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

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.

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*;

For specific measures, notably in application of Article 1(2), Article 15 and Article 85(2), other animals, such as for example of the order *Rodentia* or *Proboscidae*, may be considered susceptible to foot-and-mouth disease in accordance with scientific evidence.

(b) 'holding' means any agricultural or other premises, including circuses, 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, for the purpose of Article 10(l) this definition does not include living areas for humans on such premises, unless animals of susceptible species, including those referred to in Article 85(2), are kept on a permanent or temporary basis therein, 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 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 foot-and-mouth disease has been officially confirmed, taking into account the definitions in Annex I:

— either on clinical symptoms or post-mortem lesions consistent with foot-and-mouth disease have been officially confirmed, or

— as the result of a laboratory examination carried out in accordance with Annex XIII;

(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) 'emergency slaughter' means the slaughter in emergency cases 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, and any implementing legislation thereof, 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 of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(1)];

(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) 'wild animal' means an animal of a susceptible species living outside holdings as defined in Article 2(b) or premises referred to in Articles 15 and 16;

(y) 'primary case of foot-and-mouth disease in wild animals' means any case of foot-and-mouth disease which is detected in a wild animal in an area in which no measures are in place in accordance with Article 85(3) or (4).

CHAPTER II

CONTROL OF OUTBREAKS OF FOOT-AND-MOUTH DISEASE

SECTION 1

NOTIFICATION

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 authority 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 authority 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 legislation on notification of outbreaks of animal disease, the Member State on whose territory an outbreak of foot-and-mouth disease or a primary case of foot-and-mouth disease in wild animals 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 and 3 are carried out where a holding contains one or more animals suspected of being infected or contaminated.

2 The competent authority shall immediately activate official investigation arrangements under its supervision to confirm or rule out the presence of the foot-and-mouth disease and, in particular, have the necessary samples taken for the laboratory examinations required to confirm an outbreak in accordance with the definition of outbreak in Annex I.

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 on the holding and that, in respect of each category of animals of susceptible species, 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. Such information is produced by the owner on request of the competent authority and is checked by that authority at each visit;

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;

g to facilitate the epidemiological inquiry, the necessary samples shall be taken for laboratory testing in accordance with point 2.1.1.1 of Annex III.

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, meat products, 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 authority 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 necessary in order to avoid the spread of foot-and-mouth disease virus.

Article 6

Extension of measures to other holdings

1 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 contamination.

2 The competent authority shall apply at least the measures provided for in Articles 4 and 5(1) to premises or means of transport referred to in Article 16 should the presence of animals of susceptible species give reason to suspect infection or contamination with the foot-and-mouth disease virus.

Article 7

Temporary control zone

1 The competent authority may 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 At least the measures provided for in Article 4(2) and (3)(a), (b) and (d) and in Article 5(1) 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. However, the ban on movement of animals of species not susceptible to foot-and-mouth disease shall not exceed 72 hours, unless justified by exceptional circumstances.

Article 8

Preventive eradication programme

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

2 In that event, the taking of samples and clinical examinations of animals of susceptible species shall be carried out at least in accordance with point 2.1.1.1 of Annex III.

3 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

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 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 point 2.1.1.1 of 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 to 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. 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.

d All products and substances referred to in Article 4(3)(c) shall be isolated until contamination can be ruled out, or 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, or processed.

2 After the killing and processing of the animals of susceptible species and the completion of the measures provided for in paragraph 1(d), Member States shall ensure that:

a the buildings used for housing animals of susceptible species, their surroundings and the vehicles used for their transportation, as well as all other buildings and equipment 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 authorised and registered for placing on the market 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, which shall include appropriate pest control, 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 a 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 animals, 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, animals of species not susceptible to foot-and-mouth disease on the holding where an outbreak of foot-and-mouth disease has been confirmed shall also be killed and processed of in such a way as to avoid any risk of spreading the foot-and-mouth disease virus.

However, the first subparagraph shall not apply to animals of species not susceptible to foot-and-mouth disease which may be isolated, effectively cleansed and disinfected, and 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 at least as set out in point 2.1.1.1 of Annex III.

3 The competent authority shall, immediately upon confirmation of the first outbreak of foot-and-mouth disease prepare all arrangements necessary for emergency vaccination in an area of at least the size of the surveillance zone established in accordance with Article 21.

4 The competent authority may apply the measures provided for in Articles 7 and 8.

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 specific premises keeping on a temporary or regular basis animals of susceptible species

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 farm animal genetic resources, 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.

3 The decision referred to in paragraph 2 shall immediately be notified to the Commission. In the case of farm animal genetic resources, this notification shall include a reference to the list of premises established in accordance with Article 77(2)(f), by which the competent authority has identified these premises in advance as breeding nucleus of animals of susceptible species indispensable for the survival of a breed.

Article 16

Measures to be applied in slaughterhouses, border inspection posts and means of transportation

1 Where a case 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 shall be killed without delay;

b the carcasses of the animals referred to in paragraph (a) shall be processed under official supervision in such a way as to avoid the risk of foot-and-mouth disease virus spreading;

c other animal waste, including offal, of infected or suspected of being infected and contaminated animals shall be processed under official supervision in such a way as to avoid the risk of foot-and-mouth disease virus spreading;

d dung, manure and slurry shall be subject to disinfection and shall only be removed for treatment in accordance with point 5 of Section II in Part A of Chapter III of Annex VIII to Regulation (EC) No 1774/2002;

e cleansing and disinfection of buildings and equipment, including vehicles or means of transport, shall take place under the supervision of the official veterinarian in accordance with Article 11 and with the instructions laid down by the competent authority;

f an epidemiological inquiry shall be 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(e).

4 Where required by the epidemiological situation, in particular where contamination of animals of susceptible species in holdings adjacent to the premises ore means of transport referred to in paragraph 1 must be suspected, Member States shall ensure that by way of derogation from Article 2(b), second sentence, an outbreak is declared on the premises or means of transport referred to in paragraph 1, and the measures provided for in Articles 10 and 21 are applied.

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 PRODUCTION UNITS AND CONTACT HOLDINGS

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 production units of such holdings not affected by foot-and-mouth disease.

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, including the administration, and size of the premises allow a complete separation of housing and keeping for the distinct herds of 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, working animals of species not susceptible to foot-and-mouth disease, 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, and

b milking in each unit is carried out separately, and

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 recognised 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 subject to the measures provided for in Articles 4(3) and 5 and these measures 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 definition in Annex I and the survey requirements provided for in point 2.1.1.1 of Annex III.

3 The competent authority shall prohibit the removal of all animals 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 the closest possible designated slaughterhouse for 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 premises or means of transportation referred to in Articles 15 and 16 respectively cannot be excluded, Member States shall ensure that the measures provided for in Article 4(2) and (3) and in Article 5 shall apply to such premises or means of transportation. The competent authority may decide to apply the measures provided for in Article 8.

Article 20

Coordination 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 coordination 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, without prejudice to measures provided for in Article 7, at least the measures laid down in paragraphs 2, 3 and 4 below 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 coordination 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 without delay trace animals dispatched from the zones during the period of at least 21 days before the estimated date of earliest infection on a holding in the protection zone and they shall inform the competent authorities in other Member States and the Commission about their results from tracing of animals.

6 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 without delay:

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 as soon as possible 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 in particular the relevant documentation, notably the records referred to in subparagraph (a) and the measures applied to prevent the introduction or escape of foot-and-mouth disease virus and which may include clinical inspection as described in point 1 of Annex III or taking of samples from animals of susceptible species in accordance with point 2.1.1.1 of Annex III;

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 under official supervision for the purpose of emergency slaughter directly 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 in means of transport cleansed and disinfected under official control after each transport operation.

The movement referred to in the first subparagraph shall only be authorised if the competent authority is satisfied on the basis of a clinical examination in accordance with point 1 of Annex III by the official veterinarian of all the animals of susceptible species present on the holding and after evaluation of epidemiological circumstances that there is no reason to suspect the presence of infected or contaminated animals on the holding. The meat of such animals shall be subject to the measures provided for in Article 25.

Article 23

Movement and transport of animals and their products in the protection zone

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

(a) movement between holdings and transport of animals of susceptible species;

(b) fairs, markets, shows and other gatherings of animals including collection and dispersion of susceptible species;

(c) itinerant service for breeding of animals of susceptible species;

(d) artificial insemination of and collection of ova and embryos from animals of susceptible species.

Article 24

Additional measures and derogations

1 The competent authority may extend the prohibitions in Article 23 to:

a movement or transport of animals of non-susceptible species between holdings situated within the zone or out of or into the protection zone;

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;

d artificial insemination of or collection of ova and embryos from animals of species not susceptible to foot-and-mouth disease;

e movement of means of transport designed for the transportation of animals;

f the slaughter on the holding of animals of susceptible species for private consumption;

g transport of goods referred to in Article 33 to holdings keeping animals of susceptible species.

2 The competent authorities may authorise:

a the transit of animals of all species through the protection zone undertaken exclusively via major highways or mainline railways;

b the transport of animals of susceptible species which have been certified by the official veterinarian as coming from holdings outside the protection zone 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 official supervision at the slaughterhouse and such decontamination of transport is recorded in the logbook of the means of transport;

c the artificial insemination of animals on a holding carried out by the personnel of that holding by use of semen collected from animals on that holding or semen stored on that holding or semen delivered from a semen collection centre to the outside perimeter of that holding;

d the movement and transport of equidae taking into account the conditions set out in Annex VI.

e the transport, under certain conditions, of goods referred to in Article 33 to holdings keeping animals of susceptible species.

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 establishments situated 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 Directive 2002/99/EC and subsequently transported in sealed containers to an establishment designated by the competent authorities for transformation into meat products treated in accordance with point 1 in Part A of Annex VII of this Directive.

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 earliest infection on a holding in the protection zone 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 legislation.

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 or from animals transported to the establishment

and slaughtered therein in accordance with the provisions in Article 24(2)(b) 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 94/65/EC;

d during the whole production process 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.

7 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 protection zones maintained for more than 30 days.

Article 26

Measures in relation to meat products produced in the protection zone

1 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.

2 By way of derogation, the prohibition in paragraph 1 shall not apply to meat products which have either undergone one of the treatments as set out in point 1 in Part A of Annex VII or which have been produced from meats referred to in Article 25(4).

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 an establishment situated in the protection zone shall be prohibited.

3 By way of derogation, the prohibition provided for in paragraph 1 shall not apply to milk and milk products derived from animals of susceptible species originating in the protection zone which were produced on a date at least 21 days before the estimated date of earliest infection on a holding in the protection zone and which since production have been stored and transported separately from milk and milk products produced after that date.

4 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 6 in establishments referred to in paragraph 5 or, if there is no establishment situated in the protection zone, in establishments situated outside the protection zone under the conditions set down in paragraph 8.

5 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 6.

6 Establishments referred to in paragraphs 4 and 5 shall comply with the following conditions:

a the establishment shall be operated under permanent and strict official control;

b all milk used in the establishment shall either comply with paragraphs 3 and 4 or the raw milk shall be obtained from animals outside the protection zone;

c during the whole production process the milk shall be clearly identified and transported and stored separately from raw milk and raw 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.

7 Compliance with the conditions in paragraph 6 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.

8 Transport of raw milk from holdings situated within the protection zone to establishments situated outside the protection zone and the processing of that milk shall be subject to the following conditions:

a processing in establishments situated outside the protection zone of raw milk produced from animals of susceptible species kept within the protection zone shall be authorised by the competent authorities;

b the authorisation shall include instructions on and designation of the transport route to the designated establishment;

c transport shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, which are constructed and maintained in such a way that there is no leakage of milk during transport and which are equipped to avoid aerosol dispersion during the loading and unloading of the milk;

d before leaving the holding from where milk of animals of susceptible species was collected the connection pipes, tires, wheel cases, the lower parts of the vehicle and any spillage of milk are cleansed and disinfected and after the last disinfection and before leaving the protection zone the vehicle had no subsequent contact with holdings in the protection zone keeping animals of susceptible species;

e the means of transport are strictly assigned to a defined geographical or administrative area, they are marked accordingly and may only be moved to another area after cleansing and disinfection under official supervision.

9 The collection and transport of samples of raw milk of animals of susceptible species from holdings situated in the protection zone to a laboratory other than a veterinary diagnostic laboratory approved for diagnosis of foot-and-mouth disease and the processing of the milk in such laboratories shall be forbidden.

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 21 days before the estimated date of earliest infection with the foot-and-mouth disease virus on a holding in the zone.

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 samples taken in accordance with point 2.2 of Annex III have been subjected to a serological test to substantiate the absence of infection in the semen collection centre concerned, and

c the donor animal has been subjected with negative result to a serological test for the detection of antibodies against the foot-and-mouth disease virus on a sample taken not earlier than 28 days after the collection of the semen.

Article 29

Transport and distribution of dung and manure of animals of susceptible species produced in the protection zone

1 Member States shall ensure that the transport and distribution of dung or manure from holdings and premises or means of transport referred to in Article 16 situated in the protection zone where animals of susceptible species are kept, shall be prohibited within the protection zone.

2 By way of derogation from the prohibition in paragraph 1 the competent authority may authorise the removal of manure of animals of susceptible species from a holding situated in the protection zone to a designated plant for treatment in accordance with point 5 of Section II in Part A of Chapter III of Annex VIII to Regulation (EC) No 1774/2002 or for intermediate storage.

3 By way of derogation from the prohibition in paragraph 1 the competent authority may authorise the removal of manure of animals of susceptible species from holdings situated in the protection zone which are not subject to the measures provided for in Articles 4 or 10 for distribution on designated fields under the following conditions:

a the entire volume of manure has been produced at least 21 days before the estimated date of earliest infection on a holding in the protection zone and the manure or dung is

distributed close to the ground and in sufficient distance from holdings keeping animals of susceptible species and immediately incorporated into the ground, or

b in the case of manure from bovine animals or pigs:

(i) an examination by an official veterinarian of all the animals on the holding has ruled out the presence of animals suspected of being infected with the foot-and-mouth disease virus, and

(ii) the entire volume of manure has been produced at least 4 days prior to the examination referred to in point (i), and

(iii) the manure is incorporated into the ground on designated fields close to the holding of origin and in sufficient distance to other holdings keeping animals of susceptible species in the protection zone.

4 Member states shall ensure that any authorisation to remove dung or manure from a holding keeping animals of susceptible species is subject to stringent measures to avoid spread of the foot-and-mouth disease virus, in particular by ensuring cleansing and disinfection of the leak-proof transport vehicles after loading and before leaving the holding.

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 21 days before the estimated date of infection on the holding referred to in Article 10(1), and that have been stored separately from hides and skins produced after that date; or

b comply with the requirements laid down in point 2 in Part A of Annex VII.

Article 31

Measures in relation to sheep wool, ruminant hair and pig bristles produced in the protection zone

1 Member States shall ensure that the placing on the market of sheep wool, ruminant hair and pig 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 unprocessed wool, hair and bristles which:

a were produced at least 21 days before the estimated date of infection on the holding referred to in Article 10(1) and have been stored separately from wool, hair and bristles produced after that date; or

b comply with the requirements laid down in point 3 in Part A of Annex VII.

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 derived from animals of susceptible species 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 products referred to in paragraph 1 which:

a either have been produced at least 21 days before the estimated date of infection on the holding referred to in Article 10(1) and have been stored and transported separately from products produced after that date, or

b have undergone the treatment in accordance with point 4 in Part A of Annex VII, or

c for specific products, comply with the appropriate requirements in points 5 to 9 in Part A of Annex VII, or

d are 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, or

e are 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 21 days before the estimated date of infection on holdings referred to in Article 10(1), 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; or

c produced on premises not keeping animals of susceptible species; or

d produced in establishments not keeping animals of susceptible species and sourcing the raw material from premises referred to in paragraph (c) or from premises situated outside the protection zone.

3 By way of derogation, the prohibition provided for in paragraph 1 shall not apply to forage and straw produced on holdings keeping animals of susceptible species which comply with the requirements in point 1 in Part B of Annex VII.

Article 34

Granting of derogations and additional certification

1 Any derogation from the prohibitions provided for in Articles 24 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.

2 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.

3 Detailed rules for the implementation of the measures provided for in paragraph 2 may be adopted in accordance with the procedure referred to in Article 89(2).

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. Member States shall inform the Commission and the other Member States about such additional measures.

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 to substantiate the absence of infection and at least in compliance with the criteria of point 1 of Annex III and shall include the measures provided for in point 2.3 of Annex III based on the criteria set out in points 2.1.1. and 2.1.3. 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) and where there is no or insufficient slaughter capacity available within the surveillance zone, the competent authorities may authorise the removal from holdings situated in the surveillance zone of animals of susceptible species for transporting them directly and under official supervision

for slaughter to a slaughterhouse located outside the surveillance zone, subject to the following conditions:

a the records referred to in Article 22(1) have been subjected to official control, and the epidemiological situation of the holding does not indicate any suspicion of infection or contamination with the foot-and-mouth disease virus, and

b all the animals of susceptible species on the holding have been subjected with negative result to an inspection by the official veterinarian, and

c a representative number of animals, taking into account the statistical parameters in point 2.2 of Annex III, has been subjected to thorough clinical examination to rule out the presence or suspicion of clinically infected animals, and

d the slaughterhouse is designated by the competent authority and located as near to the surveillance zone as possible, and

e 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 be removed from holdings 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 without coming into contact with animals of susceptible species of different holdings to pasture situated within the surveillance zone 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 slaughter to a slaughterhouse located inside the same zone;

c for transporting them in accordance with Article 37(2);

d for transporting them in accordance with Article 24(2)(a) and (b).

3 Movements of animals provided for in paragraph 2(a) 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, including testing of samples taken in accordance with point 2.2 of Annex III, has ruled out the presence of animals suspected of being infected or animals suspected of being contaminated.

4 Movements of animals provided for in paragraph 2(b) shall be authorised by the competent authority only after the measures provided for in Article 37(2)(a) and (b) have been completed with satisfactory results.

5 Member States shall without delay trace animals of susceptible species dispatched from the surveillance zone during a period of least 21 days before the estimated date of earliest infection on a holding in the surveillance zone and they shall inform the competent authorities in other Member States about their results from tracing animals.

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 ensure that 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 shall be prohibited.

2 Member States shall ensure that the placing on the market of fresh meat, minced meat, meat preparations and meat products from animals of susceptible species produced in establishments situated in the surveillance zone shall be prohibited.

3 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 earliest infection on a holding in the corresponding protection zone 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 surveillance zone by means of clear mark established in conformity with Community legislation.

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 from animals transported to the slaughterhouse under conditions at least as strict as provided for in Article 37(2)(a) to (e) under the condition that the meat is subject to the measures provided for in paragraph 5.

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 surveillance 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 and subject to the additional conditions provided for in Part B of Annex VIII or obtained from animals reared and slaughtered outside the surveillance zone or obtained from animals transported in accordance with the provisions in Article 24(2)(b) 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 during the whole production process 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 surveillance zone in accordance with this Directive.

6 By way of derogation, the prohibition provided for in paragraph 1, shall not apply to meat products produced from fresh meat obtained from animals of susceptible species originating in the surveillance zone which was marked with the health mark provided for Directive 2002/99/EC and transported under official supervision to a designated establishment for treatment in accordance with point 1 in Part A of Annex VII.

7 By way of derogation, the prohibition provided for in paragraph 2, shall not apply to meat products produced in establishments situated in the surveillance zone and either complying with the provisions in paragraph 6, or produced from meat complying with paragraph 5.

8 Compliance with the conditions in paragraphs 5 and 7 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.

9 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 zone 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 and milk products derived from animals of susceptible species originating in the surveillance zone which were produced on a date at least 21 days before the estimated date of earliest infection on a holding in the corresponding protection zone and which since production have been stored and transported separately from milk and milk products produced after that date.

4 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 6 in establishments referred to in paragraph 5 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 zones.

5 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 6.

6 Establishments referred to in paragraphs 4 and 5 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 4 or be obtained from animals outside the surveillance and protection zone;

c throughout the production process 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 zones keeping animals of susceptible species.

7 Compliance with the conditions in paragraph 6 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.

8 Transport of raw milk from holdings situated within the surveillance zone to establishments situated outside the protection and surveillance zones and the processing of that milk shall be subject to the following conditions:

a processing in establishments situated outside the protection and surveillance zones of raw milk produced from animals of susceptible species kept within the surveillance zone shall be authorised by the competent authorities;

b the authorisation shall include instructions on and designation of the transport route to the designated establishment;

c transport shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, which are constructed and maintained in such a way that there is no leakage of milk during transport and which are equipped to avoid aerosol dispersion during the loading and unloading of the milk;

d before leaving the holding from where milk of animals of susceptible species was collected, the connection pipes, tires, wheel cases, the lower parts of the vehicle and any spillage of milk are cleansed and disinfected and after the last disinfection and before leaving the surveillance zone the vehicle had no subsequent contact with holdings in the protection and surveillance zones keeping animals of susceptible species;

e the means of transport are strictly assigned to a defined geographical or administrative area, they are marked accordingly and may only be moved to another area after cleansing and disinfection under official supervision.

9 The collection and transport of samples of raw milk of animals of susceptible species from holdings situated in the surveillance zone to a laboratory other than a veterinary diagnostic laboratory approved for diagnosis of foot-and-mouth disease and the processing of the milk in such laboratories shall be subject to official authorisation and measures to avoid any spread of possible foot-and-mouth disease virus.

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 and other premises such as those mentioned in Article 16 situated in the surveillance zone where animals of susceptible species are kept shall be prohibited within and outside 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 in means of transport thoroughly cleansed and disinfected prior to and after use for distribution in designated areas within the surveillance zone and at sufficient distance to holdings where animals of susceptible species are kept under the following alternative conditions:

a either 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 with the foot-and-mouth disease virus and the manure or dung is distributed close to the ground to avoid the generation of aerosols and immediately ploughed into the ground, or

b a clinical inspection by an official veterinarian of all the animals of susceptible species on the holding has been carried out with negative result and the manure is injected into ground, or;

c manure is subject to the provision of Article 29(2).

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 28 and 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 take into account 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 survey has been concluded with negative results.

2 The survey referred to in paragraph 1(c) shall be carried out to substantiate the absence of infection in the surveillance zone in compliance with the criteria of point 1 of Annex III and shall include the measures provided for in point 2.4 of Annex III based on the criteria of point 2.1 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 and free zones.

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 The restricted zone shall as far as possible be delimited on the basis of administrative boundaries or 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, the restricted zone shall be enlarged by including additional regions or sub-regions.

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 transport and movement of animals of susceptible species, 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 fresh meat and raw milk and as far as possible other 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 at least the animals of susceptible species dispatched from the restricted zone to other Member States 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 is implemented. Such fresh meat shall be treated in accordance with point 1 in Part A of Annex VII, and raw milk and milk products shall be treated in accordance with Part A or B of Annex IX depending on the use, or detained until possible contamination with the foot-and-mouth disease virus is officially ruled out.

4 Specific measures, in particular in relation to health marking of products derived from animals of susceptible species originating in the restricted zone and not intended for placing on the market outside the restricted zone may be adopted in accordance with Article 4(3) of Directive 2002/99/EC.

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, permanent and indelible 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

1 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 in the restricted zone established in accordance with Article 45:

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, in relation to all animals of susceptible species, 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.

2 Member States may extend some or all the measures provided for in paragraph 1 to a part or the entire free zone.

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 and the administration of hyperimmune sera against foot-and-mouth disease are 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, scientific research or testing of vaccines, is authorised 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 State 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).

4 The decision referred to in paragraph 3 to introduce emergency vaccination on its own territory may be requested:

a either by the Member State referred to in paragraph 1(a), or

b by a Member State referred to in paragraph 1(b), (c) or (d).

5 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.

6 If a Member State introduces emergency vaccination in accordance with paragraph 5, 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).

7 By way of derogation from paragraph 4, a decision to introduce emergency vaccination in a Member State referred to in paragraph (1)(a) may be adopted in concertation with the affected Member State in accordance with the procedure referred to in Article 89(3) on the Commission's own initiative, if the condition in paragraph (1)(a) and paragraph (1)(b) apply.

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 additional and permanent identification and special registration of the vaccinated animals pursuant to Article 47(2);

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 slaughtered or stay alive.

3 Member States shall ensure that an information programme shall be put in place to inform the public about the safety of meat, milk and dairy products from vaccinated animals for human consumption.

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, where necessary in close cooperation with neighbouring Member States;

b vaccination shall be carried out swiftly and in conformity with the rules of hygiene and bio-security so as to avoid the 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 OIE) 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 in accordance with Article 50 and taking into account all relevant circumstances, 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:

a only within a protection zone;

b only on clearly identified holdings subject to the measures provided for in Article 10(1) and in particular subparagraph (a) thereof.

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 between holdings 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 mark provided for in Directive 2002/99/EC;

b be stored and transported separately from meat not bearing the mark 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 point 1 in Part A of 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, 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. The treatment shall be carried out under the conditions set out in paragraph 5 in establishments situated in the vaccination zone or, if there is no establishment in that zone, in establishments situated outside the vaccination zone to which the raw milk is transported under the conditions set down in paragraph 7.

5 Establishments referred to in paragraphs 4 shall comply with the following conditions:

a the establishment shall be operated under permanent and strict official control;

b all milk used in the establishment shall either comply with paragraph 4 or the raw milk shall be obtained from animals outside the vaccination zone;

c during the whole production process the milk shall be clearly identified and transported and stored separately from raw milk and raw milk products which are not destined for dispatch outside the vaccination zone;

d transport of raw milk from holdings situated outside the vaccination 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 a restricted 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.

7 Transport of raw milk from holdings situated within the vaccination zone to establishments situated outside the vaccination zone and the processing of that milk shall be subject to the following conditions:

a processing in establishments situated outside the vaccination zone of raw milk produced from animals of susceptible species kept within the vaccination zone shall be authorised by the competent authorities;

b the authorisation shall include instructions on and designation of the transport route to the designated establishment;

c transport shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, which are constructed and maintained in such a way that there is no leakage of milk during transport and which are equipped to avoid aerosol dispersion during the loading and unloading of the milk;

d before leaving the holding from where milk of animals of susceptible species was collected, the connection pipes, tires, wheel cases, the lower parts of the vehicle and any spillage of milk are cleansed and disinfected and after the last disinfection and before leaving the vaccination zone the vehicle had no subsequent contact with holdings in the vaccination zone keeping animals of susceptible species;

e the means of transport are strictly assigned to a defined geographical or administrative area, they are marked accordingly and may only be moved to another area after cleansing and disinfection under official supervision.

8 The collection and transport of samples of raw milk of animals of susceptible species from holdings situated in the vaccination zone to a laboratory other than a veterinary diagnostic laboratory approved for diagnosis of foot-and-mouth disease and the processing of the milk in such laboratories shall be forbidden.

9 The collection of semen for artificial insemination from donor animals of susceptible species 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, and

b prior to dispatch of the semen:

(1) either the donor animal has not been vaccinated and the conditions of Article 28(3)(b) and (c) apply, or

(2) the donor animal has been vaccinated following a negative test for antibodies against foot-and-mouth disease virus carried out prior to vaccination; and

(i) a negative result has been achieved in a test for the detection of either virus or viral genome 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, and

(ii) the semen complies with the conditions of Article 4(3) of Chapter II of Directive 88/407/EEC.

10 Collection of ova and embryos from donor animals shall be prohibited.

11 The placing on the market of products of animal origin other than those referred to in paragraphs 9 and 10 shall be subject to the conditions provided for in Articles 30, 31, 32 and 41.

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 between holdings 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(5) to a slaughterhouse situated within or out of the vaccination zone on the following conditions:

a during transport and in the slaughterhouse 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 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 points 1, 3 and 4 in Part A of 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 throughout the production process the fresh meat shall be clearly identified, and transported and stored separately from meat of different animal health status 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 health mark provided for in Directive 2002/99/EC and shall be stored and transported separately from meat not bearing that mark and subsequently be transported in sealed containers to an establishment designated by the competent authorities for treatment in accordance with point 1 in Part A of 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 within or outside the vaccination zone in accordance with the provisions in Article 54(4) to (8).

8 For the collection of semen, ova and embryos from animals of susceptible species, the measures provided for in Article 54(9) and (10) shall continue to apply.

9 The placing on the market of products of animal origin other than those referred to in paragraphs 4, 6, 7 and 8 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. Where the competent authorities use in addition 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 the measures provided for in Articles 10 and 21.

3 Holdings containing at least one animal of susceptible species suspected of being infected through previous contact with the foot-and-mouth disease virus but where further testing including all animals of susceptible species present on the holding confirmed the absence of circulating foot-and-mouth disease virus shall be subject to at least the following measures:

a animals of susceptible species on the holding shall:

(1) either be killed and the carcasses processed, or

(2) the animals shall be classified and

(i) the animals positive to at least one of the approved tests referred to in Article 56(3) shall be killed and their carcasses processed, and

(ii) the remaining animals of susceptible species on the holding shall be slaughtered under conditions authorised by the competent authorities;

b cleansing and disinfection of the holdings in accordance with Article 11;

c restocking of animals in accordance with Annex V.

4 Member States shall ensure that the following measures are applied to products derived from animals of susceptible species and produced during the period referred to in Article 56(1):

a fresh meat produced from the animals referred to in paragraph 3(2)(ii) shall be subject to Article 55(4), for meat from ruminants, and (6), for meat from porcine animals, respectively;

b milk and milk products produced from the animals referred to in paragraph 3(2)(ii) shall undergo at least one of the treatments specified in Parts A and B of Annex IX depending on the intended use and in compliance with the provisions in Article 54(4) to (8).

5 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 Member States shall ensure that movement of animals of susceptible species between holdings situated in the vaccination zone is subject to authorisation.

3 Movement of animals of susceptible species out of the vaccination zone shall be prohibited. By way of derogation from this prohibition, direct transport to a slaughterhouse for immediate slaughter of animals of susceptible species may be authorised under the conditions provided for in Article 55(3).

4 By way of derogation from the prohibition in paragraph 2, the competent authorities may authorise the transport of unvaccinated animals of susceptible species in accordance with the following provisions:

a within 24 hours of loading, all animals of susceptible species on the holding have been subjected to clinical examination and have not shown clinical signs of foot-and-mouth disease, and

b the animals have completed a standstill on the holding of origin of at least 30 days during which no animal of susceptible species has been introduced onto the holding, and

c the holding of origin is not situated in a protection or surveillance zone, and

d the animals intended for transport were either individually subjected with negative results to tests for the detection of antibodies against the foot-and-mouth disease virus at the end of the isolation period, or a serological survey was completed on that holding in accordance with point 2.2 of Annex III irrespective of the species concerned;

e the animals were not exposed to any source of infection during their transportation from the holding of origin to the place of destination.

5 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.

6 Fresh meat produced from unvaccinated animals of susceptible species may be placed on the market inside and outside the vaccination zone under the following conditions:

a either the measures provided for in Article 57(3) have been completed in the entire vaccination zone or the animals are transported to the slaughterhouse under the conditions provided for in paragraph 3 or 4(d), and;

b the establishment shall be operated under strict veterinary control;

c only fresh meat produced from animals referred to in point (a) or from animals reared and/or slaughtered outside the vaccination zone or fresh meat referred to in paragraph 8 shall be processed in the establishment;

d 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;

e throughout the production process the fresh meat shall be clearly identified, and transported and stored separately from meat of different animal health status in accordance with this Directive.

7 Fresh meat produced from vaccinated animals of susceptible species or from non-vaccinated seropositive offspring of vaccinated dams slaughtered during the period referred to in paragraph 1 shall bear the health mark provided for in Directive 2002/99/EC 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 point 1 in Part A of Annex VII.

8 By way of derogation from paragraph 7, fresh meat and trimmed offal produced from vaccinated large and small ruminants or their non-vaccinated seropositive offspring 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 point 1, 3 and 4 in Part A of Annex VIII or fresh meat referred to in paragraph 6 or produced from animals reared and/or 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 to 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 to Directive 94/65/EC;

d throughout the production process the fresh meat shall be clearly identified, and transported and stored separately from meat which is of different animal health status in accordance with this Directive.

9 By way of derogation from paragraph 7, fresh meat from vaccinated porcine animals and their non-vaccinated seropositive offspring, produced during the period from the beginning of the survey until the measures provided for in Article 57 have been completed in the entire vaccination zone and until at least 3 months have elapsed after the last outbreak recorded in that zone, may only be placed on the national market of the Member State of origin within and outside the vaccination zone under the following conditions:

a the establishment shall be operated under strict veterinary control;

b only fresh meat from animals originating in holdings complying with the conditions in Article 57(5) 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 a health mark to be decided in accordance with Article 4(3) of Directive 2002/99/EC;

d throughout the production process the fresh meat shall be clearly identified, and transported and stored separately from meat of different animal health status in accordance with this Directive.

10 A Member State other than the Member State referred to in paragraph 9 may request a decision in accordance with the procedure provided for in Article 89(3) to extend the marketing of the meat referred to in paragraph 9 to its territory or part of its territory under conditions to be laid down under the same procedure.

11 The rules for dispatch from the vaccination zone of fresh meat from vaccinated porcine animals produced after the period referred to in paragraph 9 until free status has been regained in accordance with Article 61, shall be decided in accordance with the procedure provided for in Article 89(3).

12 Compliance with the conditions provided for in paragraph 6, paragraph 8 and where applicable under the provisions of paragraph 10, 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.

13 By way of derogation from paragraph 8 a special health mark which cannot be confused with the health mark referred to in paragraphs 8(c) and 9(c), may be decided in accordance with the procedure referred to in Article 89(3) for fresh meat of ruminants not subjected to the treatment in accordance with Part A of Annex VIII, and minced meat and meat preparations produced from such meat, which are intended for placing on the market in the a specific region of the Member State of origin.

14 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 accordance with the provisions in Article 54(4) to (7).

15 The collection and transport of samples of raw milk of animals of susceptible species, from holdings situated in the surveillance zone to a laboratory other than a veterinary diagnostic laboratory approved for diagnosis of foot-and-mouth disease, and the processing of the milk in such laboratories, shall be subject to official authorisation and to appropriate measures to avoid any possible spread of foot-and-mouth disease virus.

16 The placing on the market of products of animal origin other than those referred to in paragraphs 6 to 11 and 13 to 15 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 recovered 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 recover 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 in the foot-and-mouth disease Chapter, as last amended, 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 Decisions on recovering 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 recover 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 in the foot-and-mouth disease Chapter, as last amended, 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 established in accordance with Article 70(3);

(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 established in accordance with Article 70(3), 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 Decisions on recovering 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 and confirmed the absence of foot-and-mouth disease virus infection.

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 and confirmed the absence of foot-and-mouth disease virus infection.

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

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

2 By way of derogation from the prohibition in paragraph 1, it may be decided in accordance with the procedure referred to in Article 89(2) to adopt specific measures with regard to vaccinated animals of susceptible species kept in zoos and included in a programme for wildlife conservation or kept on premises for farm animal resources that have been listed by the competent authorities as breeding nucleus of animals indispensable for the survival of the breed, subject to appropriate provisions in the Animal Health Code of the OIE.

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 coordinating 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) liases 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 cooperation shall be formalised in a mutual agreement between the competent authorities of the Member States concerned, which shall be notified to the Commission. Such cooperation 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 guidelines for surveillance, 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 Guidelines for the surveillance required to recover the foot-and-mouth disease and infection free status may be adopted in accordance with the procedure referred to in Article 89(2).

3 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 Annex XIII.

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, it shall ensure coordination with neighbouring Member States and encourage cooperation with neighbouring third countries.

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 indications of:

a the vaccine requirements considered necessary in the event of emergency vaccination, and

b the regions containing densely populated livestock areas, taking into account the criteria set down in Annex X.

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 XVII.

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/Central disease control centres — Functions and duties

1 Member States shall ensure that a fully functional national/central disease control centre may be immediately established in the event of foot-and-mouth disease outbreaks.

2 The national/central 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/central 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/central 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 liasing with diagnostic laboratories;

g liasing with competent environmental authorities to coordinate the actions on veterinary and environmental safety;

h liasing with the media;

i liasing with the enforcement bodies to ensure adequate implementation of specific legal measures.

Article 75

National/Central disease control centres — Technical requirements

1 Member States shall ensure that the national/central 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 media;

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 coordinated;

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 processing site areas;

j lists of treatment and processing undertakings authorised to treat or process 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 — set-up, 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 act in close coordination and cooperation with the national/central disease control centre, in particular in relation to the measures provided for in Article 74(3)(b).

4 Member States shall ensure that 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 measures relating to the epidemiological inquiry, environmental protection, processing 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 accessible phone lines where farmers and other rural residents can obtain recent, accurate information about the measures taken;

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 coordinated;

e up-to-date lists of persons, including private veterinarians, 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 15 and 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 processed 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, which is composed of epidemiologists, veterinary scientists and virologists in a balanced way, to maintain expertise in order to assist the competent authority in ensuring preparedness against an outbreak of foot-and-mouth disease.

By way of derogation from the first subparagraph, Member States with a limited number of animals of susceptible species may arrange a formalised agreement with other Member States on mutual assistance in regard of the expert group. These arrangements shall be detailed in the contingency plans referred to in Article 72.

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:

(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, including advice on bio-security measures on holdings or on premises referred to in Article 16, and in relation to emergency vaccination;

d follow up and guide the epidemiological inquiry;

e supplement the epidemiological data with geographical, meteorological and other necessary information;

f analyse the epidemiological data and perform risk assessments at regular intervals;

g assist in ensuring that the processing of animal carcasses and animal waste is done with a minimum of detrimental effect on the environment.

SECTION 14

ANTIGEN AND VACCINE BANKS

Article 79

National antigen and vaccine banks

1 Member States may within the framework of the contingency plan 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.

2 Member States may 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, sterility and content of non-structural proteins.

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. The information on quantities and subtypes of antigens or authorised vaccines stored in the national antigen and vaccine bank shall be treated as classified information and in particular shall not be published.

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 in accordance with Directive 2001/82/EC 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

The Commission shall ensure that the contracted manufacturer of the concentrated inactivated antigen supplied to the Community antigen and vaccine bank, guaranties conditions for the supply and storage of concentrated inactivated antigen of the foot-and-mouth disease virus at least equivalent to those laid down in point 1 of Annex XIV.

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 guaranties conditions for the formulation, finishing, bottling, labelling and delivery of vaccines reconstituted from antigens referred to in Article 81 at least equivalent to those laid down in point 2 of Annex XIV.

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 cooperation 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 Coordinating Institute.

If necessary, the Community Coordinating 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 OIE Manual.

SECTION 15

FOOT-AND-MOUTH DISEASE IN OTHER SPECIES

Article 85

Additional measures to prevent and control foot-and-mouth disease

1 Without prejudice to Regulation (EC) No 1774/2002, and any implementing legislation, Member States shall ensure that the prohibition on swill feeding in accordance with Community and national legislation is applicable to all animals irrespective of their use or the place inhabited by these animals. Detailed rules for the control measures to be applied by Member States may be adopted in accordance with the procedure referred to in Article 89(2).

2 Detailed rules for the control of foot-and-mouth disease in animals referred to in Article 2(a) second sentence may be adopted in accordance with the procedure referred to in Article 89(2).

3 Immediately after the competent authority of a Member State has information that wild animals are suspected of being infected with foot-and-mouth disease, it shall take all appropriate measures to confirm or rule out the presence of the disease by investigations of all wild animals of susceptible species shot or found dead, including laboratory testing. It shall inform owners of animals of susceptible species and hunters on the suspicion.

4 As soon as the competent authority of a Member State has confirmation of a primary case of foot-and-mouth disease in wild animals, it shall immediately apply the measures provided for in Part A of Annex XVIII in order to reduce the spread of disease, and shall draw up a plan for the eradication of foot-and-mouth disease in accordance with Part B of Annex XVIII. It shall inform owners of animals of susceptible species and hunters of the confirmed case.

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 implementing specific articles, for the adoption of further detailed rules for the implementation of this Directive and for amending the Annexes

1 Detailed rules for the implementation of Articles 75(2) and 77(2) may be adopted in accordance with the procedure referred to in Article 89(2).

2 Further detailed rules for the implementation of this Directive may be adopted in accordance with the procedure referred to in Article 89(2).

3 The Annexes to this Directive 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).

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

Committee 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.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply,

The period laid down in Article 5(6) of that Decision shall be set at 15 days.

4 The Committee shall adopt its Rules of Procedure.

CHAPTER V

TRANSITIONAL 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, without prejudice to the obligations of the Member States concerning the time-limits for transposition and application set out in Annex XIX, and Decisions 89/531/EEC of 25 September 1989 designating a reference laboratory for the identification of foot-and-mouth diseasevirus and determining the functions of that laboratory[(2)] and 91/665/EEC of 11 December 1991 designating a Community Coordinating Institute for foot-and-mouth disease vaccines and laying down its functions[(3)], adopted in implementation thereof, are hereby repealed as from the date referred to in Article 93.

2 References made to the repealed Directive 85/511/EEC shall be construed as being made to this Directive and should be read in accordance with the correlation table in Annex XX.

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 the 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

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 2004 at the latest. They shall forthwith inform the Commission thereof.

They shall apply these provisions as from 1 July 2004.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

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 day of its publication in the Official Journal of the European Union.

Article 95

Addressees

This Directive is addressed to the Member States.

(**1**) OJ L 311, 28.11.2001, p. 1.

(**2**) OJ L 279, 28.9.1989, p. 32.

(**3**) OJ L 368, 31.12.1991, p. 19.