

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

CHAPTER II **U.K.**

CONTROL OF OUTBREAKS OF FOOT-AND-MOUTH DISEASE

SECTION 8 **U.K.**

VACCINATION

Article 49 **U.K.**

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

Member States shall ensure that:

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

Article 50 **U.K.**

Decision on introducing emergency vaccination

1 It may be decided to introduce emergency vaccination where at least one of the following conditions applies:

- a outbreaks of foot-and-mouth disease have been confirmed and threaten to become widespread in the Member State where such outbreaks have been confirmed;
- b other Member States are at risk due to the geographical situation of or the prevailing meteorological conditions in relation to reported outbreaks of foot-and-mouth disease in a Member State;
- c other Member States are at risk due to epidemiologically relevant contacts between holdings on their territories and holdings keeping animals of susceptible species in a Member State where there are outbreaks of foot-and-mouth disease;

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d Member States are at risk due to the geographical situation or the prevailing meteorological conditions in a neighbouring third country where there are outbreaks of foot-and-mouth disease.

2 When deciding on the introduction of emergency vaccination, consideration shall be given to the measures provided for in Article 15 and to the criteria listed in Annex X.

3 The decision to introduce emergency vaccination shall be adopted in accordance with the procedure referred to in Article 89(3).

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

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

5 By way of derogation from paragraph 3, the decision to introduce emergency vaccination may be taken by the Member State concerned and implemented in accordance with this Directive, after a written notification to the Commission which shall include the specifications provided for in Article 51.

6 If a Member State introduces emergency vaccination in accordance with paragraph 5, that decision shall be immediately reviewed in the Standing Committee on the Food Chain and Animal Health and Community measures shall be adopted in accordance with the procedure referred to in Article 89(3).

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

Article 51 **U.K.**

Conditions for emergency vaccination

1 The decision to introduce emergency vaccination in accordance with Article 50(3) and (4) shall specify the conditions under which such vaccination shall be carried out and these conditions must specify at least:

- a the delimitation in accordance with Article 45 of the geographical area in which emergency vaccination is to be carried out;
- b the species and the age of the animals to be vaccinated;
- c the duration of the vaccination campaign;
- d a specific prohibition on movements of vaccinated and non-vaccinated animals of susceptible species and their products;
- e the special additional and permanent identification and special registration of the vaccinated animals pursuant to Article 47(2);
- f other matters appropriate to the emergency situation.

2 The conditions for emergency vaccination as provided for in paragraph 1, shall ensure that such vaccination is carried out in accordance with Article 52, irrespective of whether the vaccinated animals are subsequently slaughtered or stay alive.

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

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Article 52 **U.K.**

Protective vaccination

- 1 Member States applying protective vaccination shall ensure that:
 - a the vaccination zone shall be regionalised in accordance with Article 45, where necessary in close cooperation with neighbouring Member States;
 - b vaccination shall be carried out swiftly and in conformity with the rules of hygiene and bio-security so as to avoid the spread of foot-and-mouth disease virus;
 - c all measures applied in the vaccination zone shall be carried out without prejudice to the measures provided for in Section 7;
 - d where the vaccination zone includes parts of or the entire protection or surveillance zone:
 - (i) the measures applicable for the protection zone or surveillance zone in accordance with this Directive shall be maintained within that part of the vaccination zone until such measures have been removed in accordance with Article 36 or Article 44;
 - (ii) after the measures applied in the protection zone and surveillance zone have been removed, the measures applicable for the vaccination zone as provided for in Articles 54 to 58 shall continue to apply.
- 2 Member States applying protective vaccination shall ensure that the vaccination zone is surrounded by a surveillance area (surveillance zone as defined by OIE) of at least 10 km width from the perimeters of the vaccination zone:
 - a in which vaccination is prohibited;
 - b in which intensified surveillance is carried out;
 - c in which the movement of animals of susceptible species is subject to controls by the competent authorities;
 - d which remains in place until the foot-and-mouth disease and infection free status is recovered in accordance with Article 61.

Article 53 **U.K.**

Suppressive vaccination

- 1 Member States shall notify the Commission if they decide in accordance with Article 50 and taking into account all relevant circumstances, to introduce suppressive vaccination and shall provide details of the control measures to be taken which shall include at least those provided for in Article 21.
- 2 Member States shall ensure that suppressive vaccination is carried out:
 - a only within a protection zone;
 - b only on clearly identified holdings subject to the measures provided for in Article 10(1) and in particular subparagraph (a) thereof.

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

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Article 54 **U.K.**

Measures applicable in the vaccination zone during the period from the beginning of emergency vaccination until at least 30 days have elapsed following the completion of such vaccination (Phase 1)

1 Member States shall ensure that the measures provided for in paragraphs 2 to 6 are applied in the vaccination zone during the period from the beginning of the emergency vaccination until at least 30 days have elapsed following the completion of such vaccination.

2 Movement of live animals of susceptible species shall be prohibited between holdings within and out of the vaccination zone.

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

3 Fresh meat produced from vaccinated animals slaughtered during the period referred to in paragraph 1 shall:

- a bear the mark provided for in Directive 2002/99/EC;
- b be stored and transported separately from meat not bearing the mark referred to in point (a), and shall subsequently be transported in sealed containers to an establishment designated by the competent authorities for treatment in accordance with point 1 in Part A of Annex VII.

4 Milk and milk products produced from vaccinated animals may be placed on the market within or outside the vaccination zone, provided that, depending on the final use for either human consumption or non-human consumption, it has undergone at least one of the treatments referred to in Parts A and B of Annex IX. The treatment shall be carried out under the conditions set out in paragraph 5 in establishments situated in the vaccination zone or, if there is no establishment in that zone, in establishments situated outside the vaccination zone to which the raw milk is transported under the conditions set down in paragraph 7.

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

- a the establishment shall be operated under permanent and strict official control;
- b all milk used in the establishment shall either comply with paragraph 4 or the raw milk shall be obtained from animals outside the vaccination zone;
- c during the whole production process the milk shall be clearly identified and transported and stored separately from raw milk and raw milk products which are not destined for dispatch outside the vaccination zone;
- d transport of raw milk from holdings situated outside the vaccination zone to the establishments shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, and which have had no subsequent contact with holdings in a restricted zone keeping animals of susceptible species.

6 Compliance with the conditions in paragraph 5 shall be certified by the competent authority for milk intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authority and in the case of intra-Community trade communicate to other Member States and the Commission a list of those establishments which it has approved for the purpose of such certification.

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

- a processing in establishments situated outside the vaccination zone of raw milk produced from animals of susceptible species kept within the vaccination zone shall be authorised by the competent authorities;
- b the authorisation shall include instructions on and designation of the transport route to the designated establishment;
- c transport shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, which are constructed and maintained in such a way that there is no leakage of milk during transport and which are equipped to avoid aerosol dispersion during the loading and unloading of the milk;
- d before leaving the holding from where milk of animals of susceptible species was collected, the connection pipes, tires, wheel cases, the lower parts of the vehicle and any spillage of milk are cleansed and disinfected and after the last disinfection and before leaving the vaccination zone the vehicle had no subsequent contact with holdings in the vaccination zone keeping animals of susceptible species;
- e the means of transport are strictly assigned to a defined geographical or administrative area, they are marked accordingly and may only be moved to another area after cleansing and disinfection under official supervision.

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

9 The collection of semen for artificial insemination from donor animals of susceptible species kept in semen collection centres situated within the vaccination zone shall be suspended.

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

- a it is ensured that the semen collected during the period referred to in paragraph 1 is stored separately for at least 30 days, and
- b prior to dispatch of the semen:
 - (1) either the donor animal has not been vaccinated and the conditions of Article 28(3)(b) and (c) apply, or
 - (2) the donor animal has been vaccinated following a negative test for antibodies against foot-and-mouth disease virus carried out prior to vaccination; and
 - (i) a negative result has been achieved in a test for the detection of either virus or viral genome or an approved test for the detection of antibody against non-structural proteins, carried out at the end of the quarantine period for the semen on samples taken from all animals of susceptible species present at that time on the semen collection centre, and
 - (ii) the semen complies with the conditions of Article 4(3) of Chapter II of Directive 88/407/EEC.

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

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

Article 55 **U.K.**

Measures applicable in the vaccination zone during the period from emergency vaccination until the survey and the classification of holdings are completed (Phase 2)

1 Member States shall ensure that the measures provided for in paragraphs 2 to 5 are applied in the vaccination zone during a period starting not earlier than 30 days from the date of completion of emergency vaccination and terminating with the completion of the measures provided for in Articles 56 and 57.

2 Movement of animals of susceptible species between holdings within and out of the vaccination zone shall be prohibited.

3 By way of derogation from the prohibition provided for in paragraph 2, the competent authorities may authorise direct transport for immediate slaughter of animals of susceptible species from holdings referred to in Article 57(5) to a slaughterhouse situated within or out of the vaccination zone on the following conditions:

- a during transport and in the slaughterhouse those animals shall not come into contact with other animals of susceptible species;
- b the animals shall be accompanied by an official document certifying that all animals of susceptible species on the holding of origin or dispatch have undergone a survey provided for in Article 56(2);
- c the transport vehicles shall be cleansed and disinfected before loading and after the animals have been delivered, with the date and time of the cleaning and disinfection being recorded in the logbook of the means of transport;
- d the animals shall have passed the ante-mortem health inspection at the slaughterhouse during the 24 hours before slaughter and have in particular undergone examination for mouth and feet disease and not shown signs of that disease.

4 Fresh meat, excluding offal, produced from vaccinated large and small ruminants during the period referred to in paragraph 1, may be placed on the market within and outside the vaccination zone under the following conditions:

- a the establishment shall be operated under strict veterinary control;
- b only fresh meat, excluding offal, which was subjected to the treatment described in points 1, 3 and 4 in Part A of Annex VIII or fresh meat obtained from animals reared and slaughtered outside the vaccination zone shall be processed in the establishment;
- c all such fresh meat shall bear the health mark in accordance with Chapter XI of Annex I to Directive 64/433/EEC or, in the case of meat from other biungulates, the health mark provided for in Chapter III of Annex I of Directive 91/495/EEC, or, in the case of minced meat and meat preparations, the health mark provided for in Chapter VI of Annex I of Directive 94/65/EC;
- d throughout the production process the fresh meat shall be clearly identified, and transported and stored separately from meat of different animal health status in accordance with this Directive.

5 Compliance with the conditions in paragraph 4 shall be certified by the competent authority for fresh meat intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authorities and, in the

case of intra-Community trade, communicate to other Member States and the Commission a list of those establishments which it has approved for the purpose of such certification.

6 Fresh meat produced from vaccinated porcine animals slaughtered during the period referred to in paragraph 1 shall bear the health mark provided for in Directive 2002/99/EC and shall be stored and transported separately from meat not bearing that mark and subsequently be transported in sealed containers to an establishment designated by the competent authorities for treatment in accordance with point 1 in Part A of Annex VII.

7 Milk and milk products produced from vaccinated animals may be placed on the market within or outside the vaccination zone, provided that depending on the final use for either human consumption or non-human consumption it has undergone at least one of the treatments referred to in Parts A and B of Annex IX. Such treatment shall have been undergone in an establishment located within or outside the vaccination zone in accordance with the provisions in Article 54(4) to (8).

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

9 The placing on the market of products of animal origin other than those referred to in paragraphs 4, 6, 7 and 8 shall be subject to the conditions provided for in Articles 30, 31, 32 and 41.

Article 56 **U.K.**

Clinical and serological survey in the vaccination zone (Phase 2-A)

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

2 A survey shall be carried out with the aim to identify herds of animals of susceptible species that had contact with the foot-and-mouth disease virus without showing overt clinical signs of the foot-and-mouth disease. That survey shall include a clinical inspection of all animals of susceptible species in all herds in the vaccination zone, and laboratory testing in accordance with paragraph 3.

3 Laboratory testing shall be carried out by use of tests complying with the criteria for diagnostic tests as set out in Annex XIII and approved in accordance with the procedure referred to in Article 89(2), and shall comply with one of the following conditions:

- a testing for infection with the foot-and-mouth disease virus, either by an assay for antibodies against non-structural proteins of the foot-and-mouth disease virus, or by another approved method, shall meet criteria for sampling on holdings set out in point 2.2 of Annex III. Where the competent authorities use in addition sentinel animals, the conditions for restocking of infected holdings in Annex V shall be taken into account;
- b testing for antibodies against non-structural proteins of the foot-and-mouth disease virus shall be carried out on samples taken from all vaccinated animals of susceptible species and their non-vaccinated offspring in all herds in the vaccination zone.

Article 57 **U.K.**

Classification of herds in the vaccination zone (Phase 2-B)

1 Member States shall ensure that the holdings containing animals of susceptible species:

- a are classified according to the outcome of the survey referred to in Article 56(2) and the criteria set out in Annex I;
- b comply with the measures set out in paragraphs 2 to 4.

2 Holdings containing at least one animal suspected of being infected and where the presence of foot-and-mouth disease virus is confirmed in accordance with the criteria laid down in Annex I shall be subject to the measures provided for in Articles 10 and 21.

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

- a animals of susceptible species on the holding shall:
 - (1) either be killed and the carcasses processed, or
 - (2) the animals shall be classified and
 - (i) the animals positive to at least one of the approved tests referred to in Article 56(3) shall be killed and their carcasses processed, and
 - (ii) the remaining animals of susceptible species on the holding shall be slaughtered under conditions authorised by the competent authorities;
- b cleansing and disinfection of the holdings in accordance with Article 11;
- c restocking of animals in accordance with Annex V.

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

- a fresh meat produced from the animals referred to in paragraph 3(2)(ii) shall be subject to Article 55(4), for meat from ruminants, and (6), for meat from porcine animals, respectively;
- b milk and milk products produced from the animals referred to in paragraph 3(2)(ii) shall undergo at least one of the treatments specified in Parts A and B of Annex IX depending on the intended use and in compliance with the provisions in Article 54(4) to (8).

5 Animals of susceptible species on holdings where the presence of previous or present infection with the foot-and-mouth disease virus has been officially ruled out in accordance with Article 56(3) may be subject to the measures provided for in Article 58.

Article 58 **U.K.**

Measures applicable in the vaccination zone after the completion of the survey and the classification of holdings until the foot-and-mouth disease and infection free status is recovered (Phase 3)

1 Member States shall ensure that the measures provided for in paragraphs 2 to 6 are applied in the vaccination zone after the completion of the measures laid down in Article 57 and until the foot-and-mouth disease and infection-free status has been recovered in accordance with Article 59.

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

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

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

- a within 24 hours of loading, all animals of susceptible species on the holding have been subjected to clinical examination and have not shown clinical signs of foot-and-mouth disease, and
- b the animals have completed a standstill on the holding of origin of at least 30 days during which no animal of susceptible species has been introduced onto the holding, and
- c the holding of origin is not situated in a protection or surveillance zone, and
- d the animals intended for transport were either individually subjected with negative results to tests for the detection of antibodies against the foot-and-mouth disease virus at the end of the isolation period, or a serological survey was completed on that holding in accordance with point 2.2 of Annex III irrespective of the species concerned;
- e the animals were not exposed to any source of infection during their transportation from the holding of origin to the place of destination.

5 Non-vaccinated offspring of vaccinated dams shall be prohibited from leaving the holding of origin unless being transported to:

- a a holding within the vaccination zone of the same health status as the holding of origin;
- b a slaughterhouse for immediate slaughter;
- c a holding designated by the competent authority, from which the offspring are to be sent directly to the slaughterhouse;
- d any holding, after having obtained a negative result in a serological test for the detection of antibody against the foot-and-mouth disease virus carried out on a sample of blood taken prior to dispatch from the holding of origin.

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

- a either the measures provided for in Article 57(3) have been completed in the entire vaccination zone or the animals are transported to the slaughterhouse under the conditions provided for in paragraph 3 or 4(d), and;
- b the establishment shall be operated under strict veterinary control;

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- c only fresh meat produced from animals referred to in point (a) or from animals reared and/or slaughtered outside the vaccination zone or fresh meat referred to in paragraph 8 shall be processed in the establishment;
- d all such fresh meat shall bear the health mark in accordance with Chapter XI of Annex I to Directive 64/433/EEC or in the case of meat from other biungulates, the health mark provided for in Chapter III of Annex I of Directive 91/495/EEC, or in the case of minced meat and meat preparations the health mark provided for in Chapter VI of Annex I of Directive 94/65/EC;
- e throughout the production process the fresh meat shall be clearly identified, and transported and stored separately from meat of different animal health status in accordance with this Directive.

7 Fresh meat produced from vaccinated animals of susceptible species or from non-vaccinated seropositive offspring of vaccinated dams slaughtered during the period referred to in paragraph 1 shall bear the health mark provided for in Directive 2002/99/EC and shall be stored and transported separately from meat not bearing that stamp and subsequently be transported in sealed containers to an establishment designated by the competent authorities for treatment in accordance with point 1 in Part A of Annex VII.

8 By way of derogation from paragraph 7, fresh meat and trimmed offal produced from vaccinated large and small ruminants or their non-vaccinated seropositive offspring may be placed on the market within and outside the vaccination zone under the following conditions:

- a the establishment shall be operated under strict veterinary control;
- b only fresh meat excluding offal, which was subjected to the treatment described in point 1, 3 and 4 in Part A of Annex VIII or fresh meat referred to in paragraph 6 or produced from animals reared and/or slaughtered outside the vaccination zone are processed in the establishment;
- c all such fresh meat shall bear the health mark in accordance with Chapter XI of Annex I to Directive 64/433/EEC or in the case of meat from other biungulates the health mark provided for in Chapter III of Annex I to Directive 91/495/EEC, or in the case of minced meat and meat preparations the health mark provided for in Chapter VI of Annex I to Directive 94/65/EC;
- d throughout the production process the fresh meat shall be clearly identified, and transported and stored separately from meat which is of different animal health status in accordance with this Directive.

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

- a the establishment shall be operated under strict veterinary control;
- b only fresh meat from animals originating in holdings complying with the conditions in Article 57(5) or fresh meat obtained from animals reared and slaughtered outside the vaccination zone are processed in the establishment;
- c all such fresh meat shall bear a health mark to be decided in accordance with Article 4(3) of Directive 2002/99/EC;
- d throughout the production process the fresh meat shall be clearly identified, and transported and stored separately from meat of different animal health status in accordance with this Directive.

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

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

12 Compliance with the conditions provided for in paragraph 6, paragraph 8 and where applicable under the provisions of paragraph 10, shall be certified by the competent authority for fresh meat intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authorities and shall in the case of intra-Community trade communicate to other Member States and the Commission a list of those establishments which they have approved for such certification.

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

14 Milk and milk products produced from vaccinated animals may be placed on the market within and outside the vaccination zone, provided that depending on the final use for either human consumption or non-human consumption it has undergone at least one of the treatments referred to in Parts A and B of Annex IX. Such treatment shall have been undergone in an establishment located in the vaccination zone or in accordance with the provisions in Article 54(4) to (7).

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

16 The placing on the market of products of animal origin other than those referred to in paragraphs 6 to 11 and 13 to 15 shall be subject to the conditions provided for in Articles 30, 31, 32 and 42.