (k) Date of suspicion;
 - (l) Date of estimation of first infection;
 - (m) Origin of disease;
 - (n) Disease control measures taken;

2. In case of primary outbreaks or cases in slaughterhouses or means of transport, in addition to the data referred to in point 1, the Member State concerned must also forward the following information:
 - (a) the number of animals of susceptible species in the outbreak, slaughterhouse or means of transport;
 - (b) for each type (breeding, fattening, slaughter, etc.), the number of dead animals of susceptible species on the holding, slaughterhouse or means of transport;
 - (c) for each type (breeding, fattening, slaughter, etc.), the morbidity of the disease and the number of animals of susceptible species in which foot-and-mouth disease has been confirmed;
 - (d) the number of animals of susceptible species killed in the outbreak, slaughterhouse or means of transport;

- (e) the number of carcasses processed and disposed of;
 - (f) the distance of the outbreak from the nearest holding on which animals of susceptible species are kept;
 - (g) if foot-and-mouth disease was confirmed in a slaughterhouse or means of transport, the location of the holding or holdings of origin of the infected animals or carcasses.
3. In case of secondary outbreaks, the information referred to in points 1 and 2 must be forwarded within the time limit laid down in Article 4 of Council Directive 82/894/EEC.
4. The Member State concerned shall ensure that the information to be provided in relation to any outbreak or case of foot-and-mouth disease in a holding, slaughterhouse or means of transport in accordance with points 1, 2 and 3 is followed as soon as possible by a written report to the Commission and the other Member States including at least:
- (a) the date on which the animals of susceptible species on the holding, slaughterhouse or means of transport were killed and their carcasses processed;
 - (b) the results of the tests carried out on samples taken when animals of susceptible species were killed;
 - (c) where the derogation provided for in Article 18 has been applied, the number of animals of susceptible animals killed and processed and the number of animals of susceptible species which are to be slaughtered at a later date and the time limit laid down for their slaughter;
 - (d) any information relating to the possible origin of the disease or the origin of the disease if this has been ascertained;
 - (e) in the case of a primary outbreak or a case of foot-and-mouth disease in a slaughterhouse or means of transport, the genetic type of virus responsible for the outbreak or the case;
 - (f) in cases where animals of susceptible species have been killed in contact holdings or in holdings containing animals of susceptible species suspected of being infected with foot-and-mouth disease virus, information on:
 - (i) the date of killing and the number of animals of susceptible species of each category killed in each holding and in cases where animals of susceptible species in contact holdings were not killed, information must be provided on the reasons for this decision,
 - (ii) the epidemiological link between the outbreak or case of foot-and-mouth disease and each contact holding or the reasons that have induced suspicion of foot-and-mouth disease in each suspected holding,

- (iii) the results of the laboratory tests carried out on the samples taken from the animals of susceptible species in the holdings and when they were killed.
- 5. Where the Animal Disease Notification System (ADNS) is for whatever reason temporarily not operational, other means of communication shall be employed.

ANNEX III

SURVEY

1. CLINICAL EXAMINATION

- 1.1. Holdings must undergo clinical examinations of all animals of susceptible species for signs or symptoms of foot-and-mouth disease.
- 1.2. Special emphasis must be laid on animals which may have been exposed to foot-and-mouth disease virus with a high probability, notably transport from holdings at risk or close contact to persons or equipment that had close contact to holdings at risk.
- 1.3. The clinical examination must take into account the transmission of foot-and-mouth disease and the way in which animals of susceptible species are kept.
- 1.4. Relevant records kept on the holding must be examined in detail with particular regard to data on morbidity, mortality and abortion, clinical observations, changes in productivity and feed intake, purchase or sale of animals, visits of persons likely to be contaminated and other anamnestically important information.

2. PROCEDURES FOR SAMPLING

2.1. General provisions

2.1.1. Serological sampling shall be carried out:

2.1.1.1. according to the recommendations of the epidemiological team established within the expert group referred to in Annex XVII (7) , and

2.1.1.2. in support of tracing and the provision of evidence for the absence of previous infection.

2.1.2. Where sampling is carried out in the framework of disease surveillance after an outbreak, actions shall not commence before at least 21 days have elapsed since the elimination of susceptible animals on the infected holding(s) and the carrying out of preliminary cleansing and disinfection.

2.1.3. Sampling of animals of susceptible species shall be carried out in accordance with the provisions of this Annex in each case where sheep and goats or other susceptible animals not displaying clear clinical signs are involved in the outbreak, and in particular where such animals have been isolated from bovine and porcine animals.

2.2. Sampling on holdings

In holdings where the presence of foot-and-mouth disease is suspected but in the absence of clinical signs, sheep and goats, and on recommendation of the epidemiological team other susceptible species, should be examined pursuant to a sampling protocol suitable to detect at least 5% prevalence with at least 95% level of confidence.

2.3. Sampling in protection zones

In order to seek the repeal in accordance with Article 36 of the measures provided for in Articles 21 to 35, all holdings within the perimeters of the protection zone where sheep and goats have not been in direct and close contact with bovine animals during a period of at least 21 days prior to taking the samples shall be examined pursuant to a sampling protocol suitable to detect at least 5% prevalence of disease with at least 95% level of confidence.

2.4. Sampling in surveillance zones

In order to seek the repeal in accordance with Article 44 of the measures provided for in Articles 37 to 43, holdings within the perimeters of the surveillance zone where the presence of foot-and-mouth disease in the absence of clinical signs must be suspected, notably where sheep and goats are kept, shall be examined. For the purpose of this survey the model of a multistage sampling shall be sufficient, provided that that samples are taken:

2.4.1. from holdings in all administrative units within the perimeter of the zone where sheep and goats have not been in direct and close contact with bovine animals during a period of at least 30 days prior to taking the samples, and

2.4.2. from as many holdings referred to above as necessary to detect with 95% level of confidence at least 1 infected holding if the estimated prevalence of the disease was 2% equally distributed throughout the zone, and

2.4.3. from as many sheep and goats per holding as necessary to detect at least 5% prevalence of disease within the herd with at least 95% level of confidence, but not more than 60 samples per holding and from all sheep and goats if there are less than 15 sheep and goats on the holding.

2.5. Sampling for monitoring

2.5.1. For monitoring the areas outside the zones established in accordance with the provisions of Article 21, and in particular to substantiate the absence of infection in the sheep and goat population which is not in close and direct contact with non-vaccinated bovine or porcine animals, a sampling protocol recommended for monitoring purposes by the OIE or a sampling protocol as provided for in paragraph 2.4. shall be applied with the difference compared to paragraph 2.4.2. that the estimated herd prevalence shall be set at 1 %.

3. In the case the diagnostic sensitivity of the test employed to carry out the survey is lower than 100 %, the number of samples calculated in accordance with requirements in paragraphs 2.2, 2.3 and 2.4.3 shall be increased in order to take into account the established diagnostic sensitivity of the test employed.

ANNEX IV

PRINCIPLES AND PROCEDURES FOR CLEANSING AND DISINFECTION

1. GENERAL PRINCIPLES AND PROCEDURES

- 1.1. Cleansing and disinfection operations as provided for in Article 11 shall be carried out under official supervision and in accordance with the instructions given by the official veterinarian.
- 1.2. The disinfectants to be used and their concentrations shall be officially approved by the competent authority to ensure destruction of foot-and-mouth virus.
- 1.3. The activity of disinfectants should be checked before use, as activity of certain disinfectants is diminished by prolonged storage.
- 1.4. The choice of disinfectants and of procedures for disinfection should be made taking into account the nature of the premises, vehicles and objects which are to be treated.
- 1.5. The conditions under which degreasing agents and disinfectants are used must ensure that their efficacy is not impaired. In particular technical parameters provided by the manufacturer, such as pressure, minimum temperature and required contact time must be observed.
- 1.6. Independently of the disinfectant used, the following general rules shall apply:
 - 1.6.1. thorough soaking of bedding and litter as well as faecal matter with the disinfectant,
 - 1.6.2. washing and cleaning by careful brushing and scrubbing of the ground, floors, ramps and walls after the removal or dismantling, where possible, of equipment or installations otherwise impairing the effective cleansing and disinfection procedures,
 - 1.6.3. then further application of disinfectant for a minimum contact time as stipulated in the manufacturers recommendations.
- 1.7. Where washing is carried out with liquids applied under pressure and following the disinfection, re-contamination of the previously cleansed or disinfected parts must be avoided.
- 1.8. Washing, disinfecting or destroying of equipment, installations, articles or compartments likely to be contaminated should be included.
- 1.9. Cleansing and disinfection required in the framework of this Directive must be documented in the holding register or, in the case of vehicles, in the log-book and where official approval is required be certified by the supervising official veterinarian.

2. SPECIAL PROVISIONS ON CLEANSING AND DISINFECTION OF INFECTED HOLDINGS

2.1. Preliminary cleansing and disinfection

- 2.1.1. During the killing of the animals all necessary measures shall be taken to avoid or minimise the dispersion of foot-and-mouth virus. This shall include among other things the installation of temporary disinfection equipment, supply of protective clothing, showers, decontamination of used equipment, instruments and facilities and the interruption of power supply to the ventilation.
- 2.1.2. Carcasses of killed animals must be sprayed with disinfectant and removed from the holding in covered and leak-proof containers for processing and disposal.
- 2.1.3. As soon as the carcasses of the animals of susceptible species have been removed for processing and disposal, those parts of the holding in which these animals were housed and any parts of other buildings, yards, etc. contaminated during killing, slaughter or post-mortem examination should be sprayed with disinfectants approved for this purpose.
- 2.1.4. Any tissue or blood which may have been spilled during slaughter or post-mortem examination and any gross contamination of buildings, yards, utensils, etc. should be carefully collected and disposed of with the carcasses.
- 2.1.5. The used disinfectant shall remain on the surface for at least 24 hours.

2.2. Final cleansing and disinfection

- 2.2.1. Grease and dirt should be removed from all surfaces by the application of a degreasing agent and washed with cold water.
- 2.2.2. After washing with cold water further spraying with disinfectant should be applied.
- 2.2.3. After seven days the premises should be treated again with a degreasing agent, rinsed with cold water, sprayed with disinfectant and rinsed again with cold water.

3. DISINFECTION OF CONTAMINATED BEDDING, MANURE AND SLURRY

- 3.1. Manure and used bedding should be stacked to heat, sprayed with disinfectant and left for at least 42 days.
- 3.2. Slurry should be stored for at least 42 days after the last addition of infective material. This period may be extended if the slurry has been heavily contaminated. Disinfectant shall be added so as to alter the pH sufficiently to destroy the foot-and-mouth disease virus.

ANNEX V

RESTOCKING OF INFECTED HOLDINGS

1. Restocking should not commence until 21 days after completion of the final disinfection of the holding.
2. Animals for restocking can only be introduced from areas not subject to animal health restrictions in relation to foot-and-mouth disease. They must be negative for antibody to foot-and-mouth disease virus prior to introduction.
3. Irrespective the type of farming practised on the holding, re-introduction must conform with the following procedures:
 - 3.1. animals must be introduced in all units and buildings of the holding involved,
 - 3.2. in the case of a holding consisting of more than one unit or building, re-introduction is not necessary for every unit or building at the same time;

However no animals of species susceptible to foot-and-mouth disease may leave the holding until all the re-introduced animals in all units and buildings have fulfilled all restocking procedures.
 - 3.3. animals must be subjected to clinical inspection every three days for the first 14 days following the introduction;
 - 3.4. during the period from 15 to 28 days after re-introduction, animals are to be subjected to clinical inspection once every week;
 - 3.5. not earlier than 28 days after the last re-introduction, all animals must be sampled at random for testing for the presence of antibody against foot-and-mouth disease virus in accordance with the requirements of Annex III point 2.2;
 - 3.6. the competent authority may impose:
 - 3.6.1. the use of sentinel animals, in particular in holdings difficult to clean and disinfect and notably open-air holdings. Detailed provision on the use of sentinels may be laid down in accordance with the procedure referred to in Article 89 (2);
 - 3.6.2. additional safeguard and control measures within the framework of restocking.

ANNEX VI

RESTRICTIONS ON THE MOVEMENT OF EQUIDAE

1. Where at least one outbreak of foot-and-mouth disease has been confirmed in accordance with Article 10, Member States shall ensure that equidae are not dispatched to other Member States, unless accompanied in addition to the identification document provided for in Commission Decisions 93/623/EEC or 2000/68/EC by an animal health certificate provided for in Annex C of Council Directive 90/426/EEC.
2. In the case the competent authorities apply a complete stand-still as provided for in Article 7 (3), transport of equidae from holdings under restrictions laid down in Articles 4 and 10 shall be authorized for equidae which need special medical attention in premises without animals of susceptible species, if the following conditions are met:
 - 2.1. the emergency must be documented by the veterinary surgeon,
 - 2.2. the agreement of the clinic of destination must be producible,
 - 2.3. the transport must be authorized by the competent authorities,
 - 2.4. equidae must be accompanied during the transport by an identification document in accordance with Commission Decisions 93/623/EEC or 2000/68/EC,
 - 2.5. the official veterinarian must be informed about the route prior to departure,
 - 2.6. equidae must be groomed and treated with an effective disinfectant,
 - 2.7. equidae must travel in dedicated equine transport which is recognizable as such and cleansed and disinfected prior to and after use.
3. Movement of equidae outside the protection and surveillance zones shall not be subject to conditions in excess of those resulting from Directive 90/426/EEC.
4. Movement of equidae within the protection and surveillance zones established in accordance with Article 21 shall be subject to the following conditions:
 - 4.1. equidae may be transported without restrictions in dedicated equine transport to a holding not keeping animals of susceptible species;
 - 4.2. the competent authorities may in exceptional cases authorize the transport of equidae in dedicated and registered equine transport from a holding not keeping animals of susceptible species to another holding keeping animals of susceptible species situated in the protection zone, subject to cleansing and disinfection of the transport prior to loading of the animals and before leaving the holding of destination.
 - 4.3. movement of equidae shall be allowed on public roads, on pastures and exercise premises;

5. The collection of equine semen, ova and embryos from donor animals not in contact with animals of susceptible species in the protection and surveillance zone and the transport of equine semen, ova and embryos to recipient equine animals not in contact with animals of susceptible species shall not be restricted.
6. Equestrian exercises on holdings in the protection and surveillance zone not keeping animals of susceptible animals shall be authorized in the protection zone, subject to appropriate cleansing and disinfection measures, and shall not be restricted on premises situated in the surveillance zone.
7. The use of equidae not in contact with animals of susceptible species in the protection zone shall not be restricted.
8. Visits from owners of equidae, riding-school students, the veterinary surgeon, the inseminator and the farrier on holdings keeping animals of susceptible species in the protection and surveillance zones but not subject to the restrictions provided for in Articles 4 and 10 shall be subject to the following conditions:
 - 8.1. equidae are kept separated from animals of susceptible species and access of the persons referred to above to animals of susceptible species is effectively prevented
 - 8.2. all visitors must be registered;
 - 8.3. cleansing and disinfecting of means of transportation of equidae and of the boots of visitors.

ANNEX VII

**TREATMENT OF MEAT AND MEAT PRODUCTS TO ENSURE THE DESTRUCTION OF
FOOT-AND-MOUTH DISEASE VIRUS**

Treatment recognised effective to destroy foot-and-mouth disease virus
Heat treatment in a hermetically sealed container with an F ₀ value of 3.00 or more
Heat treatment at a minimum temperature of 70°C, which must be reached throughout the meat
Heat treatment at a minimum temperature of 80°C which must be reached throughout the meat.
Heat treatment in a hermetically sealed container to at least 60°C for a minimum of 4 hours, during which time the core temperature must be at least 70°C for 30 minutes.
Heat treatment ensuring a core temperature of at least 65°C is reached for the time necessary to achieve a pasteurisation value (pv) equal to or more than 40.
Natural fermentation and maturation of not less than 9 months for boneless meat and meat on the bone, resulting in the following characteristics: <ul style="list-style-type: none">• aw value of not more than 0.93, and• pH value of not more than 6.0. All the necessary measures must be taken to avoid cross contamination.
Industrial salami processing in accordance with criteria to be laid down by the procedure of the Standing Committee on the Food Chain and Animal Health, following the opinion of the relevant Scientific Committee.

ANNEX VIII

TREATMENT OF FRESH MEAT

1. De-boned fresh meat:

Meat as described in Article 2 (a) of Council Directive 64/433/EEC together with diaphragms but excluding offal, from which the bone and the main accessible lymphatic glands have been removed.

2. Trimmed offal:

- heart from which lymphatic glands, connective tissue and adhering fat have been completely removed,
- liver from which lymphatic glands, adhering connective tissue and fat have been completely removed,
- whole masseter muscles, incised in accordance with paragraph 41 (a) of Chapter VIII of Annex I to Directive 64/433/EEC, from which lymphatic glands, connective tissue and adhering fat have been completely removed,
- tongues with epithelium and without bone, cartilage and tonsils,
- lungs from which the trachea and main bronchi and the mediastinal and bronchial lymphatic glands have been removed,
- other offal without bone or cartilage from which lymphatic glands, connective tissue, adhering fat and mucous membrane have been completely removed.

3. Maturation

- maturation of carcasses at a temperature of more than +2°C for at least 24 hours
- pH value in the middle of *Longissimus dorsi* muscle recorded as less than 6.0.

4. Effective measures must be applied to avoid cross contamination.

ANNEX IX

TREATMENT OF MILK TO ENSURE DESTRUCTION OF FOOT-AND-MOUTH VIRUS

PART A

MILK FOR HUMAN CONSUMPTION

The following treatments are recognised to provide sufficient guaranties with regard to the destruction of the foot-and-mouth disease virus in milk and milk products for human consumption. Necessary precautions must be taken to avoid contact of the milk or milk products with any potential source of foot-and-mouth virus after processing.

1. Milk for human consumption must be subject to at least one of the following treatments:
 - 1.1. sterilisation at a level of at least F₀₃,
 - 1.2. single UHT⁽¹⁾ treatment,
 - 1.3. double HTST⁽²⁾ treatment of milk with a pH above 7.0,
 - 1.4. single HTST treatment of milk with a pH below 7.0,
 - 1.5. single HTST combined with another physical treatment by:
 - 1.5.1. either lowering the pH below 6 for at least one hour, or
 - 1.5.2. additional heating to 72°C or more, combined with desiccation.
2. Milk products must either undergo one of the above treatments or be produced from milk treated in accordance with paragraph 1.

(¹) UHT = Ultra High Temperature treatment at 130°C for 2-3 sec.

(²) HTST = High Temperature Short Time pasteurisation at 72°C for 15-17 sec or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test.

PART B

MILK NOT INTENDED FOR HUMAN CONSUMPTION AND MILK FOR ANIMAL CONSUMPTION

The following treatments are recognised to provide sufficient guaranties with regard to the destruction of the foot-and-mouth disease virus in milk and milk products not intended for human consumption. Necessary precautions must be taken to avoid contact of the milk or milk products with any potential source of foot-and-mouth virus after processing.

1. Milk not intended for human consumption and milk intended for animal consumption must be subject to at least one of the following treatments:
 - 1.1. sterilisation at a level of at least F₀₃,
 - 1.2. single UHT ⁽¹⁾ combined with another physical treatment referred to in either paragraph 1.4.1. or 1.4.2.
 - 1.3. double HTST ⁽²⁾,
 - 1.4. single HTST combined with another physical treatment by
 - 1.4.1. either lowering the pH below 6 for at least one hour, or
 - 1.4.2. additional heating to 72°C or more, combined with desiccation.
2. Whey to be fed to pigs and produced from milk treated as described in paragraph 1 must be collected at least 16 hours after milk clotting and its pH must be recorded as <6.0 before transport to pig holdings.

⁽¹⁾ UHT = Ultra High Temperature treatment at 130°C for 2-3 sec.

⁽²⁾ HTST = High Temperature Short Time pasteurisation at 72°C for 15-17 sec or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test.

ANNEX X

CRITERIA FOR THE DECISION TO APPLY PROTECTIVE VACCINATION AND GUIDELINES FOR THE EMERGENCY VACCINATION PROGRAMMES

1. CRITERIA FOR THE DECISION TO INTRODUCE EMERGENCY VACCINATION

Taking into account the additional criteria in point 2, emergency vaccination shall be introduced, if for more than two consecutive days:

- (a) infected herds on holdings referred to in Article 10 cannot be stamped out within 24 hours after the confirmation of the disease, and
- (b) the pre-emptive killing of animals likely to be infected or contaminated cannot be safely carried out within less than 48 hours.

2. ADDITIONAL CRITERIA FOR THE DECISION TO APPLY PROTECTIVE VACCINATION

Criteria	Decision	
	For vaccination	Against vaccination
Population density of susceptible animals	High	Low
Clinically affected species	Predominantly pigs	Predominantly ruminants
Movement of potentially infected animals or products out of the protection zone	Evidence	No evidence
Predicted airborne spread of virus from infected holdings	High	Low or absent
Suitable vaccine	Available	Not available
Origin of outbreaks (traceability)	Unknown	Known
Incidence slope of outbreaks	Rising rapidly	Shallow or slow rise
Distribution of outbreaks	Widespread	Restricted
Public reaction to total stamping out policy	Strong	Weak
Acceptance of regionalisation after vaccination	Yes	No

3. CRITERIA FOR THE DEFINITION OF DENSELY POPULATED LIVESTOCK AREAS

When deciding about the measures to be taken in application of this Directive, and in particular the measures provided for in Article 52 (2), Member States shall in addition to a thorough epidemiological assessment consider the provisional definitions of densely populated livestock areas (DPLA) for the relevant species of susceptible animals predominantly kept in the area in question and use the definition which is the more stringent.

The provisional definition may be modified in the light of new scientific evidence in accordance with the procedure referred to in Article 89 (2).

4.1. Porcine animals:

In the case of pigs a DPLA is a geographical area with a radius of 10 km around a holding containing susceptible animals suspected of or infected with foot-and-mouth disease, where there is a pig density higher than 800 pigs per km². The holding in question must be situated either in a sub-region as defined in Article 2 (s) where there is a density of pigs higher than 300 pigs per km² or at a distance of less than 20 km from such a sub-region.

4.2. Bovine animals:

In the case of bovine animals a DPLA is a geographical area with a radius of 10 km around a holding containing susceptible animals suspected of or infected with foot-and-mouth disease, where there is a cattle density higher than 1000 head per km². The holding in question must be situated either in a sub-region as defined in Article 2 (s) where there is a density of cattle higher than 450 head per km² or at a distance of less than 20 km from such a sub-region.

ANNEX XI**PART A****NATIONAL LABORATORIES
AUTHORISED TO HANDLE LIVE FOOT-AND-MOUTH DISEASE VIRUS**

MEMBER STATE WHERE LABORATORY IS SITUATED	LABORATORY	MEMBER STATES USING THE SERVICES OF LABORATORY
BELGIUM	Veterinary and Agrochemical Research Centre CODA-CERVA-VAR	BELGIUM LUXEMBOURG
DENMARK	Danish Veterinary Institute Department of Virology Lindholm DK- 4771 Kalvehave	DENMARK FINLAND SWEDEN
FEDERAL REPUBLIC OF GERMANY	Bundesforschungsanstalt für Viruskrankheiten der Tiere, <ul style="list-style-type: none"> • Anstaltsteil Tübingen • Anstaltsteil Friedrich Loeffler Institute, Insel Riems 	GERMANY
GREECE	Institoýto Afthódoys Pyretoý, Agía Paraskeví Attikís	GREECE
SPAIN	Laboratorio Central de Sanidad Animal, Madrid	SPAIN
FRANCE	Agence Francaise de Securite Sanitaire des Aliments (AFSSA) <ul style="list-style-type: none"> • Laboratoire d'études et de recherches en pathologie bovine et hygiene des viandes, Lyon • Laboratoire d'études et de recherches en pathologie animale et zoonoses, Maison- Alfort 	FRANCE
ITALY	Istituto zooprofilattico sperimentale della Lombardia e dell'Emilia Romagna, Brescia 25124 Brescia	ITALY
NETHERLANDS	ID-Lelystad Institute for Animal Health POBox 65 8200 AB Lelystad	NETHERLANDS
AUSTRIA	Österreichische Agentur für Gesundheit und Ernährungssicherheit Veterinärmedizinische Untersuchungen Mödling	AUSTRIA
PORTUGAL	Laboratório Nacional de Investigação Veterinária, Lisboa	PORTUGAL
UNITED KINGDOM	Institute for Animal Health, Pirbright, Woking, Surrey	UNITED KINGDOM IRELAND SWEDEN FINLAND

PART B

LABORATORIES AUTHORISED TO HANDLE LIVE FOOT-AND-MOUTH VIRUS FOR VACCINE PRODUCTION

MEMBER STATE	MANUFACTURER
GERMANY	Bayer AG Osteratherstraße 1a D-50739 Köln
FRANCE	Meriel, S.A.S., Laboratoire IFFA 29 avenue Tony Garnier F- 69349 Lyon Cedex 07
NETHERLANDS	ID-Lelystad Institute for Animal Health POBox 65 8200 AB Lelystad
UNITED KINGDOM	Meriel, S.A.S., Pirbright Laboratory Ash Road Pirbright, Woking, Surrey.

ANNEX XII

BIOSECURITY STANDARDS

1. The laboratories and establishments handling live foot-and-mouth disease virus must meet or exceed the minimum requirements laid down in the “Minimum standards for Laboratories working with foot-and-mouth virus in vitro and in vivo” established by the European Commission for the control of foot-and-mouth disease, 26th session, Rome, April 1985, as modified in 1993.
2. The laboratories and establishments handling live foot-and-mouth disease virus must be subject to at least two inspections within five years, with one of the inspections being carried out unannounced.
3. The inspection team shall comprise at least of
 - one expert from the Commission,
 - one expert in foot-and-mouth disease,
 - one independent expert for questions of bio-security in laboratories working with microbiological hazards.
4. The inspection team shall submit a report to the Commission and the Member States in accordance with the provisions set up in Commission Decision 98/139/EC.

ANNEX XIII

DIAGNOSTIC TESTS FOR FOOT-AND-MOUTH DISEASE AND FOR THE DIFFERENTIAL DIAGNOSIS OF OTHER VESICULAR VIRUS DISEASES

In the context of this Annex, a 'test' refers to a laboratory diagnostic procedure and a 'standard' to a reference reagent that has become an internationally accepted standard following a procedure of comparative testing carried out in several different laboratories.

1. Recommended procedures

Diagnostic tests described in the "Manual of Standards for Diagnostic Tests and Vaccines" of the Office International des Epizooties (OIE), hereinafter the "OIE Manual", as the 'Prescribed Tests' for international trade, constitute the reference tests for vesicular disease diagnosis within the Community. National Laboratories must adopt standards and tests at least as stringent as those defined in the OIE Manual.

The Commission may, in accordance with the procedure referred to in Article 89 (2) decide to adopt more stringent testing procedures than those defined in the OIE Manual.

2. Alternative procedures

The use of tests defined in the OIE Manual as 'Alternative Tests', or other tests not included in the OIE Manual, is permitted provided that the performance of the test has been shown to match or exceed the sensitivity and specificity parameters laid down in the OIE Manual or in the annexes to Community legislation, whichever is the more stringent.

National Laboratories generating results for the purposes of national, intra-Community or international trade must generate and store the necessary records demonstrating compliance of their testing procedures with the relevant OIE or Community requirements.

3. Standards and quality control

National Laboratories shall participate in periodic standardisation and external quality assurance exercises organised by the Community Reference Laboratory.

In the framework of such exercises, the Community Reference Laboratory may take account of the results achieved by a National Laboratory which has within a reasonable timespan participated in a quality assurance exercise organised by one of the international organisations responsible for external quality assurance of vesicular virus disease diagnosis, such as OIE, the Food and Agriculture Organization (FAO) of the United Nations or the International Atomic Energy Agency.

National Laboratories shall operate internal quality assurance programmes. The specification of such programmes may be laid down in accordance with the procedure referred to in Article 89 (2). Pending the adoption of detailed provisions, the specifications in the OIE Guidelines for Laboratory Quality Evaluation shall apply (OIE Standards Commission, September 1995).

As part of quality assurance, National Laboratories shall demonstrate compliance of the tests in routine use with the requirements for sensitivity and specificity defined in the OIE Manual, or in Annexe XIV of this directive, whichever is more stringent.

4. Procedures for adoption and review of tests and standards for vesicular virus disease diagnosis.

Tests and standards for vesicular virus disease diagnosis shall be adopted in accordance with the procedure referred to in Article 89 (2).

The Commission may consider the scientific advice produced by the meetings of the National Laboratories to be organised by the Community Reference Laboratory.

5. Compliance procedure

Data from standardisation and external quality assurance exercises organised by the Community Reference Laboratory shall be assessed at the annual meetings of the National Laboratories and communicated to the Commission for review of the list of National Laboratories as laid down in Part A of Annex XI.

Those laboratories whose tests do not meet the prescribed requirements for sensitivity and specificity shall be required by the Commission to adapt their procedures within an appropriate period of time to ensure that these requirements are met. Failure to demonstrate the required level of proficiency within the time limit required shall result in loss of recognition within the Community of all testing performed after that deadline.

6. Selection and transportation of samples

An aliquot of field material should be sent to one of the laboratories listed in Part A of Annex XI. However, where such samples are not available or not suitable for transport, animal passage material, obtained from the same host species, or low passage cell culture material is acceptable.

The history of animal or cell passage material should be provided.

Samples for vesicular virus diagnosis can be transported at 4°C if the anticipated transport time to the recipient laboratory is less than 24 hours.

For oesophageal-pharyngeal (probang) samples, transportation above solid carbon dioxide or liquid nitrogen is recommended, especially if delays at airports cannot be excluded.

Special precautions are required for the safe packaging of material from suspect cases of foot-and-mouth disease both within and between countries. These regulations are mainly designed to prevent breakage or leakage of containers and the risk of contamination, but are also important to ensure that specimens arrive in a satisfactory state. Ice-packs are preferred to wet ice to prevent the possibility of escape of water from the package.

Prior notice of arrival, and agreement for receipt, must be arranged with the receiving laboratory before despatch of samples.

Compliance with the import and export regulations of the Member States involved must be ensured.

ANNEX XIV

STANDARDS FOR THE DIAGNOSIS OF FOOT-AND-MOUTH DISEASE AND FOR THE DIFFERENTIAL DIAGNOSIS OF OTHER VESICULAR VIRUS DISEASES

In the context of this Annex, a 'test' refers to a laboratory diagnostic procedure and a 'standard' to a reference reagent that has become an internationally accepted standard following a procedure of comparative testing carried out in several different laboratories.

The protocols specified in the "Manual of Standards for Diagnostic Test and Vaccines" of the O.I.E. provide reference procedures for virus isolation, antigen detection and antibody detection for vesicular diseases.

1. FOOT AND MOUTH DISEASE

1.1. Antigen detection

The standards for detecting foot-and-mouth disease virus antigen shall be established in accordance with the procedure referred to in Article 89 (2) after consultation of the Community Reference Laboratory.

Standardised, inactivated antigens of all seven serotypes are available from the OIE/FAO World Reference Laboratory (WRL) for foot-and-mouth disease.

National Laboratories should ensure that their antigen detection system complies with these minimum standards. They shall where necessary receive advice from the Community Reference Laboratory on the dilutions of these antigens to be used as strong and weak positive controls.

1.2. Virus isolation

The standards for foot-and-mouth disease virus detection shall be established in accordance with the procedure referred to in Article 89 (2) after consultation of the Community Reference Laboratory.

Isolates of foot-and-mouth disease virus are available from the WRL for foot-and-mouth disease.

National Laboratories shall ensure that the tissue culture systems in use for foot-and-mouth virus isolation are sensitive to the full range of serotypes and strains for which the laboratory maintains a diagnostic capacity.

1.3. Nucleic acid detection methods

The standards for the detection of foot-and-mouth disease viral RNA shall be established in accordance with the procedure referred to in Article 89 (2) after consultation of the Community Reference Laboratory.

The Commission may arrange that for future standardisation, comparative testing of the sensitivity of RNA detection methods is carried out between National Laboratories.

The Commission may arrange that, taking into account the practical difficulties of storing nucleic acids for prolonged periods of time, standardised quality assurance reagents for the detection of foot-and-mouth viral RNA will become available from the Community Reference Laboratory.

1.4. Antibody detection (structural proteins)

The standards for the detection of antibody to foot-and-mouth disease virus shall be established in accordance with the procedure referred to in Article 89 (2) after consultation of the Community Reference Laboratory.

Standardised antisera for foot-and-mouth disease virus types O1-Manisa, A22-Iraq and C-Noville have been defined by the 'FAO Phase XV Standardisation Exercise in foot-and-mouth disease antibody detection' in 1998.

The Commission may arrange that standardised reference sera for all the main antigenic variants of foot-and-mouth disease virus are adopted as a result of standardisation exercises between the Community Reference Laboratory and the National Laboratories. These reference sera will be adopted as the standards for use by National Laboratories within the Community.

1.5. Antibody detection (non-structural proteins)

The standards for the detection of antibody to foot-and-mouth disease virus shall be established in accordance with the procedure referred to in Article 89 (2) after consultation of the Community Reference Laboratory.

The Commission may arrange that standardised reference sera are adopted as a result of standardisation exercises between the Community Reference Laboratory and the National Laboratories. These reference sera will be adopted as the standards for use by National Laboratories within the Community.

2. **SWINE VESICULAR DISEASE (SVD)**

Diagnosis of SVD must be carried out in accordance with Commission Decision 2000/428/EC.

3. **OTHER VESICULAR DISEASES**

Where necessary, the Commission may arrange that standards for the laboratory diagnosis of vesicular stomatitis or vesicular exanthema of swine are established in accordance with the procedure referred to in Article 89 (2).

Member States may maintain the laboratory capacity to diagnose the vesicular virus diseases other than foot-and-mouth disease and SVD, i.e. vesicular stomatitis and vesicular exanthema of swine.

National Laboratories wishing to maintain a diagnostic capacity for these viruses can obtain reference reagents from the World Reference Laboratory for foot-and-mouth disease, Pirbright or from the relevant OIE Reference Laboratory.

ANNEX XV

FUNCTIONS AND DUTIES OF NATIONAL LABORATORIES

The functions and duties of National Laboratories referred to in Article 68 for foot-and-mouth and other vesicular diseases shall be as follows:

1. All laboratories in Member States handling live foot-and-mouth disease virus must operate under high security conditions laid down in 'Minimum Standards for Laboratories working with foot-and-mouth disease virus *in vitro* and *in vivo*', European Commission for the Control of Foot-and-Mouth Disease – 26th Session, Rome, 1985, as amended by Appendix 6 (ii) of the Report of the 30th Session, Rome, 1993.
2. National Laboratories must provide an uninterrupted service for diagnosing vesicular viral diseases and must be equipped and skilled for providing a rapid initial diagnosis.
3. Laboratories must keep inactivated reference strains of all serotypes of foot-and-mouth disease virus, and immune sera against the viruses, as well as all other reagents necessary for a rapid diagnosis. Appropriate cell cultures should be in constant readiness for confirming a negative diagnosis.
4. National Laboratories must be equipped and skilled for large-scale serological surveillance.
5. In all suspected primary outbreaks appropriate samples must be collected and quickly transported, according to a set protocol, to a National Laboratory. In anticipation of a suspicion of foot-and-mouth disease, the National Authority shall ensure that the necessary equipment and materials for sample collection and transportation to a National Laboratory are stored in readiness at local sites.
6. Antigenic typing and genomic characterisation must be carried out on all viruses responsible for new incursions into the Community. This can be performed by the National Laboratory, if facilities exist, or, at the earliest possible occasion, the National Laboratory must send a sample of virus from the primary case to the Community Reference Laboratory for confirmation and further characterisation, including advice on the antigenic relationship of the field strain to vaccine strains in the Community Vaccine Banks. The same procedure should be followed for viruses received by National Laboratories from third countries in situations where characterisation of the virus is likely to be of benefit to the Community.
7. National Laboratories should provide disease data to their State Veterinary Service, which shall provide these data to the Community Reference Laboratory.
8. National Laboratories should collaborate with the Community Reference Laboratory in ensuring that members of the field section of State Veterinary Services have the opportunity of seeing clinical cases of foot-and-mouth disease in National Laboratories as part of their training.

9. National Laboratories shall collaborate with the Community Reference Laboratory and other National Laboratories to develop improved diagnostic methods and exchange relevant materials and information.
10. National Laboratories shall participate in external quality assurance and standardisation exercises organised by the Community Reference Laboratory.
11. National Laboratories shall use tests and standards that meet or exceed the criteria laid down in Annexes XIII and XIV respectively. National Laboratories shall provide the Commission on request with data proving that the tests in use meet or exceed the requirements.
12. National Laboratories should have the competence to identify all vesicular disease viruses and encephalomyocarditis virus in order to avoid delays in diagnosis and consequently in implementing control measures by the competent authorities.
13. National Laboratories shall cooperate with other laboratories designated by the competent authorities for performing tests, for example serological tests, that do not involve handling of live foot-and-mouth disease virus. These laboratories shall not carry out virus detection in samples taken from suspect cases of vesicular diseases. Such laboratories need not to comply with the bio-security standards referred to in Annex XII point 1, but must have established procedures which ensure that the spread of possible foot-and-mouth disease virus is effectively prevented.

Samples giving inconclusive results in tests carried out by must be passed on to the National Reference Laboratory for carrying out confirmatory tests.

ANNEX XVI

FUNCTIONS AND DUTIES OF A COMMUNITY REFERENCE LABORATORY FOR FOOT-AND-MOUTH DISEASE

The functions and duties of the Community Reference Laboratory referred to in Article 69 for foot-and-mouth disease shall be as follows:

1. To ensure liaison between the national laboratories of the Member States and to provide optimal methods for the diagnosis of foot-and-mouth disease in livestock, and differential diagnosis of other vesicular viral diseases, where necessary, for each Member State specifically by:
 - 1.1. regularly receiving field samples from Member States and countries geographically or commercially linked to the European Union in terms of trade in animals of susceptible species or products derived from such animals with a view to monitoring the disease situation globally and regionally, to estimating and where possible predicting the risk evolving from emerging virus strains and particular epidemiological situations and determining the identity of the virus, where necessary in close collaboration with OIE designated regional reference laboratory and the World Reference Laboratory;
 - 1.2. typing and full antigenic and genomic characterisation of vesicular viruses from the samples referred to in point 1.1. and communicating the results of such investigations without delay to the Commission, the Member State, and the National Laboratory concerned;
 - 1.3. building up and maintaining an up-to-date collection of vesicular virus strains;
 - 1.4. building up and maintaining a collection of specific sera against vesicular virus strains;
 - 1.5. advising the Commission on all aspects related to foot-and-mouth disease vaccine strain selection and use.
2. To support the functions of National Laboratories, in particular by:
 - 2.1. storing and supplying National Laboratories with reagents and materials for use in diagnosis of foot-and-mouth disease such as virus and/or inactivated antigens, standardised sera, cell lines and other reference reagents;
 - 2.2. retaining expertise on foot-and-mouth disease virus and other pertinent viruses to enable rapid differential diagnosis;
 - 2.3. promoting harmonisation of diagnosis and ensuring proficiency of testing within the Community by organising and operating periodic comparative trials and external quality assurance exercises on foot-and-mouth disease diagnosis at Community level and the periodic transmission of the results of such trials to the Commission, the Member States, and National Laboratories;

- 2.4. carrying out research studies with the objective of developing improved methods of disease control in collaboration with National Laboratories and as agreed in the annual work plan of the Community Reference Laboratory.
3. To provide information and carry out further training, in particular by:
 - 3.1. gathering data and information on the methods of diagnosis and differential diagnosis used in National Laboratories and the distribution of such information to the Commission and the Member States;
 - 3.2. making and implementing the necessary arrangements for the further training of experts in laboratory diagnosis with a view to harmonising diagnostic techniques;
 - 3.3. keeping abreast of developments in foot-and-mouth disease epidemiology;
 - 3.4. organising an annual meeting where representatives of the National Laboratories may review diagnostic techniques and the progress of co-ordination.
4. To perform experiments and field trials in consultation with the Commission directed towards an improved control of foot-and-mouth disease.
5. To review at the annual meeting of National Reference Laboratories the contents of Annexes XIII and XIV defining the tests and standards for foot-and-mouth disease diagnosis within the European Union.
6. To cooperate with the national reference laboratories of candidate countries in accordance with this Annex.
7. The Community Reference Laboratory shall operate according to recognised conditions of strict disease security as indicated in 'Minimum Standards for Laboratories working with foot-and-mouth disease virus *in vitro* and *in vivo*', European Commission for the control of foot-and-mouth disease - 26th Session, Rome, April 1985, as amended by Appendix 6(ii) of the report to the 30th Session of the European Commission for the control of foot-and-mouth disease 1993, referred to in Annex XII to this Directive.
8. The Community Reference Laboratory shall provide assistance to the Commission as required on the disease security measures to be taken by the National Laboratories in matters of foot-and-mouth disease diagnosis.

ANNEX XVII

CRITERIA AND REQUIREMENTS FOR CONTINGENCY PLANS

Member States shall ensure that contingency plans meet at least the following requirements:

1. Provision shall be made to ensure the legal powers necessary for the implementation of contingency plans and allow for a rapid and successful eradication campaign.
2. Provision shall be made for access to emergency funds, budgetary powers and financial resources to cover the cost of dealing with all aspects of a foot-and-mouth disease epizootic.
3. A chain of command shall be established guaranteeing a rapid and effective decision-making process for dealing with foot-and-mouth disease epizootics. A central decision-making unit shall be in charge of the overall direction of control strategies and the chief veterinary officer shall be a member of this unit.
4. Each Member State must be prepared to immediately establish a functional national disease control centre in the event of an outbreak, which shall co-ordinate the implementation of all decisions taken in the central decision-making unit. A permanently operational co-ordinator shall be appointed to guarantee the prompt establishment of the centre.
5. Detailed plans shall be available to enable a Member State to be prepared for the immediate set-up of local disease control centres in the event of foot-and-mouth disease outbreaks in order to implement disease control and environment protection measures at a local level.
6. Member States shall ensure the co-operation between the national disease control centre, the local disease control centres and environmental competent authorities and bodies in order to ensure that actions on veterinary and environmental safety issues are appropriately co-ordinated.
7. A permanently operational expert group shall be created to maintain expertise and assist the relevant authority in qualitative disease preparedness.
8. Provision must be made for adequate resources to ensure a rapid and effective campaign, including personnel, equipment and laboratory capacity.
9. An up- to- date operations manual shall be available. It shall describe in detail and in a comprehensive and practical way all the actions procedures, instructions and control measures to be employed in handling an outbreak of foot-and-mouth disease.
10. Detailed plans shall be available for emergency vaccination.
11. Staff shall be regularly involved in:
 - 11.1. training in clinical signs, epidemiological enquiry and control of epizootic diseases,
 - 11.2. real- time alert exercises, conducted on at least a biennial basis,

- 11.3. training in communication skills to provide ongoing disease awareness campaigns for authorities, farmers and veterinarians.
12. Contingency Plans shall be prepared taking into account the resources needed to control a large number of outbreaks occurring within a short time and caused by several antigenically distinct serotypes or strains as it may be necessary amongst others in the case of deliberate release of foot-and-mouth disease virus.
13. Without prejudice to veterinary requirements, contingency plans shall be prepared with a view to ensuring that in the event of an outbreak of foot-and-mouth disease, any mass disposal of animal carcasses and animal waste is done without endangering human health and without using processes or methods which could harm the environment and in particular:
 - (i) without risk to soil, air, surface and groundwater, to plants and animals,
 - (ii) without causing a nuisance through noise or odours,
 - (iii) without adversely affecting the countryside or places of special interest.
14. Such plans shall include the identification of appropriate sites and undertakings for the treatment or disposal of animal carcasses and animal waste in the event of an outbreak.

ANNEX XVIII

PART A

1. Directive 85/511/EEC and its successive amendments:
 - 1.1. Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot- and-mouth disease.
 - 1.2. Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease, 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 countries¹.
2. Implementing Council Decisions
 - 2.1. Council Decision 89/531/EEC of 25 September 1989 designating a reference laboratory for the identification of foot-and-mouth disease virus and determining the functions of that laboratory².
 - 2.2. Council Decision 91/665/EEC of 11 December 1991 designating a Community Co-ordinating Institute for foot-and-mouth disease vaccine and laying down its functions³.

PART B

Deadlines for transposition into national law

Directive	Deadline for transposition
85/511/EEC	1 January 1987
90/423/EEC	1 January 1992

¹ OJ L 224, 18.8.1990, p. 13.

² OJ L 279, 28.9.1989, p. 32.

³ OJ L 368, 31.12.1991, p. 19.

ANNEX XIX

Correlation Table

This Directive	Directive 85/511/EEC
Article 1, paragraph 1 (a)	Article 1
Article 1, paragraph 1 (b)	-
Article 1, paragraph 2	-
Article 2 (a)	Article 2 (a)
Article 2 (b) to (h) and (l) to (x)	-
Article 2 (i)	Article 2 (d)
Article 2 (j)	Article 2 (e)
Article 2 (k)	Article 2 (c)
Article 3 (1) (a)	Article 3
Article 3 (1) (b) and (c)	-
Article 3 (2)	-
Article 4 (1)	-
Article 4 (2)	Article 4 (1), first sub-paragraph
Article 4 (3) first sentence	Article 4 (1) second sub-paragraph
Article 4 (3) (a)	Article 4 (1) second sub- paragraph first indent, first part of sentence
Article 4 (3) (b)	Article 4 (1) second sub- paragraph first indent, second part of sentence
Article 4 (3) (c)	-
Article 4 (3) (d)	Article 4 (1) second sub-paragraph second and third indent
Article 4 (3) (e)	Article 4 (1) second sub-paragraph ninth indent
Article 4 (3) (f)	Article 4 (1) second sub-paragraph tenth indent

This Directive	Directive 85/511/EEC
Article 5 (1) (a)	Article 4 (1) second sub-paragraph fifth indent
Article 5 (1) (b)	Article 4 (1) second sub-paragraph fourth indent
Article 5 (1) (c)	Article 4 (1) second sub-paragraph seventh indent
Article 5 (1) (d)	Article 4 (1) second sub-paragraph eighth indent
Article 5 (2)	Article 4 (1) second sub-paragraph sixth indent
Article 5 (3)	-
Article 6	Article 4 (2)
Article 7	-
Article 8	-
Article 9	Article 4 (3)
Article 10 (1) (a) first sentence	Article 5 (2) first indent
Article 10 (1) (a) second sentence	-
Article 10 (1) (b) first subparagraph	Article 5 (1)
Article 10 (1) (b) second subparagraph	Article 5 (3)
Article 10 (1) (c) first sentence	Article 5 (2) second and fourth indent
Article 10 (1) (c) second and third sentences	-
Article 10 (1) (d)	Article 5 (2) fifth and sixth indent
Article 10 (2) (a)	Article 5 (2) seventh indent
Article 10 (2) (b)	-
Article 10 (2) (c)	Article 5 (2) eighth indent
Article 11 (1)	Article 10
Article 11 (2)	-
Article 11 (3)	-

This Directive	Directive 85/511/EEC
Article 11 (4)	-
Article 12 (relating to meat)	Article 5 (2) third indent
Article 12 (relating to other substances)	-
Article 13 (1)	Article 5 (2) ninth indent and Article 7
Article 13 (2)	-
Article 15	-
Article 16	-
Article 17	-
Article 18 (1)	Article 6
Article 18 (2)	Decision 88/397/EEC
Article 18 (3)	Article 6 (1) second subparagraph
Article 18 (4)	-
Article 19	Article 8
Article 20	Article 6 (3)
Article 21 (1)	-
Article 21 (2)	Article 9 (1)
Article 21 (3)	-
Article 21 (4)	-
Article 22 (1) (a)	Article 9 (2) (a) first indent
Article 22 (1) (b)	Article 9 (2) (a) second indent
Article 22 (1) (c)	Article 9 (2) (a) third indent first part of sentence
Article 22 (2)	Article 9 (2) (a) third indent second part of sentence
Article 23 (a), (b) and (c)	Article 9 (2) (a) fourth to sixth indent

This Directive	Directive 85/511/EEC
Article 24 (1) (a)	Article 9 (2) (a) seventh indent first part of sentence
Article 24 (1) (b) and (c)	-
Article 24 (2) (a)	Article 9 (2) (a) seventh indent last part of sentence
Article 24 (2) (b)	-
Article 25	-
Article 26	-
Article 27	-
Article 28	-
Article 29	-
Article 30	-
Article 31	-
Article 32	-
Article 33	-
Article 34	-
Article 35	-
Article 36	Article 9 (2) (b)
Article 37 (1)	Article 9 (3) (a)
Article 37 (2)	-
Article 38 (1)	-
Article 38 (2) (a)	Article 9 (3) (a) second indent
Article 38 (2) (b)	-
Article 38 (3)	-
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Article 40	-
Article 41	-

This Directive	Directive 85/511/EEC
Article 42	-
Article 43	-
Article 44	Article 9 (3) (b)
Article 45	-
Article 46	-
Article 47 (1)	Article 12, first indent first sentence
Article 47 (2)	Article 12, first indent second and third sentence
Article 48	Article 12, second and third indent
Article 49 (a)	Article 13 (1) first indent
Article 49 (b)	Article 13 (1) third indent
Article 49 (c) and (d)	-
Article 50 (1) (a)	Article 13 (3) first sub-paragraph first sentence
Article 50 (1) (b), (c) and (d)	-
Article 50 (2)	-
Article 50 (3)	Article 13 (3) second sub-paragraph
Article 50 (4) and (5)	Article 13 (3) third sub-paragraph
Article 51 (1)	Article 13 (3) first sub-paragraph first to sixth indent
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Article 55	-
Article 56	-
Article 57	-

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Article 60	-
Article 61	-
Article 62	-
Article 63	-
Article 64	-
Article 65 (a), (b) and (c)	Article 13 (1) second indent
Article 65 (d)	Article 13 (1) fourth indent
Article 66	Article 13 (2) first and second sub- paragraph
Article 67	Article 13 (2) second sub-paragraph
Article 68(1) (a) and (b)	Article 11 (1) first indent
Article 68 (1) (c) and (e)	Article 11 (1) second and third indent
Article 68 (1) (d)	-
Article 68 (2), (3) and (4)	-
Article 69	Council Decision 89/531/EEC
Article 70 (1)	-
Article 70 (2)	Article 13 (2) third sub-paragraph
Article 71	-
Article 72	Article 5 of Directive 90/423/EEC
Article 73	-
Article 74	-
Article 75	-
Article 76	-
Article 77	-
Article 78	-

This Directive	Directive 85/511/EEC
Article 79 (1)	Article 14 (1) first sub-paragraph second half sentence
Article 79 (2)	Article 14 (1) third sub-paragraph second half sentence
Article 79 (3)	Article 14 (1) second sub-paragraph third part of sentence
Article 79 (4)	-
Article 80	Council Decision 91/666/EEC
Article 81	-
Article 82	-
Article 83	-
Article 84	Council Decision 91/665/EEC
Article 85	-
Article 86	-
Article 87	-
Article 88	-
Article 89	Articles 16 and 17
Article 90	-
Article 91	-
Article 92 (1)	Article 6 of Council Directive 90/423/EEC
Article 92 (2) and (3)	-
Article 93	Article 19
Article 94	-
Article 95	Article 20
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This Directive	Directive 85/511/EEC
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Annex IX Part A	-
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Annex XVI	Council Decision 89/531/EEC
Annex XVII	Commission Decision 91/42/EEC
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Financial Statement	-

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): Health and Consumer Protection

Activit(y/ies): Control measures for foot-and-mouth disease

**TITLE OF ACTION: COUNCIL DIRECTIVE 2003/.../EC OF ...ON COMMUNITY MEASURES
FOR THE CONTROL OF FOOT-AND-MOUTH DISEASE**

1. BUDGET LINE(S) + HEADING(S)

- A-703 Standing Committees (and their sections) referred to in the relevant articles of the above mentioned Directive (ABB Code: 17010210)
- A-11 Staff in active employment (ABB Code: 170101)
- B1-3310 Other Animal Health Measures (ABB Code: 170402)
- B1-3320 Emergency Fund (ABB Code: (170403)

2. OVERALL FIGURES

2.1. Total allocation for action (Part B): 14,700 € million for commitment

No new financial implications

The legal base for Community contributions to measures for the control and prevention of foot-and-mouth disease are laid down in Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field, and in particular Articles 11 to 15 thereof (OJ 224, 18.8.1990, p. 19)

2.2. Period of application:

Duration of measures is unlimited, however for the purpose of calculation a period of ten years is considered

2.3. Overall multiannual estimate of expenditure:

- (a) Schedule of commitment appropriations/payment appropriations (financial intervention) (see point 6.1.1)

€ million (to three decimal places)

	Year [n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Commitments	2.450	2.450	2.450	2.450	2.450	2.450 every year	14.700
Payments	2.450	2.450	2.450	2.450	2.450	2.450 every year	14.700

- (b) Technical and administrative assistance and support expenditure (see point 6.1.2)

Commitments	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Payments	0.000	0.000	0.000	0.000	0.000	0.000	0.000

Subtotal a+b							
Commitments	2.450	2.450	2.450	2.450	2.450	2.450 every year	14.700
Payments	2.450	2.450	2.450	2.450	2.450	2.450 every year	14.700

- (c) Overall financial impact of human resources and other administrative expenditure (see points 7.2 and 7.3)

Commitments/ payments	0.246	0.246	0.246	0.246	0.246	0.246 every year	1.476
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TOTAL a+b+c							
Commitments	2.696	2.696	2.696	2.696	2.696	2.696 every year	16.176
Payments	2.696	2.696	2.696	2.696	2.696	2.696 every year	16.176

2.4. Compatibility with financial programming and financial perspective

Proposal is compatible with existing financial programming.

Proposal will entail reprogramming of the relevant heading in the financial perspective.

Proposal may require application of the provisions of the Interinstitutional Agreement.

2.5. Financial impact on revenue¹

Proposal has no financial implications (involves technical aspects regarding implementation of a measure)

OR

Proposal has financial impact – the effect on revenue is as follows:

(NB All details and observations relating to the method of calculating the effect on revenue should be shown in a separate annex.)

(€ million to one decimal place)

		Prior to action [Year n-1]	Situation following action					
Budget line	Revenue		[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5]
	(a) Revenue in absolute terms							
	(b) Change in revenue	Δ						

(Please specify each budget line involved, adding the appropriate number of rows to the table if there is an effect on more than one budget line.)

¹ For further information, see separate explanatory note.

3. BUDGET CHARACTERISTICS

Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
Comp	Non-differentiated	NO	NO	NO	No [1A]

4. LEGAL BASIS

Article 37 of the Treaty

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention²

5.1.1. Objectives pursued

The objectives of the proposal is to lay down harmonized provisions on

- Community measures to control foot-and-mouth disease in the event of an outbreak
- Community measures to enhance preparedness of the Member States for a possible outbreak of foot-and-mouth disease

5.1.2. Measures taken in connection with ex ante evaluation

Community measures for the control of foot-and-mouth disease (FMD) are currently laid down in Directive 85/511/EEC, as amended by Directive 90/423/EEC, and are primarily based on stamping out of infected herds and herds likely to be infected or contaminated with the FMD virus. Emergency vaccination is provided for as an instrument of last resort when the disease threatens to become extensive.

The current Community measures do not provide for detailed rules on other aspects of an outbreak, such as for example the use of products derived from animals of susceptible species originating in restricted areas. It therefore has been necessary so far to specify these conditions by Commission Decision in accordance with Directives 90/425/EEC and 89/662/EEC.

The present proposal provides more details on the measures to be taken in the event of an outbreak. With the aim to reduce the number of animals to be killed within the framework of the disease control measures, it particularly emphasises the role of emergency vaccination.

² For further information, see separate explanatory note.

The proposal also provides for details on contingency planning, laboratory diagnosis and the establishment of reserves of antigen for the formulation of vaccines in order to enhance disease preparedness and awareness for a possible large-scale outbreak.

5.1.3. Measures taken following ex post evaluation

Not applicable

5.2. Action envisaged and budget intervention arrangements

- (1) Purchase and storage of antigen of FMD virus for vaccine production and formulation of antigen into vaccine in emergency cases
- (2) Testing of antigen in stock
- (3) Community Reference Laboratory

5.3. Methods of implementation

Transposition by Member States into national legislation.

Procedure of the Standing Committee on the Food Chain and Animal Health

6. FINANCIAL IMPACT

6.1. Total financial impact on Part B - (over the entire programming period)

6.1.1. Financial intervention

Commitments (in € million to three decimal places)

Breakdown	[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Action 1	2.000	2.000	2.000	2.000	2.000	2.000 every year	12.000
Action 2	0.250	0.250	0.250	0.250	0.250	0.250 every year	1.500
Action 3	0.200	0.200	0.200	0.200	0.200	0.200 every year	1.200
TOTAL	2.450	2.450	2.450	2.450	2.450	2.450 every year	14.700

6.1.2. *Technical and administrative assistance, support expenditure and IT expenditure (commitment appropriations)*

	[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. years]	Total
1. Technical and administrative assistance							
a) Technical assistance							
b) Other technical and administrative assistance: - intra muros: - extra muros: of which for construction and maintenance of computerised management systems							
Subtotal 1							
2. Support expenditure							
a) Studies							
b) Meetings of experts							
c) Information and publications							
Subtotal 2							
TOTAL							

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)³

(Where there is more than one action, give sufficient detail of the specific measures to be taken for each one to allow the volume and costs of the outputs to be estimated.)

Commitments (in € million to three decimal places)

Breakdown	Type of outputs (projects, files)	Number of outputs (total for years 1...n)	Average unit cost	Total cost (total for years 1...n)
	1	2	3	4=(2X3)
<u>Action 1</u> - Measure 1 - Measure 2				
<u>Action 2</u> - Measure 1 - Measure 2 - Measure 3 etc.				
TOTAL COST				

If necessary explain the method of calculation

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

7.1. Impact on human resources

Types of post	Staff to be assigned to management of the action using existing and/or additional resources		Total	Description of tasks deriving from the action
	Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A B C	1	1	<i>If necessary, a fuller description of the tasks may be annexed.</i>
Other human resources				
Total			1	

³ For further information, see separate explanatory note.

7.2. Overall financial impact of human resources

Type of human resources	Amount (€)	Method of calculation*
Officials Temporary staff	108.000,000	Costs of one official per year
Other human resources (specify budget line)		
Total	108.000,000	

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

Budget line (number and heading)	Amount €	Method of calculation
Overall allocation (Title A7)		
A0701 – Missions	33.600,000	5 missions per year control implementation of contingency plans in 25 Member States over a period of 5 years (5x 6.720,000)
A07030 – Meetings		
A07031 – Compulsory committees ¹	104.000,000	1 meeting of the Standing Committee on the Food Chain and Animal Health only on the subject of FMD
A07032 – Non-compulsory committees ¹		
A07040 – Conferences		
A0705 – Studies and consultations		
Other expenditure (specify)		
Information systems (A-5001/A-4300)		
Other expenditure - Part A (specify)		
Total	137.600,000	

The amounts are total expenditure for twelve months.

¹ Specify the type of committee and the group to which it belongs.

I.	Annual total (7.2 + 7.3)	€ 245.600,000
II.	Duration of action	[n] to [n+5]
III.	Total cost of action (I x II)	€ 1.473.600,000

(In the estimate of human and administrative resources required for the action, DGs/Services must take into account the decisions taken by the Commission in its orientation/APS debate and when adopting the preliminary draft budget (PDB). This means that DGs must show that human resources can be covered by the indicative pre-allocation made when the PDB was adopted.

Exceptional cases (i.e. those where the action concerned could not be foreseen when the PDB was being prepared) will have to be referred to the Commission for a decision on whether and how (by means of an amendment of the indicative pre-allocation, an ad hoc redeployment exercise, a supplementary/amending budget or a letter of amendment to the draft budget) implementation of the proposed action can be accommodated.)

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

- Verification of transposition into national legislation;
- Missions for the assessment of implementation of contingency plans, annual reports by Member States on exercises carried out in accordance with the contingency plan;
- Missions for the assessment of bio-security measures in premises handling live FMD virus and for the approval of such laboratories;
- Purchase and storage of antigens for vaccine production depending on the epidemiological situation
- Financial contribution to a designated Community Reference Laboratory.

8.2. Arrangements and schedule for the planned evaluation

Not applicable.

9. ANTI-FRAUD MEASURES

Not applicable.