

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(82) 505 final

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Proposal for a
COUNCIL DIRECTIVE
introducing Community measures for the control of foot-and-mouth disease

(submitted to the Council by the Commission)

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EXPLANATORY MEMORANDUM

Foot and mouth disease is a serious contagious disease which spreads rapidly. It affects all bi-ungulate domestic and wild animals. It has a high morbidity with dramatic consequences on animals and their productivity.

A study of the evolution of foot and mouth disease in the Community shows that the situation is generally relatively satisfactory, but it may vary from one Member State to the other often in relation with the control measures undertaken when the disease appears, thus producing important barriers to intra-Community trade.

For these reasons, the object of the present draft directive is to assure the effectiveness and the harmonization of control measures against foot and mouth disease in the Community. For this purpose, it is particularly necessary to provide for a rapid diagnosis of the disease and the identification of virus-type involved by the responsible national laboratories, the elimination of outbreaks of the disease by the slaughter of infected animals or those likely to transmit the disease and the application of rigorous disinfection and control measures at holdings suspected to be contaminated.

This draft is the basis for a Community action for establishment and maintenance of a uniform and satisfactory health level in respect of foot and mouth disease.

DEVELOPMENT OF FOOT-AND-MOUTH IN THE COMMUNITY

Foot-and-mouth disease is a virulent, infectious epizootic disease which it is extremely difficult to prevent spreading. It affects all cloven-hoofed animals, both domestic and wild. In its acute form it tends to be fatal mainly to young animals. In all cases it has a very serious effect on the productivity of livestock farms, and the economic future of animals which recover is jeopardized. All in all, FMD is one of the greatest threats to livestock farming and a major obstacle to trade in livestock and livestock products.

It should also be noted that the FMD virus (Picornavirus Aphthae) breaks down into 7 different immunological types known at present (O, A, C, SAT1, SAT 2, SAT3 and Asia), within which there are sub-types and varieties which often hamper prevention work and lead to the possibility of a breakdown in the immunity of animals infected with types or varieties against which any vaccine used does not give enough protection.

Of these different types only O, A and C have been identified in Europe. However, there are some varieties of these types in various parts of the world which have not so far appeared in the Community.

I. Development of FMD

In studying the development of FMD in the ten Member States now making up the Community, we have to include a period which is long enough to give an idea of the epizootiology of the disease, which also has to be seen in its European context. Nor can the situation in other neighbouring countries be ignored. The subtle ways in which the disease spreads and the time the virus can survive, depending on climate and weather, mean that there is a risk of contamination not only over short distances but also at long range, and this sometimes renders conventional protection measures concerning trade or imports inadequate.

Generally speaking, over the last ten years (1971-1981) the incidence of disease has been kept very low both in the Member States (except Greece in 1972) and in neighbouring countries. Of the latter, however, Turkey and to a lesser extent Spain and Portugal have encountered problems.

1. Development and present situation in the Member States

Table I annexed hereto, concerning the development of FMD in the Member States, confirms the low incidence of the disease, especially if we ignore the special situation in Greece in 1972-1973, when Europe was seriously threatened by an epizootic in the Middle East and Turkey. Setting up a vaccination buffer zone in Turkish Thrace and in the Greek prefecture of Eyros saved the situation. Generally speaking the number of outbreaks recorded in the Community has been less than 100. In 1974, a relatively high total of 188 outbreaks was reported, this being due mainly to an accident in vaccine manufacture (62 outbreaks in Belgium) and a localized occurrence in France (89 outbreaks). The rate at which outbreaks occur and the type of virus involved, which is different from one series of outbreaks to another, show that in all cases the appearance of the disease has been accidental and sporadic. The long periods with no outbreaks at all demonstrate the complete disappearance of the wild FMD, which is the determining factor in making the disease a permanent feature of a territory. It should be noted that during the period under consideration Ireland, Denmark (1), Luxembourg and the United Kingdom were free of FMD.

2. Control and prevention in the Member States

In no case has FMD in the Community reached epizootic proportions : the measures adopted in the Member States as soon as the disease has accidentally appeared have enabled it to be confined to a particular region or sector and its spread avoided, both within countries and in the Community as a whole, even though trade has become freer and has increased. The measures adopted by the Member State when a case of the disease occurs differ appreciably, even though a country

(1) An epidemic occurred in the country in the first quarter of 1982.

such as Denmark, has changed its basic approach. Generally speaking, the national rules in all Member States provide for slaughter of susceptible animals on the farm where the disease is discovered, but the precise scope of this slaughtering is not the same in all Member States, as it takes into account the practice of systematic annual vaccination of some livestock.

On the basis of whether preventive vaccination is practiced and precisely what livestock is slaughtered, the methods of combatting the disease may be divided into four groups :

(a) Ireland and the United Kingdom, and Denmark since 1977 :

These three countries ban vaccination on their territory. Control measures are based on immediate slaughter of animals of species susceptible to FMD and the destruction of the carcasses, and on the application of strict animal health protection measures within a particular radius around the farm and surveillance measures in a larger area;

(b) Greece, and Denmark up to 1977 :

As regards slaughter and animal health measures, the same principles apply here as in Ireland and the United Kingdom. There is no systematic annual preventive vaccination, but all livestock of susceptible species within a given radius of the infected farm is vaccinated in order to protect farms in that area and avoid secondary outbreaks. It should be noted that Greece has a buffer zone in the prefecture of Evros, along the frontier with Turkey, in which all ruminants are vaccinated against virus 0 and A22.

(c) France and Luxembourg :

These two countries practice annual vaccination of all cattle of more than 4 or 6 months. If the disease breaks out on a farm (breakdown of immunity, or appearance in non-vaccinated stock such as young cattle, pigs, etc) all livestock of susceptible species is slaughtered and destroyed, whether vaccinated or not, and animal health protection measures are applied.

If necessary vaccination of all animals of susceptible species within a given radius of the farm is undertaken (ring vaccination) in order to protect or help protect farms in the threatened area;

(d) Belgium, Italy, the Netherlands and the Federal Republic of Germany :

These countries practice annual vaccination of all cattle over 4 months. If the disease breaks out on a farm, animal health protection measures are applied but not all animals of susceptible species on the farm are slaughtered and destroyed. Only so called receptive animals are slaughtered, and this excludes vaccinated livestock, which is kept on the farm. Generally speaking, cattle which have been vaccinated in two successive years are regarded as having sufficient immunity. However, vaccinated cattle which show symptoms of the disease (breakdown of immunity) are slaughtered and destroyed. This is supplemented by vaccination or revaccination of all animals of susceptible species within a given radius of the infected farm (ring vaccination).

In addition, since a number of vaccinated animals which may healthy carriers of the virus are kept on the farm and may spread the disease, the period during which animal health protection measures are applied is appreciably lengthened.

The vaccine used in the Community is trivalent types O, A and C, inspected by the competent authorities of each Member State.

3. Development and present situation in neighbouring non-Community countries

Table II annexed hereto, concerning the development of FMD in certain neighbouring countries shows that the present situation and development of the disease there may by and large be considered as similar to that in the Member States. This applies to Bulgaria, the German Democratic Republic (1), Switzerland, Sweden,

(1) An epidemic occurred in the country in the first quarter of 1982

Czechoslovakia and Yugoslavia, where the disease has broken out only sporadically and accidentally. In Austria a serious epizootic occurred in 1973 : the Austrian authorities had at that time given up systematic preventive vaccination and this allowed the disease to spread dramatically before suitable countermeasures could be taken (1 691 outbreaks). The situation was quickly restored by the following year, after a vaccination campaign.

On the other hand the present situation and development of the disease are much more serious in two areas : the Iberian peninsula and the part of south-eastern Europe in close contact with the Middle East.

From the epizootiological point of view, the Iberian peninsula has to be considered as a single whole, in view of the relationship between Spain and Portugal, which includes trade across the frontier. The two countries have met serious difficulties : there has been enzootic FMD in Spain with a large number of outbreaks in 1971 (510), 1972 (371), 1973 (453) and 1974 (244). After a major epizootic in 1971 (1 058 outbreaks) Portugal was free of the disease until 1980, when it broke out again (519 outbreaks).

The second area is directly connected with Turkey and with FMD in Asia and the Middle East. The situation in Turkey as a whole (several hundred outbreaks each year) means that there is a permanent threat of contamination of European Turkey (Thrace) including contamination by exotic viruses from Asia.

This is why the Community is making a financial contribution, together with other European countries, to the measures advocated by the European Commission for the Control of Foot-and-Mouth Disease (FAO) and the International Office of Epizootics to maintain a vaccination buffer zone along Turkey's borders with Greece and Bulgaria.

This rapid survey shows that, whatever the situation in the Community countries and whatever the development of the disease over the last ten years, there is still in Europe a risk of the disease spreading from permanent focuses of infection in a

number of Middle Eastern countries. The risk is all the greater as the resources for combatting the disease in these areas and in the countries near to the Community vary appreciably.

4. Control and prevention in neighbouring countries

Not all the countries practice a policy of eliminating all affected livestock when the disease breaks out. The methods used vary from keeping the animals on the farm until the symptoms disappear, together with measures to isolate the farm, as in Turkey and Portugal; to slaughter of all animals of susceptible species, as in Sweden. A number of countries, such as Spain, follow a policy similar to that of the Member States in slaughtering susceptible animals.

The situation regarding vaccination also varies greatly, from a total ban as in Sweden to systematic annual vaccination as in Switzerland, Czechoslovakia, the German Democratic Republic and Spain. Intermediate solutions are compulsory vaccination in certain areas, as in Austria, Bulgaria or Turkey, or voluntary vaccination, as in Portugal. The vaccine used is mainly trivalent against types O, A and C. Some countries, however, use monovalent vaccine, depending on the degree of risk, the epidemiological development of the disease and the virus concerned.

The FAO's European Commission for the Control of Foot-and-Mouth Disease advocates better coordination in Europe of the control and prevention of FMD. It is indeed difficult to say in advance what the consequences would be if a major epizootic spread from the permanent sources of infection, and specifically if the buffer zones in south-east Europe were overruled.

II. Approaches to a common policy

A Community policy on foot-and-mouth disease has to take account not only of the disease as it exists in the Member States but also of the European and wider international context, as the Community is close to and has trade links with a number of non-Community countries.

Implementation of such a policy is in line with the basic principles of the common market, having regard to the disease's effects on farm incomes and the way of trade in livestock and livestock products, both because of the risk of spreading the virus and in view of the differing conceptions lying behind the Member States' control and prevention methods. Some Member States have a policy of preventing FMD by systematic vaccination of species of livestock susceptible to the disease, while others forbid the use of any FMD vaccine and do not allow imports of vaccinated livestock or fresh meat of vaccinated animals.

If we look at the way the disease has developed over the past ten years in the countries now composing the Community, we see that the general incidence of the disease is low and that it would be possible to harmonize, in the first instance, the measures to be taken by the Member States when the disease breaks out, in order to limit the consequences at both national and Community levels by avoiding the spread of the virus through trade. Without embarking on a debate of the principles of systematic prevention by vaccination, we may say that the risk of spread through healthy carries (vaccinated animals kept on farms where the disease had broken out) could be limited by eliminating sources of infection through slaughter and destruction of animals of susceptible species on the farm. This basic measure must be accompanied by strict animal health protection measures covering the infected farm and the area likely to become

infected, where there must be restrictions and surveillance during sufficient time over and above the incubation period of the disease, in order to ensure that there are no secondary outbreaks. According to the policy followed by the particular Member State, animal health measures may be reinforced by setting up a vaccination barrier covering all animals of susceptible species in the area concerned. The disease being a contagious one, the need for immediate action should be emphasized, and certain restrictions and surveillance measures should be adopted as soon as the presence of the disease is suspected rather than when it is confirmed. The vaccines used in emergencies should be as innocuous and as effective as necessary and should comply with harmonized, Community-wide control criteria for manufacture. The application of these reinforced measures in the implementation of the provisions concerning imports from non-Community countries, as adapted to the situation in the Community, should help in the total elimination of the disease.

When sufficient time has elapsed, and in the light of the results of experience in this first phase, it will be possible to look at the future development of the Community policy on FMD. This should take full account of what happens in neighbouring countries, so that we can fully assess the risks of contamination and define the conditions of this policy in the Community's European and wider international.

The action of the European Commission for the Control of Foot-and-Mouth Disease must be supported and continued, and the initial phase of harmonization undertaken by the Community will constitute an appreciable advance.

The accidental infections which occurred in the United Kingdom in 1981 and more recently still in Denmark, after many years of freedom from the disease, underline the major risk of contamination from neighbouring countries; in both cases, although the competent authorities in the two countries were not able to determine the precise origin of the infection, they regarded it as very likely that the virus had been brought by the wind, in view of the weather over the few days preceding the first outbreak.

Moving on to a second, more long-term phase will raise the question of prevention of FMD by systematic annual vaccination of livestock of susceptible species, as practised by some Member States. The long period of absence of the disease which should result from measures to eliminate sources of FMD will lead people to consider systematic vaccination as useless and expensive and will be an argument in favour of its progressive abandonment. However, we should point out the main conditions which would need to be met if such an approach were to be envisaged:

- a) the abandonment of systematic annual vaccination should not mean a ban on the use of vaccine in emergencies (vaccination of animals of susceptible species in areas threatened by an outbreak of the disease);
- b) if they have to resort to emergency vaccination, Member States should be certain of being able to obtain immediately the necessary quantities of a suitable vaccine meeting all the requirements involved;
- c) protection against possible contamination from outside the Community should be reinforced in the light of the development of the disease in other European countries, especially those bordering the Community, and this might go as far as setting up buffer zones for the areas most threatened;
- d) animal health policy concerning imports from outside the Community would have to be brought in line with the new situation inside the Community, by making the conditions for permission to export to the Community more strict;

- e) Member States which still had vaccine production plants on their territory would have to reinforce safety measures in order to avoid any escape of virus, both during manufacture and during tests for innocuousness and effectiveness.

All these conditions will have to be studied more thoroughly later, especially during the period when Community measures to control FMD are being applied by all the Member States in the light of the development of the disease. Only after the situation has stabilized in a satisfactory manner will it be possible to make a valid assessment of the financial implications of the measures that will have to be adopted.

OUTBREAKS OF FOOT-AND-MOUTH DISEASE 1971 TO 1981

MEMBER STATES

TABLE I

Member State	1971		1972		1973		1974		1975		1976		1977		1978		1979		1980		1981	
	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus
B	2		/		/		62	0	21	0	1	0	/		/		/		/		/	
DK	/		/		/		/		/		/		/		/		/		/		/	
FR	8	OC	2	0	1	0	89	C	2	0	/		/		1	C	21	0	/		18	OC
GR	27	OAC	330	OA ₂₂	317	0	14	OA	1	0	1	A ₂₂	3	A ₂₂	/		/		/		6	0
NL	21	OC	7	0	/		3	0	2	0	/		1	A	/		/		/		/	
IR	/		/		/		/		/		/		/		/		/		/		/	
IT	15	OAC	9	0	13	AC	5	OC	31	OAC	61	C	18	OAC	43	OAC	4	OA	1	A	2	0
LUX	/		/		/		/		/		/		/		/		/		/		/	
FRG	9	OAC	22	OAC	9	OAC	14	C	13	0	5	C	2	C	3	C	/		3	0	/	
U.K.	/		/		/		1		/		/		/		/		/		/		2	0
TOTAL	82		370		340		188		70		68		24		47		25		4		29	

OUTBREAKS OF FOOT-AND-MOUTH DISEASE 1971 TO 1981

COUNTRIES NEAR THE COMMUNITY

TABLE II

COUNTRY	1971		1972		1973		1974		1975		1976		1977		1978		1979		1980		1981	
	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus	No	Virus
Austria	/		/		1691	OC	7	0	1	0	/		/		/		/		/		2	0
Bulgaria	/		/		4	A	/		/		/		/		/		/		/		/	
G D R	3	0	/		/		/		/		9	C	1	0	1	C	/		1	0	/	
Spain	510	OC	371	AC	453	OAC	244	C	90	C	29	C	26	C	/		10	C	5	C	22	C
Portugal	1058	0	/		/		/		/		/		/		/		/		519	C	302	C
Sweden	/		/		/		/		/		/		/		/		/		/		/	
Switzerland	/		/		1	0	/		/		/		/		1	C	/		1	C	/	
Czechoslovakia	/		11	C	17	C	/		1	A	/		/		/		/		/		/	
Turkey	267	OA	1361	OA	1118	OA Asia1	465	OA ₂₂	361	OA ₂₂	862	OA ₂₂	733	OA ₂₂	824	OA ₂₂	755	OA ₂₂	856	OA ₂₂	833	OA
Yugoslavia	/		12	C	9	OC	4	C	/		/		/		1	A	/		/		/	
TOTAL	1838		1755		3293		720		453		900		760		827		765		1382		1159	

Proposal for a
COUNCIL DIRECTIVE

introducing Community measures for the control of foot-and-mouth disease

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,
and in particular Article 43 thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Parliament,

Having regard to the Opinion of the Economic and Social Committee,

Whereas one of the Community's tasks in the veterinary field is to improve the
state of health of livestock, thereby increasing the profitability of stockfarming;

Whereas such action should also help to remove those remaining barriers to trade
between Member States in live animals and fresh meat which are caused by
differences in their respective animal health situations;

Whereas an outbreak of foot-and-mouth disease can quickly take on epizootic
proportions, causing mortality and disturbances on a scale liable to reduce
sharply the profitability of farming of pigs and ruminants as a whole;

Whereas action must be taken as soon as the presence of the disease is suspected
so that immediate and effective control measures can be implemented as soon as
its presence is confirmed;

Whereas it is necessary to prevent any spread of the disease as soon as an
outbreak occurs, by carefully monitoring movements of animals and the use of
products liable to be contaminated, and, where appropriate, by vaccination;

Whereas diagnosis of the disease and identification of the relevant virus must be carried out under the auspices of responsible laboratories the co-ordination of which must be ensured by a laboratory appointed by the Community;

Whereas the vaccine used for emergency vaccination must be verified both for efficacy and safety under the auspices of a laboratory appointed by the Community, and whereas special coordinated measures must be implemented where virus types or variants are detected against which the vaccines usually used in the Community do not provide sufficient protection;

Whereas a procedure for close cooperation between the Member States and the Commission must be provided for,

HAS ADOPTED THIS DIRECTIVE :

Article 1

This Directive introduces Community measures for the control of foot-and-mouth disease, whatever the type of virus concerned.

Article 2

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

- (a) "animal of a susceptible species" means any domestic or wild ruminant or swine,
- (b) "holding" means any establishment (agricultural or other), situated in the territory of a Member State, in which animals of susceptible species are kept or bred;
- (c) "animal suspected of being infected with foot-and-mouth disease" means any animal of a susceptible species showing clinical symptoms, post-mortem lesions, or reactions to laboratory tests indicating the possible presence of foot-and-mouth disease;
- (d) "animal infected with foot-and-mouth disease" means any animal of a susceptible species :
 - in which clinical symptoms or post-mortem lesions of foot-and-mouth disease have been officially ascertained,
 - or
 - in which the presence of foot-and-mouth disease has been officially ascertained following a laboratory examination;
- (e) "official veterinarian" means the veterinarian appointed by the competent central authority of the Member State.

Article 3

Member States shall ensure that the presence or the suspected presence of foot-and-mouth disease are compulsorily and immediately notifiable to the competent authority.

Article 4

1. Where a holding contains one or more animals suspected of being infected with foot and mouth disease, Member States shall ensure that the official veterinarian immediately sets in motion official means of investigation to confirm or rule out the presence of the said disease, in particular by taking the necessary samples for laboratory examination.

As soon as the suspected infection is notified, the competent authority shall have the holding placed under official surveillance and shall in particular order that :

- a census be made of all categories of animals of susceptible species on the holding, and that, in respect of each of these categories, the number of animals already dead or liable to be infected be recorded; the census must be kept up to date to take account of animals born or dying during the suspect period; the information in the census must be produced on request and be liable to verification at each visit,
- all animals of susceptible species on the holding be kept in their living quarters or some other place where they can be isolated;
- no animals of susceptible species enter or leave the holding,
- no animals of other species enter or leave the holding without an authorization issued by the competent authority,
- failing authorization issued in each case by the competent authority, all dispatching from the holding of meat or carcasses of animals of susceptible species or of animal feed, utensils or other objects and waste liable to transmit the disease be prohibited,

- no milk leave the holding and, where it is used on the holding, that proper heat treatment be applied,
 - the movement of persons to or from the holding be made subject to authorization by the competent authority,
 - the movement of vehicles to or from the holding be made subject to authorization by the competent authority,
 - appropriate means of disinfection be used at the entrances and exits of buildings housing animals of susceptible species and of the holding itself,
 - an epizootiological inquiry be carried out in accordance with Article 7 and 8.
2. The competent authority shall have power to extend the measures provided for in paragraph 1 to holdings adjoining the relevant holding should their location, their configuration, or contacts with animals from the relevant holding give reason to suspect possible contamination.
3. The measures referred to paragraphs 1 and 2 shall not be lifted until the suspicion of foot-and-mouth disease has been officially refuted.

Article 5

1. In cases where the presence of foot-and-mouth disease has been officially confirmed, Member States shall ensure that :
- (a) the official veterinarian takes adequate samples for laboratory examination when the confirmation of disease has not been preceded by a period of suspicion.
 - (b) the competent authority, in addition to the measures listed in Article 4(1) requires that :
 - all animals of susceptible species of the holding be killed on the spot without delay under official control, and in such a way as to avoid all risk of dispersion of the foot-and-mouth virus. However, when killing on the spot is impossible, the animals must be transported in specially equipped vehicles to the place of slaughter, the whole operation being carried out in such a way as to avoid all risk of dispersion of the foot-and-mouth virus,

- after slaughter the animals referred to above be destroyed under official supervision in such a way that there is no risk of dispersion of the foot-and-mouth virus,
 - meat of animals of susceptible species slaughtered during the period between the probable introduction of the disease to the holding and the implementation of official measures be, wherever possible, traced and destroyed under official supervision in such a way as to avoid any risk of dispersion of the foot-and-mouth virus,
 - the carcasses of animals of susceptible species which have died on the holding be destroyed under official supervision in such a way as to avoid any risk of dispersion of the foot-and-mouth virus,
 - all substances such as wool or waste likely to be contaminated, such as feedingstuffs, dung, etc., be destroyed or treated in such a way as to ensure the destruction of any foot-and-mouth virus present; this treatment must be carried out in accordance with the instructions of the official veterinarian,
 - milk and milk products be destroyed in such a way as to avoid all risk of dispersion of the foot-and-mouth virus,
 - after elimination of the animals of susceptible species, the buildings used for housing the animals, their surroundings and the vehicles used for transporting them and all equipment likely to be contaminated be cleaned and disinfected in accordance with Article 10,
 - no animals of susceptible species be reintroduced to the holding within at least 15 days after completion of the cleaning and disinfection operations carried out in accordance with Article 10,
 - an epizootiological inquiry be carried out in accordance with Articles 7 and 8.
2. The competent authority shall have power to extend the measures provided for in paragraph 1 to holdings adjoining the relevant holding should their location, their configuration, or contacts with animals from the relevant holding give reason to suspect contamination.

Article 6

1. In the case of holdings which consist of two or more separate production units and in order that fattening of susceptible species of animal may be completed, the competent authority may derogate from the first and second indents of Article 5(1)(b) as regards healthy production units on a holding which is infected provided that the official veterinarian has confirmed that the structure and size of these production units and the operations carried out there are such that the production units provide completely separate facilities for housing, keeping and feeding, so that the virus cannot spread from one production unit to another.

The same measures, and the possibility of derogating from the requirements of the sixth indent of Article 5(1)(b) may be extended to holdings producing milk, provided that in addition milking in each unit is usually carried out completely separately.

Where recourse is had to paragraph 1, the Member States shall draw up detailed rules for applying it in the light of the animal health guarantees which can be given. They shall notify the Commission thereof.

3. A decision may be taken, in accordance with the procedure laid down in Article 16, that the measures referred to in paragraph 1 are to be amended in order to ensure their coordination with those adopted by the Member States.

Article 7

The epizootiological inquiry shall deal with :

- the length of time during which the foot and mouth disease may have existed on the holding before being notified or suspected,
- the possible origin of the foot-and-mouth disease on the holding and the identification of other holdings on which there are animals of susceptible species which may have become infected from the same source,
- the movement of persons, vehicles, animals, carcasses, meat, material or agents likely to have carried the virus to or from the holdings.

Article 8

1. Where the official veterinarian finds, or considers on the basis of confirmed data, that foot-and-mouth disease could have been introduced from other holdings on to the holding referred to in Article 4, or from the latter holding on to other holdings, as a result of the movement of persons, animals, vehicles or in any other way, those other holdings shall be placed under official surveillance in accordance with paragraph 3, and this surveillance shall not be lifted until the suspicion of foot-and-mouth disease in relation to the holding referred to in Article 4 has been officially refuted.

2. Where the official veterinarian finds, or considers on the basis of confirmed data, that foot-and-mouth disease could have been introduced on to the holding referred to in Article 5 from other holdings as a result of the movement of persons, animals or vehicles or in any other way, those other holdings shall be placed under official surveillance in accordance with paragraph 3.

Where the official veterinarian finds, or considers on the basis of confirmed data, that foot-and-mouth disease could have been introduced from the holding referred to in Article 5 on to other holdings as a result of the movement of persons, animals or vehicles or in any other way, those other holdings shall become subject to the provisions of Article 4.

3. The purpose of the official surveillance shall be to detect immediately any suspicion of foot-and-mouth disease, to make a census of animals of a susceptible species, to check their movements and, where appropriate, to implement any or all of the measures provided for in Article 4(1).

Article 9

1. Once the diagnosis of foot and mouth disease has been officially confirmed, the Member States shall ensure that the competent authority establishes, around the infected holding, a protection zone based on a minimum radius of two kilometres and a surveillance zone based on a minimum radius of ten kilometres, endeavouring to include in one of the two zones a slaughterhouse capable of receiving the animals from the protection zone. The establishment of zones must take account of natural boundaries and control facilities.
2. (a) The following measures shall be applied in the protection zone :
- a census shall be carried out of all the holdings having animals of a susceptible species, these holdings being visited periodically,
 - the movement of animals of susceptible species on public or private roads, excluding means of access within holdings, shall be prohibited,
 - animals of susceptible species may be removed from the holding on which they are kept only to be transported directly under official supervision for the purpose of immediate slaughter to the slaughterhouse defined in paragraph 1. Such transport may be authorized by the competent authority only after the official veterinarian has carried out an examination of all the animals of susceptible species on the holding and confirmed that none of the animals is suspected of being infected with foot-and-mouth disease,
 - itinerant service for breeding shall be prohibited,
 - artificial insemination shall be prohibited,
 - fairs, markets, shows or other gatherings of animals, including collection and distribution of animals, shall be prohibited,

- the transport of animals of susceptible species in transit is prohibited except for transit by major highways or main-line railways.

(b) The measures applied in the protection zone shall be maintained until at least 15 days after elimination of all animals of susceptible species on the holding referred to in Article 5 and the execution on this holding of the cleaning and disinfection operations in accordance with Article 10. However, the measures set out in paragraph 3 for the surveillance zone shall remain in force in the protection zone.

3. (a) The following measures shall be applied in the surveillance zone :

- a census shall be made of all holdings which have animals of susceptible species,
- the movement of animals of susceptible species on public roads is prohibited,
- the transport of animals of susceptible species within the surveillance zone shall be subject to authorization issued by the competent authority,
- animals of susceptible species may be removed from the surveillance zone only under official control, and during the 15 days following the date of establishment of this zone only to a slaughterhouse for immediate slaughter. Such removals shall be authorized by the competent authority only after examination by the official veterinarian of all the animals of susceptible species on the holding has ruled out the presence of animals suspected of being infected with foot-and-mouth disease,
- itinerant service for breeding shall be prohibited,
- fairs, markets, shows and other gatherings of animals shall be prohibited.

(b) The measures in the surveillance zone shall be kept in force until at least 30 days after the elimination of all the animals of susceptible species on the holding referred to in Article 5 and the execution on this holding of the cleaning and disinfection operations in accordance with Article 10.

Article 10

The Member States shall ensure that :

- the disinfectants to be used and their concentrations are officially approved by the competent authority,
- the cleaning and disinfection operations are carried out under official supervision, in accordance with the instructions given by the official veterinarian.

Article 11

1. The Member States shall ensure that :

- laboratory examinations carried out in order to detect the presence of foot-and-mouth disease, if necessary and especially on the first appearance of disease, show the type and sub-type and, where appropriate, the variant of the relevant virus,
- the examinations are carried out by a national laboratory in accordance with Annex I,
- the type or sub-type and, where appropriate, the variant of the relevant virus, are confirmed, if necessary, by a reference laboratory assigned by the Community,
- liaison between the national laboratories defined in the second indent is ensured by a laboratory designated by the Community.

2. The Council, acting on a proposal from the Commission, shall designate the laboratories referred to in the third and fourth indents of paragraph 1 and shall determine their powers and the conditions of their operation.

Article 12

1. Without prejudice to existing Community provisions in this field, Member States shall inform the Commission and the other Member States about the epizootiology and development of the disease in accordance with Annex II.

2. Annex II may be amended in accordance with the procedure laid down in Article 17.

Article 13

Member States shall ensure that :

- when animals of susceptible species are moved out of the holding on which they are kept, they are identified so as to enable the holding of origin, or the holding from which they have been transported, and their movements to be traced rapidly. However, for certain animals, and in certain circumstances, having regard to the health situation, the competent authority may authorize other ways of rapidly identifying the holding of origin or the holding from which the animals have been transported and of rapidly tracing the animals' movements. The arrangements for marking the animals or for identifying the holdings of origin shall be determined by the competent authority,

- all persons engaged in the transport or marketing of animals of susceptible species are able to supply the competent authority with information concerning the movements of animals which they have transported or marketed, and to furnish proper evidence concerning such information; the same obligation shall be incumbent upon all persons keeping such animals in respect of animals entering or leaving their holdings.

Article 14

1. When foot-and-mouth disease is diagnosed on a holding, the measures to control the disease may be supplemented by the vaccination of animals of susceptible species on holdings threatened with contamination in a territorial area specified by the competent authority.
2. In the case referred to in paragraph 1, the Member State shall ensure that :
 - (a) without prejudice to national arrangements where such arrangements provide for the preventive vaccination against foot-and-mouth disease of any or all of the animals of susceptible species on part or all of the national territory, the vaccination or re-vaccination of animals of susceptible species on the holdings referred to in Articles 4 and 5 is prohibited;
 - (b) serum injection is prohibited;
 - (c) the anti foot-and-mouth disease vaccine used and the method of use are in accordance with the rules established under the procedure provided for in Article 17;
 - (d) the vaccine used is verified by the competent authority under the aegis of a specialized institute designated by the Community;
 - (e) any vaccine imported from a non-member country meets the requirements set out under (c) and is verified as indicated under (d).
3. Where types, sub-types or variants of virus are detected against which the vaccines usually used provide no protection or insufficient protection, the Member State concerned shall immediately inform the Commission and the other Member States stating what emergency measures it believes necessary for the adaptation of vaccine formulae and their use. If the adoption of Community measures prove necessary, such measures shall, in the light of the national measures referred to above, be adopted according to the procedure provided for in Article 16.

4. On a proposal from the Commission the Council shall designate the laboratory referred to in paragraph 2(d) and shall decide upon its powers and conditions of operation.

Article 15

Should foot-and-mouth disease assume alarming proportions on the territory of a Member State, and, despite the measures taken, particularly in application of Article 14, the epidemic take on an extensive character and extend widely outside the limits of the vaccinated zone, it may be decided in accordance with the procedure laid down in Article 16, at the request of that Member State and where justified by an assessment of the situation, to permit derogations from certain provisions of Article 5, to the extent of a selective reduction of the slaughter and destruction of susceptible animals in the holdings where the disease occurs. In this case, the conditions of application for the measures which are decided upon shall be established if necessary according to the same procedure.

Article 16

1. Where the procedure laid down in this Article is to be followed, the matter shall without delay be referred by the chairman, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter referred to as "the Committee") set up by the Council Decision of 15 October 1968.
2. Within the Committee the votes of the Member States shall be weighted as laid down in Article 148(2) of the Treaty. The chairman shall not vote.
3. The representative of the Commission shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on these measures within two days. Opinions shall be delivered by a majority of forty-five votes.
4. The Commission shall adopt the measures and shall implement them immediately, where they are in accordance with the opinion of the Committee. Where the measures are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal on the measures to be taken. The Council shall adopt the measures by qualified majority.

If the Council has not adopted any measures within 15 days of the date on which the matter is referred to it, the Commission shall adopt the proposed measures and shall implement them immediately unless the Council has voted against the said measures by a simple majority.

Article 17

1. Where the procedure laid down in this Article is to be followed, the matter shall without delay be referred by the chairman, either on his own initiative or at the request of a Member State, to the Committee.
2. Within the Committee the votes of the Member States shall be weighted as laid down in Article 148(2) of the Treaty. The chairman shall not vote.
3. The representative of the Commission shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion by a date which the Chairman may set in the light of the urgency of the matters submitted for examination. Opinions shall be delivered by a majority of forty-five votes.
4. The Commission shall adopt the measures and shall implement them immediately, where they are in accordance with the opinion of the Committee. Where the measures are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal on the measures to be taken. The Council shall adopt the measures by qualified majority.

If the Council has not adopted any measures within three months of the date on which the matter is referred to it, the Commission shall adopt the proposed measures and shall implement them immediately unless the Council has voted against the said measures by a simple majority.

Article 18

On the basis of a report, containing proposals, where appropriate, on the experience gained in controlling foot-and-mouth disease, the Council shall review the situation with a view to further harmonization, by 31 December 1985.

Article 19

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive on 1 July 1983.

Article 20

This Directive is addressed to the Member States.

Done at Brussels,

For the Council

ANNEX I

The national foot and mouth laboratories are as follows :

- Belgium and Luxembourg : Institut national de recherches vétérinaires,
Groeselenberg 99, 1180 Bruxelles
- Denmark : Statens veterinære Institut for Virusforskning,
Lindholm
- Italy : Istituto zooprofilattico sperimentale della Lombardia
e della Emilia Romagna - Brescia
- United Kingdom and Ireland : Animal virus research institute
Pirbright Woking - Surrey
- France : Laboratoire national de pathologie bovine
Lyon
- Greece : Institute for foot and mouth disease
Aghia Paraskevi Attikis
- Germany : Bundesforschungsanstalt für Viruskrankheiten der Tiere;
Tübingen
- Netherlands : Centraal Diergeneeskundig Instituut
Lelystad

ANNEX II

EPIZOOTIOLOGICAL INFORMATION

1. Within 24 hours of notification of the first outbreak of foot and mouth disease, the Member State concerned must forward the following information to the Commission and the other Member States :
 - the date on which the disease was suspected;
 - the date on which the disease was confirmed :
 - type, sub-type and, as appropriate, variant of the relevant virus (where such information is not yet available at the time of notification, it must be sent as soon as possible);
 - location of the holding infected, distance of the nearest livestock holdings;
 - number of animals by species on the holding;
 - for each species, number of animals found to be infected and the level of morbidity of the disease.

2. The information specified in paragraph 1 must be followed as soon as possible by a report stating the following :
 - the date on which the animals of susceptible species on the holding were slaughtered and destroyed;
 - any available information concerning the possible origin of the disease or the origin of the disease if this has been ascertained.

3. The Member State concerned must forward the information specified in paragraph 1 to the Commission and the other Member States, within the time limit laid down therein, in respect of each subsequent outbreak of foot and mouth disease until the number of infected holdings and the dispersion of the disease show it to be extensive.

