

The Ministry of Food, Agriculture and Livestock

REGULATION ON CONTROL OF FOOT AND MOUTH DISEASE

SECTION ONE

Objective, Scope, Legal Basis and Definitions

Objective

ARTICLE 1 – (1) The objective of this Regulation is to regulate the procedures and principles pertaining to the measures to be taken ensure preparedness, protection and response to the Foot-and-Mouth Disease.

Scope

ARTICLE 2 – (1) This Regulation sets out the minimum control measures to be applied in the event of an outbreak of foot-and-mouth disease of whatever type of virus and certain preventative measures aimed at increasing awareness and preparedness of the competent authorities and the farming community for foot-and-mouth disease.

Legal Basis

ARTICLE 3 – (1) This Regulation has been prepared on the basis of Article 4 of the Law No.5996 and dated 11/06/2010 on Veterinary Services, Plant Health, Food and Feed in parallel with the Council Directive No. 2003/85/EEC on the control of foot-and-mouth disease.

Definitions

Article 4

- a) Emergency vaccination: vaccination in accordance with Article 49,
- b) Emergency slaughter: the slaughter in emergency cases 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.
- c) Minister: Minister of Agriculture and Rural Affairs,
- ç) Ministry: Ministry of Agriculture and Rural Affairs,
- d) Suppressive vaccination: 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,

e) Primary outbreak: an outbreak with no epidemiological link with the first outbreak observed in the same zone or an outbreak observed primarily in another zone of the country.

f) Region: a section of the country with an area, subject to the supervision of the competent unit, of at least 2000 km² covering one province as a minimum,

g) Regionalisation: the delimitation of a restricted zone in line with Article 44 in order to prevent the spread of foot-and-mouth disease into the free zone where no restrictions are applied in accordance with this Regulation,

ğ) Animal of a susceptible species: any domestic or wild animal of the suborders Ruminantia, Suina, and Tylopoda of the order Artiodactyla; for specific measures, notably in application of Article 17 and Article 66, animals susceptible to the foot-and-mouth disease of the suborders Rodentia or Proboscidae.

h) Animal owner: 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.

ı) HTST (High-Temperature-Short-Time): pasteurisation at a high temperature, i.e. 72 °C, for a short period of time or equivalent pasteurisation effect achieving a negative reaction to an alkali phosphatase test,

i) Processing: one of the treatments for high risk material laid down in Annexes 6, 7 and 8 of this Regulation, applied in such a way as to avoid the risk of spread of foot-and-mouth disease virus,

j) Holding:

1) any agricultural or other premises, including circuses, located in the national territory of a country where animals of susceptible species are being bred or kept on a permanent or temporary basis.

2) However, for the purpose of Article 12, this definition does not include living areas for humans on such premises, unless animals of susceptible species, including those referred to in the second paragraph of Article 66, 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 12 inapplicable,

k) Permission: written permission issued by competent authorities and required, under the relevant legislation, to be kept in copies for further inspections of the country,

l) Protective vaccination: 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,

m) Incubation period: the length of the time between infection and the occurrence of clinical signs of foot-and-mouth disease. Namely, for the purposes of this Regulation, fourteen days for bovine and porcine animals, and twenty-one days for ovine and caprine animals and any other animal of susceptible species,

n) Directorate: FMD Institute Directorate of the Ministry of Agriculture and Rural Affairs,

o) Killing: any operation causing the death of animals,

ö) Official veterinarian: the veterinarian employed at the central or field organization of the Ministry of Food, Agriculture and Livestock,

p) Herd: 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 distinct herd with the same health status,

r) 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 1,

s) Case of foot-and-mouth disease or animal infected with foot-and-mouth disease: 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 1 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 11,

ş) Animal suspected of being infected: 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,

t) Animal suspected of being contaminated: 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,

u) UHT (Ultra-High Temperature): treatment at 132 °C for at least one second,

ü) Wild animal: an animal of a susceptible species living outside holdings as defined in indent (j) of the first paragraph of Article 4 or premises referred to in Articles 17 and 18,

v) Primary case of foot-and-mouth disease in wild animals: 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 second and third paragraphs of Article 66,

y) Authorized veterinarian: the veterinarian authorized by the Ministry of Food, Agriculture and Livestock to act in the capacity and responsibility of an official veterinarian.

z) Competent authority: provincial and district directorates of the Ministry of Food, Agriculture and Livestock.

SECTION TWO

Notification of Foot-and-Mouth Disease, Relevant Measures and Control

Notification of foot-and-mouth disease

ARTICLE 5 – (1) Throughout the country;

a) Foot-and-mouth disease is 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) Authorized veterinarians, veterinarians, senior staff of veterinary or other official or private laboratories and any person with an 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 Regulation.

Measures in case of suspicion of an outbreak of foot-and-mouth disease

ARTICLE 6 – (1) The Competent Authority shall take the following measures where a holding contains one or more animals suspected of being infected or contaminated.

a) The competent authority shall initiate official inspection to confirm the presence or absence of the foot-and-mouth disease in the shortest time possible.

b) The Competent Authority shall ensure that the necessary samples are taken under its supervision for the laboratory examinations required to confirm an outbreak in accordance with the definition of outbreak in Annex I.

(2) The official veterinarian shall place the holding accommodating one or more suspected animals 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 and such information is checked by the Competent Authority on request or at each visit during the disease suspicion period,

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,

ç) 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 19, and that all animals of susceptible species on the holding are kept in their living quarters or another place where they can be isolated,

d) 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,

e) An epidemiological inquiry is carried out in accordance with Article 1,

f) To facilitate the epidemiological inquiry, the necessary samples shall be taken for laboratory testing in accordance with point (1) of indent (a) of the fifth paragraph of Annex-2.

Movements onto and off a holding in case of suspicion of an outbreak of foot-and-mouth disease

ARTICLE 7 – (1) 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;

ç) 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 (ç) 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.

Extension of measures to other holdings

ARTICLE 8 – (1) The competent authority shall extend the measures provided for in Articles 6 and 7 to other holdings where their location, their construction and layout, or contacts with animals from the holding referred to in Article 6, give reason to suspect contamination.

(2) The competent authority shall apply at least the measures provided for in Articles 6 and 7(1) to premises or means of transport referred to in Article 18 should the presence of animals of susceptible species give reason to suspect infection or contamination with the foot-and-mouth disease virus.

Temporary control zone

ARTICLE 9 – (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 the first paragraph of Article 6 and indents (a), (b) and (d) of the second paragraph thereof, as well as the first paragraph of Article 7, 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 the country. However, the ban on movement of animals of species not susceptible to foot-and-mouth disease shall not exceed seventy-two hours, unless justified by exceptional circumstances.

Preventive eradication programme

ARTICLE 10 – (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 the first, second, third and fourth paragraphs of Annex-2 and point (1) of indent (a) of its fifth paragraph.

Maintenance of measures

ARTICLE 11 – (1) The Competent Authority shall not withdraw the measures provided for in Articles 6, 7, 8 and 9 until the suspicion of foot-and-mouth disease has been officially ruled out.

SECTION THREE

Measures in case of confirmation of an outbreak of foot-and-mouth disease

Necessary measures

ARTICLE 12 – (1) As soon as an outbreak of foot-and-mouth disease is confirmed, the Competent Authority shall ensure that, in addition to the measures provided for in Articles 6, 7 and 8, 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.

b) The Competent Authority 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 15 have been taken in accordance with point (1) of indent (a) of the fifth paragraph of Annex-2, and in sufficient numbers. The competent authority may decide that Article 15 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 6 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 57.

ç) All products and substances referred to in indent (c) of the second paragraph of Article 6 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 indent (ç) of the first paragraph, the Competent Authority 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 13;

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-4.

Cleaning and disinfection

ARTICLE 13 – (1) The Competent Authority shall ensure that cleansing and disinfection operations, as integral parts of the measures provided for in this Regulation, 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 Ministry as veterinary hygiene biocidal products.

(2) The Competent Authority 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) The Competent Authority 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) The Competent Authority shall ensure that cleansing and disinfection operations are carried out in accordance with Annex-3.

Tracing and treatment of products and substances derived from or having been in contact with animals of an outbreak of foot-and-mouth disease

ARTICLE 14 – (1) The Competent Authority shall ensure that the products and substances referred to in indent (c) of the second paragraph of Article 6 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 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.

Epidemiological inquiry

ARTICLE 15 – (1) The Competent Authority 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 57, to ensure standardised, speedy and targeted inquiries. Such inquiries shall deal 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,

ç) The movement of animals, persons, vehicles and the substances referred to in indent (c) of the second paragraph of Article 6 likely to have carried the foot-and-mouth disease virus to or from the holdings in question.

(2) The Competent Authorities shall inform and regularly update the Ministry about the epidemiology and spread of the foot-and-mouth disease virus.

Additional measures in case of confirmation of outbreaks of foot-and-mouth disease

ARTICLE 16 – (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 provided that they are individually identified.

(2) The competent authority may apply the measures provided for in indent (a) of the first paragraph of Article 12 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 Ministry, 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

the first, second, third and fourth paragraphs, as well as point (1) of indent (a) of the fifth paragraph, of Annex-2.

(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 9 and 10.

SECTION FOUR

Measures to be applied in Special Cases

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

ARTICLE 17 – (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 the Law No.5996 and where animals are kept for scientific purposes or purposes related to conservation of species or farm animal genetic resources, the Competent Authority 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 Competent Authority concerned may decide to derogate from indent (a) of the first paragraph of Article 12 provided 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 as to derogate from indent (a) of paragraph (a) of Article 12 shall immediately be notified to the Ministry. In the case of farm animal genetic resources, this notification shall include a reference to the list of premises established in accordance with indent (e) of the second paragraph of Article 62, 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.

(4) The special cases referred to in this Article shall be evaluated by the Ministry and the Ministry shall decide upon and ensure the implementation of the measures necessary, including those related to regionalization under Article 44 and to emergency vaccination under Articles 50 and 51, with a view to preventing the spread of the foot-and-mouth disease virus.

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

ARTICLE 18 – (1) Where a case of foot-and-mouth disease is confirmed in a slaughterhouse, a border inspection post 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,

ç) dung, manure and slurry shall be subject to disinfection and shall only be removed for treatment by the Ministry for a treatment in line with legislative provisions pertaining to animal by-products for non-human consumption,

d) 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 13 and with the instructions laid down by the competent authority.

e) An epidemiological inquiry shall be carried out in accordance with Article 15.

(2) The Competent Authority shall ensure that the measures provided for in Article 20 are applied in contact holdings.

(3) The Competent Authorities 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 twenty-four hours after completion of the cleansing and disinfection operations referred to in indent (d) of the first paragraph.

(4) Where required by the epidemiological situation, in particular where contamination of animals of susceptible species in holdings adjacent to the premises or means of transport referred to in paragraph 1 must be suspected, the Competent Authority shall ensure that by way of derogation from point (2) of indent (j) of the first paragraph of Article 4, an outbreak is declared on the premises or means of transport referred to in paragraph 1, and the measures provided for in Articles 12 and 21 are applied.

SECTION FIVE

Holdings Consisting of Different Epidemiological Production Units and Contact Holdings

Holdings

ARTICLE 19 – (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 indent (a) of the first paragraph of Article 12 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 the second paragraph of Article 6, 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 indent (ç) of the first paragraph of Article 12 may be granted by the Competent Authority 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-8.

(4) Where a derogation is granted in accordance with paragraph 1, such derogation shall be implemented within the framework of the rules prescribed in the relevant instructions issued by the Ministry.

(5) The Ministry shall revise the situation of the holdings referred to in this Article and if necessary, notify the competent authority of the instructions required for the coordination of the implementation of the measures specified in this Article.

Contact holdings

ARTICLE 20 – (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 6 or 12 or from these holdings to other holdings.

(2) Contact holdings shall be subject to the measures provided for in the second paragraph of Article 6 and Article 7 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-1 and the survey requirements provided for in point (1) of indent (a) of the fifth paragraph of Annex-2.

(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 indent (m) of the first paragraph of Article 4. However, the competent authority may, by way of derogation from indent (ç) of the second paragraph of Article 6, 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 the first, second, third and fourth paragraphs of Annex-2.

(4) Where the official veterinarian considers that the epidemiological situation permits, they 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 19.

(5) Where an epidemiological link between an outbreak of foot-and- mouth disease and premises or means of transportation referred to in Articles 17 and 18 respectively cannot be excluded, the Competent Authority shall ensure that the measures provided for in the first and second paragraphs of Article 6 and Article 7 shall apply to such premises or means of transportation. The competent authority may decide to apply the measures provided for in Article 10.

(6) The Ministry shall revise the situation of the holdings referred to in this Article and if necessary, notify the competent authority of the instructions required for the coordination of the implementation of the measures specified in this Article.

SECTION SIX

Protection and Surveillance Zones

Establishment of protection and surveillance zones

ARTICLE 21 – (1) The official veterinarian shall ensure that, without prejudice to measures provided for in Article 9, 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 official veterinarian 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 59 and 61 shall be established. For the purpose of carrying out the epidemiological inquiry as provided for in Article 15, those centres shall be assisted by an expert group as provided for in Article 63.

(5) The official veterinarian shall without delay trace animals dispatched from the zones during the period of at least twenty-one days before the estimated date of earliest infection on a holding in the protection zone.

(6) The Official Veterinarian 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.

Measures to be taken at holdings in the protection zone

ARTICLE 22 – (1) The Official Veterinarian 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 an inspection by the official veterinarian, 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 the first, second, third and fourth paragraphs of Annex-2 or taking of samples from animals of susceptible species in accordance with the (1) point of indent (a) of the fifth paragraph of the same Annex.

(c) animals of susceptible species shall not be removed from the holding on which they are kept.

(2) By way of derogation from indent (c) of the first paragraph, 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.

(3) The movement referred to in the second indent shall only be authorised if the competent authority is satisfied on the basis of a clinical examination in accordance with the first, second, third and fourth paragraphs of Annex-2 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.

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

ARTICLE 23 – (1) 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,
- ç) artificial insemination of and collection of ova and embryos from animals of susceptible species.

Additional measures and derogations

ARTICLE 24 – (1) The official veterinarian 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,
- ç) Artificial insemination of or collection of ova and embryos from animals of species not susceptible to foot-and-mouth disease,
- d) Movement of means of transport designed for the transportation of animals,
- e) The slaughter on the holding of animals of susceptible species for private consumption;
- f) 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 the means 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,
- ç) The movement and transport of equidae taking into account the conditions set out in Annex-5,
- d) The transport, under certain conditions, of goods referred to in Article 33 to holdings keeping animals of susceptible species,

Measures in relation to fresh meat produced in the protection zone

ARTICLE 25 – (1) 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) 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) Fresh meat, minced meat and meat preparations as referred to in paragraph 1, shall be marked in accordance with the relevant legislation by the official veterinarian and subsequently transported in sealed containers to an establishment designated by the competent authorities for transformation into meat products treated in accordance with Part (A) of Annex-6.

(4) 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 twenty-one 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.

(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 indent (b) of the second paragraph of Article 24 shall be processed in the establishment.

c) All such fresh meat, minced meat or meat preparations, must be stamped by the official veterinarian in accordance with the relevant legislation.

ç) 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 Regulation.

(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 foreign trade. The Ministry shall inspect the compliance check conducted by the official veterinarian and maintain a list of facilities approved for such certification.

(7) Derogation from the prohibition provided for in paragraph 1 may be granted subject to specific conditions. This derogation applies in particular with regard to the health marking of meat produced from animals.

Measures in relation to meat products produced in the protection zone

ARTICLE 26 – (1) 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 Part (A) of Annex-7 or which have been produced from meats referred to in the fourth paragraph of Article 25.

Measures in relation to milk and milk products produced in the protection zone

ARTICLE 27 – (1) 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) 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-8, 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 foreign trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authority and maintain a list of establishments approved for 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.

ç) 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;

d) 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.

Measures in relation to semen, ova and embryos collected from animals of susceptible species in the protection zone

ARTICLE 28 – (1) 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 twenty-one 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 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 35, and

b) All animals accommodated in the semen collection centre have undergone a clinical examination, and samples taken in accordance with the sixth paragraph of Annex-2 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 twenty-eight days after the collection of the semen.

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

ARTICLE 29 – (1) The Competent Authority 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 the relevant legislation 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 6 or 12 for distribution on designated fields under the following conditions:

a) The entire volume of manure has been produced at least twenty-one 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:

1) 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

2) the entire volume of manure has been produced at least 4 days prior to the examination referred to in point (1) of indent (b) of the third paragraph, and

3) 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) The Competent Authority 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.

Measures in relation to hides and skins from animals of susceptible species in the protection zone

ARTICLE 30 – (1) 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 twenty-one days before the estimated date of infection on the holding referred to in Article 12, and that have been stored separately from hides and skins produced after that date; or

b) Comply with the requirements laid down in Part (A) of Annex-6.

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

ARTICLE 31 – (1) 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 twenty-one days before the estimated date of infection on the holding referred to in the first paragraph of Article 12 and have been stored separately from wool, hair and bristles produced after that date; or

b) comply with the requirements laid down in Part (A) of Annex-6.

Measures in relation to other animal products produced in the protection zone

ARTICLE 32 – (1) The Competent Authority 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 the first paragraph of Article 12 and have been stored and transported separately from products produced after that date, or

b) have undergone the treatment in accordance with Part (A) of Annex-6, or

c) for specific products, comply with the appropriate requirements in Part (A) of Annex-6,
or

ç) 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 Regulation, or

d) are packed products intended for use as in-vitro diagnostic or laboratory reagents.

Measures in relation to feed, forage, hay and straw produced in the protection zone

ARTICLE 33 – (1) 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 the first paragraph of Article 12, 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

ç) 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.

d) produced at establishments accommodating animals of susceptible species and comply with the conditions specified in Part (B) of Annex-6.

Granting of derogations and additional certification

ARTICLE 34 – (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.

Removal of measures in the protection zone

ARTICLE 35 – (1) 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 the first paragraph of Article 12 and the completion of the preliminary cleansing and disinfection on that holding, carried out in accordance with Article 13.

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 36 to 41, shall continue to apply for at least 15 days until those measures are removed in accordance with Article 43.

(3) The survey referred to in the indent (b) of the first paragraph shall be carried out to substantiate the absence of infection and at least in compliance with the criteria specified in the first, second, third and fourth paragraphs of Annex-2 and shall include the measures provided for in indents (a) and (c) of the fifth paragraph of Annex-2 based on the criteria set out in the seventh paragraph of Annex-2.

Measures to be applied to holdings in the surveillance zone

ARTICLE 36 – (1) The measures provided for in the first paragraph of Article 22 shall be applied in the surveillance zone.

(2) By way of derogation from the prohibition provided for in indent (c) of the first indent of Article 22 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 the first paragraph of Article 22 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 the sixth paragraph of Annex-2, has been subjected to thorough clinical examination to rule out the presence or suspicion of clinically infected animals, and

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

d) the meat produced from such animals shall be subject to the treatment specified in Article 38.

Movement of animals of susceptible species within the surveillance zone

ARTICLE 37 – (1) 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 fifteen 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 the second paragraph of Article 36;

ç) for transporting them in accordance with indents (a) and (b) of the second paragraph of Article 24.

(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 the sixth paragraph of Annex-2, 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 indents (a) and (b) of the second paragraph of Article 36 have been completed with satisfactory results.

(5) The official veterinarian shall without delay trace animals of susceptible species dispatched from the surveillance zone during a period of least twenty-one days before the estimated date of earliest infection on a holding in the surveillance zone and they shall inform the competent authorities about their results from tracing animals.

Measures to be applied to fresh meat of animals of susceptible species originating in the surveillance zone and meat products produced from such meat

ARTICLE 38 – (1) 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) 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 twenty-one 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.

(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 indents (a) to (d) of the second paragraph of Article 36 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-7 or obtained from animals reared and slaughtered outside the surveillance zone or obtained from animals transported in accordance with the provisions in indent (b) of the second paragraph of Article 24 shall be processed in the establishment.

c) All such fresh meat, minced meat or meat preparations must be stamped by the official veterinarian in line with the relevant legislation.

ç) All such fresh meat, minced meat or meat preparations obtained in this manner must be clearly identified and it must be ensured that such products are transported and stored separately from fresh meat, minced meat or meat preparations that are not suitable for distribution outside the surveillance zone.

(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 transported under official supervision to a designated establishment for treatment in accordance with Part (A) of Annex-6.

(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 internal and foreign trade. The Ministry or competent authority shall supervise the control of compliance undertaken by the official veterinarian and maintain a list of all establishments approved for such certification.

(9) Derogation from the prohibition provided for in paragraph 1 may be granted, subject to specific conditions, with regard to the health marking of meat produced from animals of susceptible species originating in surveillance zone maintained for more than thirty days.

Measures to be applied to milk and milk products of animals of susceptible species produced in the surveillance zone

ARTICLE 39 – (1) The 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) 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 twenty-one 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-8 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.
- ç) 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 checked by the official veterinarian for milk intended for trade. The Ministry or competent authority shall supervise the control of compliance undertaken by the local veterinary authority and maintain a list of facilities approved for 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;

ç) 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.

d) 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.

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

ARTICLE 40 – (1) The Competent Authority shall ensure that the transport and distribution of dung or manure from holdings and other premises such as those mentioned in Article 18 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 official veterinarian 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 the second paragraph of Article 29.

Measures in relation to other animal products produced in the surveillance zone

ARTICLE 41 – (1) The placing on the market of products of animal origin other than those referred to in Articles 38 to 40 shall be subject to the conditions provided for in Articles 28, 30, 31 and 32.

Additional measures in the surveillance zone

ARTICLE 42 – (1) In addition to the measures provided for in Articles 36 to 41, the Competent Authority 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-5.

Removal of measures in the surveillance zone

ARTICLE 43 – (1) 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 the first paragraph of Article 12 and the completion of the preliminary cleansing and disinfection on that holding, carried out in accordance with Article 13.

b) The requirements provided for in Article 35 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 the first, second, third and fourth paragraphs of Annex-2 and shall include the measures provided for in the eighth paragraph of Annex-2 based on the criteria of the fifth paragraph of Annex-2.

SECTION 7

Regionalization, Movement Control and Identification

Regionalisation

ARTICLE 44 – (1) Where the foot-and-mouth disease virus appears to be spreading despite the measures taken in accordance with this Regulation and the epizootic becomes extensive and in any case when emergency vaccination is implemented, the territory shall be regionalised into one or more restricted and free zones.

(2) Prior to the delimitation of the restricted zone, a thorough epidemiological assessment of the situation shall be carried out by the Ministry, 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.

(3) 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 as defined in indent (f) of the first paragraph of Article 4. The restricted zone may be reduced in the light of the results of the epidemiological inquiry provided for in Article 15, 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 provinces in its periphery.

Measures applied in a restricted zone of

ARTICLE 45 – (1) Where regionalisation is applied, the following measures shall be taken.

a) 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 shall be checked.

b) Fresh meat and raw milk and as far as possible other products in stock not eligible for dispatch outside the restricted zone shall be marked and traced in accordance with the legislation of;

c) Specific certification shall be issued by the official veterinarian of animals of susceptible species and products derived from such animals and health marking, of products for human consumption intended and eligible for dispatch outside the restricted zone.

(2) Where regionalisation is applied, the animals of susceptible species dispatched from the restricted zone to any other place in or out of the country during the time between the date of estimated introduction of the foot-and-mouth disease virus and 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) Competent authorities shall trace 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 and the date regionalisation is

implemented. Such fresh meat shall be treated in accordance with Part (A) of Annex-6, and raw milk and milk products shall be treated in accordance with Part (A) or (B) of Annex-8 depending on the use, or detained until possible contamination with the foot-and- mouth disease virus is officially ruled out.

Identification of animals of susceptible species

ARTICLE 46 – (1) Without prejudice to other legislation on identification of domestic bovine, ovine and caprine animals and swine, in the event of an outbreak of foot-and-mouth disease, 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 17 and Article 18, 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 Ministry.

(2) The measures taken by the Competent Authority 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 50 and 51 shall be revised, and when necessary modified, by the Ministry.

Movement control in case of an outbreak of foot-and-mouth disease

ARTICLE 47 – (1) 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 44.

a) Owners shall supply the official veterinary, on request of that veterinarian, with appropriate information concerning animals entering or leaving their holding. That information shall, in relation to all animals of susceptible species, include all details required by the Ministry such as date of birth, sex, colour and maternal identification of animals.

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 the Ministry such as the name and address of the establishment of delivery or departure, date and place of departure and delivery, species and number of transported animals, date and place of disinfection, registration number of the transporter and serial number of the relevant health certificate.

(2) The Ministry may extend some or all the measures provided for in paragraph 1 to a part or the entire free zone.

SECTION EIGHT

Vaccination

Use, manufacture, sales and controls of foot-and-mouth disease vaccines

ARTICLE 48 – (1) Production, storage, supply, distribution and sale of foot-and-mouth disease vaccines shall be subject to the official control of the Ministry.

(2) The marketing of foot-and-mouth disease vaccines is under the supervision of Ministry.

(3) 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, shall be authorised by the Ministry and carried out under appropriate bio-security conditions.

Decision on introducing emergency vaccination

ARTICLE 49 – (1) It shall 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 throughout the country,

b) Neighbouring are at risk due to the geographical situation of or the prevailing meteorological conditions in relation to reported outbreaks of foot-and-mouth,

c) other states are at risk due to epidemiologically relevant contacts between holdings on their territories and holdings keeping animals of susceptible species in a country where there are outbreaks of foot-and-mouth disease,

ç) Turkey is 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 17 and to the criteria listed in Annex-9.

(3) The decision to introduce emergency vaccination shall be adopted by the Ministry.

Conditions for emergency vaccination

ARTICLE 50 – (1) The decision to introduce emergency vaccination in accordance with the third paragraph of Article 49 shall specify the conditions under which such vaccination shall be carried out and these conditions are given below.

- a) The delimitation in accordance with Article 44 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,
- ç) A specific prohibition on movements of vaccinated and non-vaccinated animals of susceptible species and their products,
- d) The special additional and permanent identification and special registration of the vaccinated animals pursuant to the second paragraph of Article 46,
- e) Other measures 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 51, irrespective of whether the vaccinated animals are subsequently slaughtered or stay alive.

(3) The Ministry shall put in place an information programme to inform the public about the safety of meat, milk and dairy products from vaccinated animals for human consumption.

Protective vaccination

ARTICLE 51 – (1) The competent authority in charge of the administration of protective vaccination shall ensure that the following conditions have been satisfied.

- a) Regionalization of the vaccination area under Article 44 in close cooperation, when so required, with neighbouring countries.
- b) Administration of vaccination in due compliance with hygiene and bio-security rules and in an expeditious manner with a view to preventing the spread of the foot-and-mouth virus.
- c) Performance of all measures to be applied in the vaccination without prejudice to the measures prescribed in Articles 44, 45, 46 and 47.
- ç) Where the vaccination area covers a part or the whole of a protection or surveillance zone;

1) Measures applicable to the protection or surveillance zone in question under this Regulation shall be applied until the said measures have been lifted in line with Article 35 or 43 in the specified part of the zone.

2) Following the termination of the measures applied in the protection and surveillance zones, the application of the measures specified in Article 52 as applicable to the vaccination area shall be continued.

(2) A surveillance zone shall be designated with a diameter of at least 10 km starting from the periphery of the vaccination region where protective vaccination is administered and in this surveillance zone,

a) Comprehensive surveillance shall be conducted.

b) Movements of animals of susceptible species shall be subject to checks conducted by the competent authority.

c) Surveillance shall be continued until the eradication of the foot-and-mouth disease and acquisition of freedom from infection.

Clinical and serological survey in the vaccination zone

ARTICLE 52 – (1) The competent authority 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 thirty 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-11 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 the sixth paragraph of Annex-2.

b) Where the competent authorities use in addition sentinel animals, the conditions for restocking of infected holdings in Annex-4 shall be taken into account.

SECTION NINE

Laboratories and Establishments Handling Foot-and-Mouth Disease

Laboratories and establishments

ARTICLE 53 – (1) 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 Ministry.

(2) 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 establishments and laboratories approved and supervised by the Ministry.

(3) Research and diagnosis activities related to live foot-and-mouth disease virus shall be conducted only by the FMD Institute.

(4) the laboratories and establishments referred to paragraphs 2 and 3 shall be operated at least according to the bio-security standards set out in Annex-10.

Checks of laboratories and establishments

ARTICLE 54 – (1) Bio-security experts designated by the Ministry shall check the laboratories and establishments handling live foot-and-mouth disease virus in terms of their compliance with the bio-security standards prescribed in Annex-10.

Foot-and-Mouth Disease Institute

ARTICLE 55 – (1) laboratory testing for foot-and-mouth disease is carried out in laboratories authorised for such testing by the competent authorities..

(2) Laboratory testing to confirm the presence of foot-and-mouth disease virus or other vesicular disease viruses is carried out in accordance with Article 56 by the FMD Institute.

(3) The national reference laboratory for foot-and-mouth disease is the FMD Institute. The Institute is in charge of the functions and duties specified in Annex-12.

(4) The laboratory inquiries given in this Regulation shall be conducted with the primary purpose of confirming the presence of the foot-and-mouth disease, followed by the elimination of both this disease and other vesicular diseases.

(5) In a region where the prior emergence of the foot-and-mouth disease has been confirmed and the virus serotype identified by the Institute, the virus shall be classified in antigenic terms on the basis of the vaccine strains.

(6) When thusly necessitated, the Institute shall be involved in joint activities with international or regional reference laboratories for FMD diagnosis.

SECTION TEN

FMD Diagnosis, Contingency Plans and Real-time alert exercises

Diagnosis of the foot-and-mouth disease

ARTICLE 56 – (1) The differential diagnosis of the foot-and-mouth disease and other vesicular diseases shall be performed by using the standards and tests specified in Annex-11.

Contingency plans

ARTICLE 57 – (1) The Ministry 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. When deemed appropriate, it shall specify the actions to be taken to ensure coordination with other countries.

(3) The contingency plan shall provide for measures to be implemented in the event of a worst case scenario as referred to in the thirteenth paragraph of Annex-13 and shall give indications of:

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

b) Densely Populated Livestock Areas, taking into account the criteria set down in Annex-9.

(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. These arrangements cover the methods to be utilized in cases where it is necessary to bury or burn the carcasses of dead or killed animals on site.

(5) The criteria and requirements given in Annex-13 shall be taken into consideration during the preparation of the contingency plan.

(6) In the light of real-time alert exercises, the Ministry shall update the contingency plan every five years.

Real-time alert exercises

ARTICLE 58 – (1) Real-time alert exercises are carried out in accordance with the contingency plans and Annex-13. Where appropriate, cooperation is sought with the competent authorities of neighbouring countries in the implementation of these exercises.

SECTION ELEVEN

Control Centres and Expert Groups

National/Central disease control centres — Functions and duties

ARTICLE 59 – (1) The Ministry shall ensure that a fully functional national/central disease control centre is 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 61. Certain functions originally attributed to the national/central disease control centre may subsequently be transferred to the local disease control centre.

(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,
- ç) Organising an emergency vaccination campaign and also the delimitation of vaccination zones,
- d) Liaising with the Institute and other laboratories,
- e) Liaising with competent environmental authorities to coordinate the actions on veterinary and environmental safety,
- f) Liaising with the media,
- g) Liaising with the enforcement bodies to ensure adequate implementation of specific legal measures,
- ğ) Ensuring flow of information to international agencies and other countries.

National/Central disease control centres — Technical requirements

ARTICLE 60 – (1) The Ministry shall take all measures necessary to 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,
- ç) Maps and other sources of information that can be used in directing control measures,
- 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 disease and allowing different activities to be linked and coordinated,
- e) 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,
- f) 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 63 in the event of an outbreak of foot-and-mouth disease,
- g) Lists of competent environmental protection authorities and bodies to contact in the event of an outbreak of foot-and-mouth disease,
- ğ) Maps identifying appropriate processing site areas,
- h) 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,
- ı) 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 ground waters.

Establishment, functions and duties of local disease control centres

ARTICLE 61 – (1) In the event of an FMD outbreak, the competent authority shall immediately establish fully functional local disease centres to implement the decisions to be taken by the Animal Health Control Commission.

(2) Within the scope of the contingency plans, the Ministry shall include provisions pertaining to the possible establishment, organizational structure, personnel, location, facilities and equipment, management systems, communication tools and information methods of local disease control centres.

(3) Local disease control centres shall work in coordination and close cooperation with national/central disease control centre specifically on the measures stipulated in indent (b) of the third paragraph of Article 59.

(4) In the event of an FMD outbreak, the competent authority shall ensure that local disease control centres have the organizational structure required to provide for the timely implementation of the measures stipulated in this Regulation.

Local disease control centres — Technical requirements

ARTICLE 62 – (1) The competent authority shall take all measures necessary to 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,

ç) 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,

d) Up-to-date lists of persons, including private veterinarians, and local organisations in each region that shall be contacted and may be involved in the event of an outbreak of foot-and-mouth disease,

e) Up-to-date lists of holdings to which the provisions of Article 17 and 19 may be applied in the case of an outbreak of foot-and-mouth disease,

f) Up-to-date inventories of possible burning or burial places for animals killed in accordance with this Regulation and to be processed in accordance with national legislation on the protection of the environment,

g) 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,

ğ) 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 ground waters,

h) List of treatment and disposal undertakings authorised to treat or dispose of animal carcasses and animal waste,

ı) 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 ground waters.

Expert Group

ARTICLE 63 – (1) The Ministry 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.

(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;

- 1) The origin of the infection,
- 2) The date of introduction of the infectious agent,
- 3) 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 18, and in relation to emergency vaccination,

ç) Follow up and guide the epidemiological inquiry,

d) Supplement the epidemiological data with geographical, meteorological and other necessary information,

e) Analyse the epidemiological data and perform risk assessments at regular intervals,

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

SECTION TWELVE

Antigen and Vaccine Banks

National antigen and vaccine banks

ARTICLE 64 – (1) The Ministry shall 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 authorized for use.

(2) The Ministry may retain establishments for the packaging and storage of vaccines in the case of emergency vaccination.

(3) Under this Article, the specifications of antigens and vaccines in antigen or vaccine banks shall be designated by the Ministry.

Testing of foot-and-mouth disease vaccines

ARTICLE 65 – (1) The Ministry shall organize efficacy and innocuity testing required for the vaccines.

SECTION THIRTEEN

Foot-and-Mouth Disease in Other Species

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

ARTICLE 66 – (1) The prohibition on swill feeding is applicable to all animals irrespective of their use or the place inhabited by these animals.

(2) Immediately after the official veterinarian has information that animals of susceptible species belonging to ruminants, suinae, domestic and wild animals of the subspecies camel and lama of tylopodae and rodents or proboscidea 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.

(3) As soon as the Official Veterinarian receives information to the effect that animals are suspected to have been infected with the foot-and-mouth disease, he Official Veterinarian shall immediately apply the measures given in Annex-14 to prevent the further spread of the disease and prepare a plan to eradicate the foot-and-mouth disease in accordance with Part (B) of Annex-14. The competent authority shall inform farmers and hunters handling animals of susceptible species on confirmed disease cases.

SECTION FOURTEEN

Miscellaneous and Final Provisions

Regulatory Power

ARTICLE 67 – (1) Provisions in this Regulation pertaining to the culling of animals suspected or confirmed to have been infected with the foot-and-mouth disease shall be applicable in all areas designated by the Ministry.

Entry into force

ARTICLE 68 – (1) This Regulation shall be effective as of its date of publication.

Execution

ARTICLE 69 – (1) This Regulation shall be executed by the Ministry of Food, Agriculture and Livestock.

ANNEX-1

DEFINITION OF OUTBREAK

(1) An outbreak shall be declared where a holding meets one or more of the following criteria.

a) Foot-and-mouth disease virus has been isolated from an animal, any product derived from that animal, or its environment.

b) Clinical signs consistent with foot-and-mouth disease are observed in an animal of a susceptible species, and the viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of foot-and-mouth disease virus has been detected and identified in samples collected from the animal or animals of the same epidemiological group.

c) Clinical signs consistent with foot-and-mouth disease are observed in an animal of a susceptible species and the animal or its cohorts are positive for antibody to foot-and-mouth disease virus structural or non-structural proteins, provided that previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity.

ç) Viral antigen or viral RNA specific to one or more of the serotypes of foot- and-mouth disease virus has been detected and identified in samples collected from animals of susceptible species and the animals are positive for antibody to foot-and-mouth disease virus structural or non-structural proteins, provided that in the case of antibodies to structural proteins previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity.

d) An epidemiological link has been established to a confirmed foot-and-mouth disease outbreak and at least one of the following conditions applies,

1) One or more animals are positive for antibody to foot-and-mouth disease virus structural or non-structural proteins, provided that previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity,

2) Viral antigen or viral RNA specific to one or more of the serotypes of foot-and-mouth disease virus has been detected and identified in samples collected from one or more animals of susceptible species,

3) Serological evidence of active infection with foot-and-mouth disease by detection of seroconversion from negative to positive for antibody to foot- and-mouth disease virus structural or non-structural proteins has been established in one or more animals of susceptible species, and previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity (Where a previously seronegative status cannot be reasonably expected, this detection of seroconversion is to be carried out in paired samples collected from the same animals on two or more occasions at least five days apart, in the case of structural proteins, and at least twenty-one days apart, in the case of non-structural proteins),

4) Clinical signs consistent with foot-and-mouth disease are observed in an animal of a susceptible species.

ANNEX-2

SURVEY

Clinical examination

(1) Holdings must undergo clinical examinations of all animals of susceptible species for signs or symptoms of foot-and-mouth disease.

(2) Special emphasis must be laid on animals which may have been exposed to foot-and-mouth disease virus with a high probability, notably transport from holdings at risk or close contact to persons or equipment that had close contact to holdings at risk.

(3) The clinical examination must take into account the transmission of foot-and-mouth disease, including the incubation period referred to in indent (m) of the first paragraph of Article 4 and the way in which animals of susceptible species are kept.

(4) Relevant records kept on the holding must be examined in detail with particular regard to data required for animal health purposes and, where available, on morbidity, mortality and abortion, clinical observations, changes in productivity and feed intake, purchase or sale of animals, visits of persons likely to be contaminated and other anamnesticly important information.

Procedures for sampling

(5) General provisions,

a) Serological sampling shall be carried out:

1) According to the recommendations of the epidemiological team established within the expert group referred to in Article 63, and

2) In support of tracing and the provision of evidence, taking also into account the definition in Annex I, for the absence of previous infection.

b) Where sampling is carried out in the framework of disease surveillance after an outbreak, actions shall not commence before at least twenty-one days have elapsed since the elimination of susceptible animals on the infected holding(s) and the carrying out of preliminary cleansing and disinfection, unless otherwise provided for in this Annex.

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

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

(7) Sampling in protection zones,

a) In order to seek the repeal in accordance with Article 35 of the measures provided for in Articles 21 to 34, all holdings within the perimeters of the protection zone where sheep and goats

have not been in direct and close contact with bovine animals during a period of at least 21 days prior to taking the samples shall be examined pursuant to a sampling protocol suitable to detect 5% prevalence of disease with at least 95% level of confidence.

b) However, the competent authorities may decide where epidemiological circumstances allow and in particular in application of the measures provided for in indent (b) of the first paragraph of Article 35, that samples are taken not earlier than fourteen days after the elimination of susceptible animals on the infected holding(s) and the carrying out of preliminary cleansing and disinfection, under the condition that the sampling is carried out in accordance with indent (a) of the seventh paragraph of this Annex using statistical parameters suitable to detect 2 % prevalence of disease within the herd with at least 95 % level of confidence.

(8) Sampling in surveillance zones

a) In order to seek the repeal in accordance with Article 43 of the measures provided for in Articles 36 to 42, holdings within the perimeters of the surveillance zone where the presence of foot-and-mouth disease in the absence of clinical signs must be suspected, notably where sheep and goats are kept, shall be examined. For the purpose of this survey the model of a multistage sampling shall be sufficient, provided that samples are taken:

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

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

3) from as many sheep and goats per holding as necessary to detect 5% prevalence of disease within the herd with at least 95% level of confidence, and from all sheep and goats if there are less than 15 sheep and goats on the holding.

(9) Sampling for monitoring for monitoring the areas outside the zones established in accordance with the provisions of Article 21, and in particular to substantiate the absence of infection in the sheep and goat population which is not in close and direct contact with non-vaccinated bovine or porcine animals, a sampling protocol recommended for monitoring purposes by the OIE or a sampling protocol as provided for in the second point of indent (a) of the eighth paragraph of this Annex 4 shall be applied with the difference compared to that the estimated herd prevalence shall be set at 1%.

(10) The number of samples calculated in accordance with requirements in the sixth and seventh paragraphs of this Annex, as well as the third point of indent (a) of the eighth paragraph

shall be increased in order to take into account the established diagnostic sensitivity of the test employed.

ANNEX-3

PRINCIPLES AND PROCEDURES FOR CLEANSING AND DISINFECTION

(1) General principles and procedures

a) Cleansing and disinfection operations as provided for in Article 13 shall be carried out under official supervision and in accordance with the instructions given by the official veterinarian.

b) The disinfectants to be used and their concentrations shall be officially recognised by the Ministry to ensure destruction of foot-and- mouth virus.

c) The activity of disinfectants must not be impaired by prolonged storage.

ç) The choice of disinfectants and of procedures for disinfection should be made taking into account the nature of the premises, vehicles and objects which are to be treated.

d) The conditions under which degreasing agents and disinfectants are used must ensure that their efficacy is not impaired. In particular technical parameters provided by the manufacturer, such as pressure, minimum temperature and required contact time must be observed. The activity of the disinfectant must not be compromised by interaction with other substances, such as degreasing agents.

f) Independently of the disinfectant used, the following general rules shall apply:

1) Thorough soaking of bedding and litter as well as faecal matter with the disinfectant,

2) Washing and cleaning by careful brushing and scrubbing of all surfaces possibly contaminated and in particular of the ground, floors, ramps and walls after the removal or dismantling, where possible, of equipment or installations otherwise impairing the effective cleansing and disinfection procedures,

3) Following the first and second points of this indent, further application of disinfectant for a minimum contact time as stipulated in the manufacturers' recommendations,

4) The water used for cleaning operations is to be disposed of in such a way as to avoid any risk of spreading the foot-and-mouth disease virus and in accordance with the instructions of the official veterinarian.

5) Where washing is carried out with liquids applied under pressure and following the disinfection, re-contamination of the previously cleansed or disinfected parts must be avoided.

6) Washing, disinfecting or destroying of equipment, installations, articles or compartments likely to be contaminated should be included.

7) Cleansing and disinfection operations required in the framework of this Regulation must be documented in the holding register or, in the case of vehicles, in the log-book and where official approval is required be certified by the supervising official veterinarian.

(2) Special provisions on cleansing and disinfection of infected holdings:

a) Preliminary cleansing and disinfection

1) During the killing of the animals all necessary measures shall be taken to avoid or minimise the dispersion of foot-and-mouth virus. This shall include among other things the installation of temporary disinfection equipment, supply of protective clothing, showers, decontamination of used equipment, instruments and facilities and the interruption of power supply to the ventilation.

2) Carcasses of killed animals must be sprayed with disinfectant and removed from the holding in covered and leak-proof containers for processing and disposal.

3) As soon as the carcasses of the animals of susceptible species have been removed for processing and disposal, those parts of the holding in which these animals were housed and any parts of other buildings, yards, etc. contaminated during killing, slaughter or post-mortem examination should be sprayed with disinfectants approved for this purpose.

4) Any tissue or blood which may have been spilled during slaughter or post-mortem examination and any gross contamination of buildings, yards, utensils, etc. should be carefully collected and disposed of with the carcasses.

5) The used disinfectant shall remain on the surface for at least 24 hours.

b) Final cleansing and disinfection,

1) Grease and dirt should be removed from all surfaces by the application of a degreasing agent and washed with cold water.

2) After washing with cold water further spraying with disinfectant should be applied.

3) After seven days the premises should be treated again with a degreasing agent, rinsed with cold water, sprayed with disinfectant and rinsed again with cold water.

(3) Disinfection of contaminated bedding, manure and slurry,

a) The solid phase of manure and used bedding should be stacked to heat, preferably by adding 100 kg granulated quick lime on 1 m³ manure, ensuring a temperature of at least 70 °C

throughout the stack, sprayed with disinfectant and left for at least 42 days, during which the stack should be either covered or re-stacked to ensure thermic treatment of all layers.

b) The liquid phase of manure and slurry should be stored for at least forty-two days after the last addition of infective material. This period may be extended if the slurry has been heavily contaminated or during adverse weather conditions. This period may be shortened if disinfectant has been added so as to alter the pH sufficiently throughout the substance to destroy the foot-and-mouth disease virus.

(4) Special cases

a) Where for technical or security reasons the cleansing and disinfection procedures cannot be completed in accordance with this Regulation, the buildings or premises must be cleansed and disinfected as much as possible to avoid spread of the foot-and-mouth disease virus and must remain unoccupied by animals of susceptible species for at least 1 year.

b) By way of derogation from indents (a) and (b) of the second paragraph of this Annex, in case of open-air holdings, the competent authority may establish specific procedures for cleaning and disinfection, taking into account the type of holding and the climatic conditions.

c) By way of derogation from the third paragraph of this Annex, the competent authority may establish specific procedures for the disinfection of dung and manure in accordance with scientific evidence that the procedure ensure effective destruction of the foot-and-mouth disease virus.

ANNEX V

RESTOCKING OF HOLDINGS

General principles

(1) Restocking should not commence until twenty-one days after completion of the final disinfection of the holding.

(2) Animals for restocking can only be introduced under the following conditions:

a) The animals shall not come from areas subject to animal health restrictions in relation to foot-and-mouth disease.

b) The competent authorities must be satisfied that any possible residual foot-and-mouth disease virus can be detected in the animals intended for restocking either on the base of clinical signs, in the case of bovine or porcine animals, or through laboratory investigations in the case of other species susceptible to foot-and-mouth disease, carried out at the end of the observation period specified in the third paragraph of this Annex.

c) In order to ensure an adequate immune response referred to in paragraph 1.2.2 in the animals intend for restocking, the animals must either originate in and come from a holding situated in an area of at least 10 km radius centred on that holding where there was no outbreak of foot-and-mouth disease for at least thirty days, or the animals have been tested with negative results in an assay as described in Annex-11 for the detection of antibodies against the foot-and-mouth disease virus carried out on samples taken prior to introduction onto the holding.

(3) Irrespective of the type of farming practised on the holding, re-introduction must conform with the following procedures.

a) Animals must be introduced in all units and buildings of the holding involved.

b) In the case of a holding consisting of more than one unit or building, re-introduction is not necessary for every unit or building at the same time. However no animals of species susceptible to foot-and-mouth disease may leave the holding until all the re-introduced animals in all units and buildings have fulfilled all restocking procedures.

c) Animals must be subjected to clinical inspection every three days for the first 14 days following the introduction.

ç) During the period from 15 to 28 days after re-introduction, animals are to be subjected to clinical inspection once every week.

d) Not earlier than 28 days after the last re-introduction, all animals must be clinically examined and samples for testing for the presence of antibody against foot-and-mouth disease virus shall be taken in accordance with the requirements of the sixth paragraph of Annex-2.

(4) The restocking procedure shall be considered completed when the measures provided for in point (d) of the third paragraph of this Annex have been completed with negative results.

Extension of measures and derogations

(5) The competent authority may impose:

a) The use of sentinel animals, in particular in holdings difficult to clean and disinfect and notably open-air holdings.

b) Additional safeguard and control measures within the framework of restocking.

(6) The competent authorities may derogate from the measures provided for in points (b), (c) and (ç) of the third paragraph of this Annex where restocking is carried out after 3 months have elapsed following the last outbreak in an area of 10 km radius centred on the holding subject to the restocking operation.

Restocking in connection with emergency vaccination

(7) Restocking in a vaccination zone established in accordance with Article 51 shall be carried out either in accordance with paragraphs 1 and 2 of this Annex.

(8) The competent authorities may authorise the restocking of holdings situated outside the vaccination zone with vaccinated animals under the following conditions:

a) the proportion of vaccinated animals used for restocking exceeds 75% in which case, not earlier than 28 days after the last re-introduction of animals of susceptible species, the vaccinated animals are tested for the detection of antibodies against non-structural proteins, randomly, the sampling using the statistical parameters provided for in the sixth paragraph of Annex-2 and for the non-vaccinated animals the provisions of the General Principles of this Annex shall apply, or

b) The proportion of vaccinated animals does not exceed 75 % in which case the non-vaccinated animals shall be considered sentinels and provisions of paragraph 1 shall apply.

ANNEX-5

RESTRICTIONS ON THE MOVEMENT OF EQUIDAE

Minimum measures

1) Where at least one outbreak of foot-and-mouth disease has been confirmed in accordance with Article 12, it shall be ensured that equidae are not dispatched for exportation, unless the documents required by the importing country have been completed.

Recommended additional measures

(1) In the case where the competent authorities apply a complete stand-still as provided for in the third paragraph of Article 9, transport of equidae from holdings under restrictions laid down in Articles 6 and 12 may be authorised for equidae which need special veterinary treatment in premises without animals of susceptible species, if the following conditions are met:

a) The emergency must be documented by the veterinary surgeon on call twenty-four hours per day, seven days per week.

b) The agreement of the clinic of destination must be producible.

c) The transport operation must be authorised by the competent authorities who must be reachable twenty-four hours per day, seven days per week.

ç) Equidae must be accompanied during the transport by an identification document.

d) The on-call official veterinarian must be informed about the route prior to departure.

e) Equidae must be groomed and treated with an effective disinfectant.

f) Equidae must travel in dedicated equine transport which is recognisable as such and cleansed and disinfected prior to and after use.

(2) Controls on equidae in relation to protection and surveillance zones

a) Movement of equidae within the protection and surveillance zones established in accordance with Article 21 is subject to the following conditions:

1) The use of equidae kept on holdings in the protection and surveillance zone not keeping animals of susceptible animals may be authorised in the protection zone, subject to appropriate cleansing and disinfection measures, and may not be restricted on premises situated in the surveillance zone.

2) Equidae may be transported without restrictions in dedicated equine transport to a holding not keeping animals of susceptible species.

3) The competent authorities may in exceptional cases authorise the transport of equidae in dedicated or registered equine transport from a holding not keeping animals of susceptible species to another holding keeping animals of susceptible species situated in the protection zone, subject to cleansing and disinfection of the transport prior to loading of the animals and before leaving the holding of destination;

4) Movement of equidae may be allowed on public roads, on pastures belonging to holdings not keeping animals of susceptible species and exercise premises.

b) The collection of equine semen, ova and embryos from donor animals on holdings not keeping animals of susceptible species in the protection and surveillance zone and the transport of equine semen, ova and embryos to recipient equine animals on holdings not keeping animals of susceptible species shall not be restricted.

c) Visits from owners of equidae, the veterinary surgeon, the inseminator and the farrier on holdings keeping animals of susceptible species in the surveillance zones but not subject to the restrictions provided for in Articles 6 and 12 shall be subject to the following conditions.

1) Equidae are kept separated from animals of susceptible species and access of the persons referred to above to animals of susceptible species is effectively prevented.

2) All visitors must be registered.

3) Cleansing and disinfecting of means of transportation and of the boots of visitors.

ANNEX-6

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

PART A

Products of animal origin

(1) Meat products, hides and skins, sheep wool, ruminant hair and pig bristles derived from animals of susceptible species, blood and blood products of animals of susceptible species used for technical purposes, including pharmaceuticals, in vitro diagnostics and laboratory reagents, heat-treated lard and rendered fats, petfood and dogchews, game trophies of ungulates, animal casings which have been cleaned, scraped and either salted with sodium- chloride for 30 days or bleached or dried after scraping and were protected from re-contamination after treatment and other products must be treated in such a way as to eliminate the foot-and-mouth virus. Specific treatment methods for such products shall be issued by the Ministry as instructions.

PART B

Products not of animal origin

1. Straw and forage must be treated in one of the following manners:
 - a) Steam in a closed chamber for at least 10 minutes and at a minimum temperature of 80 °C, or
 - b) Formalin fumes (formaldehyde gas) produced in a chamber kept closed for at least 8 hours and at a minimum temperature of 19 °C, using commercial-type solutions at 35-40 % concentration, or
 - c) Has been stored in package or bales under shelter at premises situated not closer than two km to the nearest outbreak of foot-and-mouth disease and is not released from the premises before at least three months have elapsed following the completion of cleansing and disinfection measures provided for in Article 13 and in any case not before the end of the restrictions in the protection zone.

ANNEX-7

PART A

Treatment of fresh meat

- (1) De-boned fresh meat: together with diaphragms but excluding offal, from which the bone and the main accessible lymphatic glands have been removed,
- (2) Trimmed offal,
 - a) Heart from which lymphatic glands, connective tissue and adhering fat have been completely removed,

b) Liver from which lymphatic glands, adhering connective tissue and fat have been completely removed,

c) Whole masseter muscles, incised from which lymphatic glands, connective tissue and adhering fat have been completely removed,

ç) Tongues with epithelium and without bone, cartilage and tonsils,

d) Lungs from which the trachea and main bronchi and the mediastinal and bronchial lymphatic glands have been removed,

e) Other offal without bone or cartilage from which lymphatic glands, connective tissue, adhering fat and mucous membrane have been completely removed.

(3) Maturation,

a) Maturation of carcasses at a temperature of more than + 2 °C for at least 24 hours,

b) pH value in the middle of Longissimus dorsi muscle recorded as less than 6,0.

(4) Effective measures must be applied to avoid cross-contamination.

PART B

Additional measures applicable to the production of fresh meat from animals of susceptible species originating in the surveillance zone

(1) Fresh meat, excluding heads, viscera and offal, intended for placing on the market outside the protection and surveillance zone shall be produced according to at least one of the following additional conditions.

a) In the case of ruminants:

1) The animals have been subjected to the controls provided for in the second paragraph of Article 24.

(2) The meat is subject to the treatment provided for in the first, third and fourth paragraphs of Part A of this Annex.

b) in the case of all animals of susceptible species:

1) The animals have been resident on the holding for at least 21 days and are identified so as to allow the tracing of the holding of origin.

2) The animals have been subjected to the controls provided for in the second paragraph of Article 24.

3) The meat is clearly identified and detained under official supervision for at least 7 days and is not released until any suspicion of infection with the foot-and-mouth disease virus on the holding of origin has been officially ruled out at the end of the detention period;

c) In the case of all animals of susceptible species:

1) The animals have completed a 21-day standstill on the holding of origin during which no animal of a species susceptible to foot-and-mouth disease has been introduced onto the holding, and

2) The animals have been subjected to the controls provided for in the second paragraph of Article 24 within 24 hours of loading, and

3) Samples taken in accordance with the statistical requirements provided for in the sixth paragraph of Annex-2 Within 48 hours of loading have been tested with negative result in an assay for the detection of antibodies against the foot-and-mouth disease virus, and

4) The meat is detained under official control for 24 hours and not released before a repeat inspection of the animals in the holding of origin has ruled out on clinical inspection the presence of infected or suspected of being infected animals.

(2) Trimmed offal shall be marked with the health mark and treated with one of the procedures given in Part A of Annex-6.

(3) Other products shall be subjected to the treatment provided for in Article 32.

ANNEX-8

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

PART A

Milk and milk products intended for human consumption

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

Milk intended for human consumption must be subject to at least one of the following treatments:

a) Sterilisation at a level of at least F 0 3,

b) UHT (1) treatment,

c) HTST (2) treatment applied twice to milk with a pH equal to or above 7,0,

ç) HTST treatment of milk with a pH below 7,0,

d) HTST combined with another physical treatment by:

1) Either lowering the pH below 6 for at least one hour, or

2) Additional heating to 72 °C or more, combined with desiccation.

(2) Milk products must either undergo one of the above treatments or be produced from milk treated in accordance with paragraph 1.

PART B

Milk and milk products not intended for human consumption and milk and milk products for animal consumption

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

a) Milk not intended for human consumption and milk intended for animal consumption must be subject to at least one of the following treatments:

1) Sterilisation at a level of at least F 0 3,

2) UHT (1) combined with another physical treatment referred to in indent (b),

3) HTST (2) applied twice,

b) HTST combined with the following other treatments,

1) Lowering the pH below 6 for at least one hour, or

2) Additional heating to 72 °C or more, combined with desiccation.

(2) Milk products must either undergo one of the above treatments or be produced from milk treated in accordance with paragraph 1.

ANNEX-9

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

(1) Criteria for the decision to apply protective vaccination

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

(2) Additional criteria for the decision to introduce emergency vaccination

Criteria	Decision
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	For vaccination	Against vaccination
Acceptance of regionalisation by third countries	Known	Unknown
Economic assessment of competing control strategies	If it is foreseeable that a control strategy without emergency vaccination would lead to significantly higher economic losses in the agricultural and non-agricultural sectors.	If it is foreseeable that a control strategy with emergency vaccination would lead to significantly higher economic losses in the agricultural and non-agricultural sectors.
It is foreseeable that the 24/48 hours rule cannot be implemented effectively for two consecutive days (¹).	Yes	No
Significant social and psychological impact of total stamping out policy	Yes	No

Existence of large holdings of intensive livestock production in a non-densely populated livestock	Yes	No
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(1) 24/48 hours rule means:

a) infected herds on holdings referred to in Article 10 cannot be stamped out within 24 hours after the confirmation of the disease, and

(b) the pre-emptive killing of animals likely to be infected or contaminated cannot be safely carried out within less than 48 hours.

(3) Definition of Densely Populated Livestock Areas (DPLAs)

a) When deciding about the measures to be taken in application of this Regulation, and in particular the measures provided for in the second paragraph of Article 51, the competent authority shall in addition to a thorough epidemiological assessment consider the Densely Populated Livestock Areas (DPLAs).

b) In the case of animals of susceptible species a DPLA shall be a geographical area, with a radius of 10 km around a holding containing animals of susceptible species suspected of or infected with foot-and-mouth disease, where there is a density of animals of susceptible species higher than 1 000 head per km². The holding in question must be situated either in a sub-region as defined in indent (p) of the first paragraph of Article 4 where there is a density of animals of susceptible species higher than 450 head per km² or at a distance of less than 20 km from such a sub- region.

ANNEX-10

BIOSECURITY STANDARDS FOR LABORATORIES AND ESTABLISHMENTS HANDLING LIVE FOOT-AND-MOUTH DISEASE VIRUS

(1) The laboratories and establishments handling live foot-and-mouth disease virus must operate at least according to the ‘Minimum standards for laboratories working with foot-and-mouth disease virus in vitro and in vivo’ in Appendix 10 to the Report adopted by the 38th General Session of the European Commission for the control of foot-and-mouth disease (EuFMD) in April 2009 in Rome bio-security standards.

(2) The laboratories and establishments handling live foot-and-mouth disease virus must be subject to at least two inspections within five years, with one of the inspections being carried out unannounced.

(3) The inspection team shall comprise at least of

- a) One expert from the Ministry,
- b) One expert in foot-and-mouth disease,
- c) One independent expert for questions of bio-security in laboratories working with microbiological hazards .

(4) The inspection team shall submit a report to the Ministry and the competent authority.

ANNEX-11

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

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

PART A

Diagnostic tests

(1) Recommended Procedures; Diagnostic tests described in the OIE Manual, hereinafter the ‘OIE Manual’, as the ‘Prescribed Tests’ for international trade, constitute the reference tests for vesicular disease diagnosis. The Foot-and-Mouth Institute must adopt standards and tests at least as stringent as those defined in the OIE Manual.

(2) Alternative procedures; The use of tests defined in the OIE Manual as ‘Alternative Tests’, or other tests not included in the OIE Manual, is permitted provided that the performance of the test has been shown to be more stringent and match or exceed the sensitivity and specificity parameters laid down in the OIE Manual. The Foot-and-Mouth Institute generating results for the purposes of national or international trade must generate and store the necessary records demonstrating compliance of their testing procedures with the relevant OIE requirements.

(3) Standards and quality control;

a) The Foot-and-Mouth Institute shall participate in periodic standardisation and external quality assurance exercises organised by the World Reference Laboratory or when appropriate, reference laboratories of regional organizations.

b) As part of quality assurance, the Foot-and-Mouth Institute shall demonstrate compliance of the tests in routine use with the requirements for sensitivity and specificity defined in the OIE Manual.

(4) Selection and transportation of samples;

a) An aliquot of field material should be sent to one of the laboratories approved under the second paragraph of Article 53. However, where such samples are not available or not suitable for transport, animal passage material, obtained from the same host species, or low passage cell culture material is acceptable.

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

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

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

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

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

f) Compliance with the import and export regulations of the Competent Authority involved must be ensured.

PART B

Standards

(1) The protocols specified in the OIE Manual provide reference procedures for virus isolation, antigen detection and antibody detection for vesicular diseases.

(2) Foot-and-Mouth Disease:

a) Antigen detection

1) The standards for detecting foot-and-mouth disease virus antigen shall be established in accordance with the procedure referred to in OIE Manual of Diagnostic Tests and Vaccines.

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

3) The Foot-and-Mouth Institute should ensure that their antigen detection system complies with these minimum standards. They shall where necessary receive advice from the OIE/FAO World Reference Laboratory on the dilutions of these antigens to be used as strong and weak positive controls.

b) Virus isolation

1) The standards for foot-and-mouth disease virus detection shall be established in accordance with the procedure referred to in OIE Manual and upon consultation with the Foot-and-Mouth Institute, the National Reference Laboratory.

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

3) The Foot-and-Mouth Institute shall ensure that the tissue culture systems in use for foot-and-mouth virus isolation are sensitive to the full range of serotypes and strains for which the laboratory maintains a diagnostic capacity.

c) Nucleic acid detection; the standards for the detection of foot-and-mouth disease viral RNA shall be established in accordance with the procedure referred to in the OIE Manual.

ç) Antibody detection (structural proteins); The standards for the detection of antibody to foot-and-mouth disease virus shall be established in accordance with the procedure referred to in the OIE Manual.

d) Antibody detection (non-structural proteins); The standards for the detection of antibody to foot-and-mouth disease virus shall be established in accordance with the procedure referred to in the OIE Manual.

(3) Other vesicular diseases; Where deemed necessary by the Ministry, the Ministry may arrange that standards for the laboratory diagnosis of swine vesicular disease (SVD) vesicular stomatitis (VS) or vesicular exanthema (VE) of swine are established in accordance with the procedure referred to in the OIE Manual.

ANNEX-12

FUNCTIONS AND DUTIES OF THE FOOT-AND-MOUTH INSTITUTE

(1) The Foot-and-Mouth Institute;

a) The Foot-and-Mouth Institute must operate in line with the conditions given in “Minimum conditions for laboratories handling the foot-and-mouth virus in vivo or in vitro” specified by the European Commission for the Control of Foot-and-Mouth Disease.

b) The Foot-and-Mouth Institute must provide an uninterrupted service for diagnosing vesicular viral diseases and must be equipped and skilled for providing a rapid initial diagnosis.

c) The Foot-and-Mouth Institute must keep inactivated reference strains of all serotypes of foot-and-mouth disease virus, and immune sera against the viruses, as well as all other reagents necessary for a rapid diagnosis.

ç) The Foot-and-Mouth Institute must be equipped and skilled for large-scale serological surveillance.

d) In all suspected primary outbreaks appropriate samples must be collected and quickly transported, according to a set protocol, to the Foot-and-Mouth Institute. In anticipation of a suspicion of foot-and-mouth disease, the competent authority shall ensure that the necessary equipment and materials for sample collection and transportation to a National Laboratory are stored in readiness at local sites.

e) The Foot-and-Mouth Institute must provide, at the earliest opportunity, information regarding diagnosis, further characterization and antigenic relationship with existing vaccine strains on the basis of the FMD virus obtained from the index case. In addition, when necessary, the Institute must submit virus samples and/or results to OIE/FAO World Reference Laboratory.

f) The Foot-and-Mouth Institute shall participate in quality assurance and standardisation exercises organised by the OIE/FAO World Reference Laboratory.

g) The Foot-and-Mouth Institute should have the competence to identify all vesicular disease viruses and encephalomyocarditis virus in order to avoid delays in diagnosis and consequently in implementing control measures by the competent authorities.

ANNEX-13

CRITERIA AND REQUIREMENTS FOR CONTINGENCY PLANS

(1) The contingency plans to be prepared by the Ministry under Article 57 shall include the following points as a minimum.

(2) Powers and responsibilities of all actors involved including the central and field organization of the Ministry of Food, Agriculture and Livestock, law enforcement bodies, provincial directorates of environment and village heads in the implementation of the Contingency Plan and the rapid and successful conduct of an eradication campaign.

(3) Access to emergency funds, budgetary means and financial resources in order to cover all aspects of the fight against a foot-and-mouth disease epizootic.

(4) A chain of command shall be established guaranteeing a rapid and effective decision-making process for dealing with foot-and-mouth disease epizootics. A central decision-making unit composed of expert veterinarians operating under the General Directorate of Food and Control shall be in charge of the overall direction of control strategies.

(5) The Ministry must be prepared to immediately establish a functional national disease control centre in the event of an outbreak, which shall coordinate the implementation of all decisions taken in the central decision-making unit. A permanently operational coordinator (Deputy General Director or Department Head of Animal Health and Quarantine) shall be appointed by the General Director of Food and Control to guarantee the prompt establishment of the centre.

(6) Detailed plans to ensure the preparation for the immediate establishment of local disease control centres in the event of foot-and-mouth disease outbreaks in order to implement disease control and environment protection measures at a local level.

(7) Procedures and principles to ensure the cooperation between the national disease control centre, the local disease control centres and environmental competent authorities and bodies in order to ensure that actions on veterinary and environmental safety issues are appropriately coordinated.

(8) Permanently operational expert groups to gain experience and assist the relevant authority in qualitative disease preparedness.

(9) Arrangements as to how adequate resources will be provided to ensure a rapid and effective campaign, including personnel, equipment and laboratory capacity.

(10) An up-to-date operations manual. It shall describe in detail and in a comprehensive and practical way all the actions procedures, instructions and control measures to be employed in handling an outbreak of foot-and-mouth disease.

(11) Detailed plans for emergency vaccination.

(12) Programs and measures to ensure the participation of the personnel in the following activities:

a) Training in clinical signs, epidemiological enquiry and control of epizootic diseases

b) Real-time alert exercises, conducted as follows. These exercises shall be conducted two times within a five years period, the first of which should not have started later than three years after the approval of the plan, or during the five years period after an outbreak of a major epizootic disease has been effectively controlled and eradicated. One of the exercises to be

performed after the acceptance of the contingency plan may be replaced by a real-time exercise required within the framework of contingency plans for other major epidemic diseases affecting terrestrial animals.

c) Training in communication skills to provide ongoing disease awareness campaigns for authorities, farmers and veterinarians.

(13) Contingency Plans shall be prepared taking into account the resources needed to control a large number of outbreaks occurring within a short time and caused by several antigenically distinct serotypes or strains as it may be necessary amongst others in the case of deliberate release of foot-and-mouth disease virus.

(14) Contingency plans shall be prepared upon the consideration of the resources required for the control of cases arising from a large number of antigenically different serotypes or strains emerging in a short period of time. In particular, the Contingency Plan shall be prepared;-

- a) With a minimum risk to soil, air, surface and groundwater, to plants and animals,
- b) With a minimum nuisance through noise or odours,
- c) With a minimum adverse effect to the countryside or places of special interest.

(15) Such plans shall include the identification of appropriate sites and undertakings for the treatment or disposal of animal carcasses and animal waste in the event of an outbreak.

(16) The Ministry shall ensure that farmers, the rural populace and the population in general are kept informed. Direct and accessible contact shall be provided for the inhabitants of affected areas (inter alia via helplines), as well as information through the national and regional media.

ANNEX-14

PART A

Measures in case of confirmation of the presence of foot-and-mouth disease in wild animals

(1) As soon as confirmation of a primary case of foot-and-mouth disease in wild animals of susceptible species has taken place, in order to reduce the spread of disease, the competent authority shall immediately:

- a) Notify the primary case.
- b) Epidemiologists and the expert group shall assist the competent authority in:
 - 1) Conduct of epidemiological inquiry and defining the infected area,

2) Establishing appropriate measures to be applied in the infected area in addition to the ones referred to in indents (c) and (d) of Article 1 of this Annex; these measures may include suspension of hunting and a ban in feeding wild animals,

3) Drawing up the eradication plan to be submitted to the Ministry,

4) Carrying out audits to verify the effectiveness of the measures adopted to eradicate foot-and-mouth disease from the infected area,

c) Immediately place under official surveillance holdings keeping animals of susceptible species in the defined infected area and shall in particular order that:

1) An official census be carried out of all species and categories of animals of susceptible species on all holdings; the census shall be kept up to date by the owner. The information in the census shall be produced on request and may be checked at each inspection. However, as regards open-air holdings, the first census carried out may be done on the basis of an estimate,

2) All animals of susceptible species on the holdings situated in the infected area be kept in their living quarters or some other place where they can be isolated from wild animals. Wild animals must not have access to any material which may subsequently come in contact with animals of susceptible species on the holdings,

3) No animal of a susceptible species enter or leave the holding save where authorised by the competent authority having regard to the epidemiological situation,

4) Appropriate means of disinfection be used at the entrance and exits of buildings housing animals of susceptible species and of the holding itself,

5) Appropriate hygiene measures be applied by all persons coming in contact with wild animals, to reduce the risk of spread of foot-and- mouth disease virus, which may include a temporary ban on persons having been in contact with wild animals from entering a holding keeping animals of susceptible species,

6) All dead or diseased animals of susceptible species with foot-and- mouth disease symptoms on a holding shall be tested for the presence of foot-and-mouth disease,

7) No part of any wild animals, whether shot or found dead, as well as any material or equipment which could be contaminated with foot- and-mouth disease virus shall be brought into a holding keeping animals of susceptible species,

8) Animals of susceptible species, their semen, embryos or ova shall not be moved from the infected area for trade purposes,

ç) Arrange that all wild animals shot or found dead in the defined infected area are inspected by an official veterinarian and examined for foot-and- mouth disease to officially rule

out or confirm foot-and-mouth disease in accordance with the definition for an outbreak in Annex I. Carcasses of all wild animals found positive as regards foot-and-mouth disease shall be processed under official supervision. Where such testing proves negative as regards foot-and-mouth disease, the competent authority shall ensure that meat of wild animals originating from the infected area be banned from trade.

d) Ensure that the foot-and-mouth disease virus isolate is subject to the laboratory procedure required to identify the genetic type of virus and its antigenic characteristic in relation to existing vaccines strains.

(2) If a case of foot-and-mouth disease has occurred in wild animals in an area of a country close to the territory of another country, the country concerned shall collaborate in the establishment of disease control measures.

PART B

Plans for the eradication of foot-and-mouth disease in wild animals

(1) Without prejudice to the measures laid down in Part A, the Competent Authority shall submit to the Ministry within three months from the confirmation of the primary case of foot-and-mouth disease in wild animals a written plan of the measures taken to eradicate the disease in the area defined as infected and of the measures applied on the holdings in that area.

(2) The Ministry shall examine the plan in order to determine whether it permits the desired objective to be attained. The Ministry shall then make the necessary changes and approved the plan. The plan may subsequently be amended or supplemented to take account of developments in the situation.

(3) After the measures provided for in the plan mentioned in paragraph 1 have been approved, they shall replace the initial measures laid down in Part A, on a date which shall be decided upon when approval is given.

(4) The plan mentioned in paragraph 1 shall contain information on:

a) The results of the epidemiological investigations and controls carried out in accordance with Part A and the geographical distribution of the disease,

b) A definition of the infected area.

When defining the infected area, the competent authority shall take into account:

1) the results of the epidemiological investigations carried out and the geographical distribution of the disease,

2) the wild animal population in the area,

3) the existence of major natural or artificial obstacles to movements of wild animals.

c) the organisation of close cooperation between wildlife biologists, hunters, hunting organisations, the wildlife protection services and veterinary services

ç) the information campaign to be enforced to increase hunters' awareness of the measures they have to adopt in the framework of the eradication plan;

d) specific efforts made to determine the number and location of groups of wild animals with limited contacts to other groups of wild animals in and around the infected area;

e) the approximate number of groups of wild animals referred to in paragraph d and their size in and around the infected area;

f) plans made to determine the extent of the infection in wild animals, by investigation of wild animals shot by hunters or found dead, and by laboratory testing, including age-stratified epidemiological investigations;

g) the measures adopted to reduce spread of disease due to movements of wild animals and/or contact between groups of wild animals; these measures may include a prohibition of hunting;

ğ) the measures adopted to reduce the population of wild animals and in particular young animals of susceptible species in the wild animal population;

h) the requirements to be complied with by hunters in order to avoid any spread of the disease;

ı) the method of removal of wild animals found dead or shot, which shall be based on:

1) processing under official supervision, or

2) inspection by an official veterinarian and laboratory tests as provided for in Annex-11. Carcasses of all wild animals found positive as regards foot-and-mouth disease shall be processed under official supervision.

i) the epidemiological enquiry which is carried out on each wild animal of a susceptible species, whether shot or found dead. This enquiry must include the completion of a questionnaire which supplies information about:

1) the geographical area where the animal was found dead or shot,

2) the date on which the animal was found dead or shot,

3) the person who found or shot the animal,

- 4) the age and sex of the animal,
- 5) if shot: symptoms before shooting,
- 6) if found dead: the state of the carcass,
- 7) laboratory findings;

j) surveillance programmes and prevention measures applicable to the holdings keeping animals of susceptible species situated in the defined infected area, and if necessary, in its surroundings, including the transport and movement of animals of susceptible species within, from and to the area;

k) other criteria to be applied for lifting the measures taken to eradicate the disease in the defined area and the measures applied to holdings in the area;

l) the authority charged with supervising and coordinating the departments responsible for implementing the plan;

m) the system established in order that the expert group appointed in accordance with point 1(b) in Part A can review on a regular basis the results of the eradication plan;

n) disease surveillance measures to be in force for a minimum period of twelve months after the last foot-and-mouth disease case confirmed in the infected area; these measures shall as a minimum include the measures given in paragraphs g, k and l.

(5) A report concerning the epidemiological situation in the defined area and the results of the eradication plan shall be transmitted by the Competent Authority to the Ministry.