COMMISSION OF THE EUROPEAN COMMUNITIES

REVISED VERSION

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Report

on the Rabies situation in the Member States

Proposal for a

COUNCIL REGULATION (EEC)

instituting a certificate for dogs and cats on visits of less than one year in the Member States and introducing Community measures to set up pilot projects for the control and eradication of Rabies

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(presented by the Commission)

REPORT ON THE RABIES SITUATION IN THE MEMBER STATES

Introduction

Rabies is a disease capable of infecting all warm blooded animals, including man. It is caused by a virus and is one of the oldest diseases known. It is referred to by Homer, Hippocrates, Aristotle, Virgil and by numerous authors in subsequent centuries up to the present. It has been specifically referred to in ancient times as occurring in Cairo, Crete, Sicily and Spain; it was probably endemic throughout the Mediterranean basin in ancient times.

Clinical disease normally results from the bite of an infected animal. Once symptoms appear death is inevitable. Prior to death, symptoms are very often alarming and terrifying such as hyper-excitability, aggression and fear of water; a symptom that gave rise to the name hydro-phobia - another name for the disease in man. It is not so long ago that human sufferers of the furious form of the disease were smothered alive. Rabies is an emotive disease because of the certainty of death once symptoms have appeared, because of the possible dreadful nature of the symptoms and the social shunning of infected persons.

Types of Rabies

Although several types of rabies are spoken about, such as cat rabies, fox rabies and bat rabies, etc., it is probable that the rabies virus is a single entity and that it has become adapted to the animal species in which it is cycling. However, it can pass from one species to another species and after some time become adapted to the receiving species, and thence forward is capable of inducing classical rabies. Furthermore, strains of the rabies virus may be differentiated by using monoclonal antibodies to identify their genetic marker thus allowing to clearly distinguish between rabies of terrestrial and non-terrestrial animals, between strains imported into Europe from Asia, Africa etc. or between field and laboratory (eg. vaccine strains).

Notwithstanding the above, four types of rabies may be clearly defined as follows:

1. Dog rabies:

   The disease circulates in dogs and occasionally leaks out to other species, including man. This type of rabies has disappeared from Western Europe with the exception of Turkey and Yugoslavia. It was brought under control by compulsory vaccination of dogs and cats and destruction of strays. It was largely this type of rabies to which the great Pasteur applied his magnificent talents.

2. Mixed rabies:

   Rabies in which more than one species is involved and the disease is cycling in each species and cross infection is occurring, e.g. dog and wild carnivores. This type occurs in the Americas and Africa.

3. Bat rabies:

   There are two types of bat rabies:

   a) Vampire bat rabies:

      The rabies virus circulates in vampire bats and is then transferred to the animal on which the infected bat has sucked blood, thus causing rabies. This is a big source of loss in cattle in some South American countries. This type of rabies does not occur in Europe because there are no vampire bats.

   b) Insectivorous bat rabies:

      This condition has been identified in Germany (Hamburg 1954 and 1968, Stade 1970, Berlin 1973, Bremerhaven 1982, Hannover 1986), Yugoslavia 1954, East Germany 1963 and 1986, Denmark 1985, Netherlands 1987, Poland 1972 and 1985 and Russia 1964, 1977 and 1985 and Spain in 1987. Natural transmission of rabies from insectivorous bats to other land animals by biting has not been observed to date.

      7th Report of the WHO Expert Committee on Rabies. There are reports that rabies has been transmitted from insectivorous bats to man by bite. There is hardly any information on bat rabies in Europe but one thing is clear, with the possible exception of man (where it is a self limiting disease), European bat rabies plays no part in the dissemination of rabies outside its own species.

4) Fox rabies:

The disease circulates in foxes on a continuous basis, the fox is the main target and carrier of the disease. Sometimes the disease is transmitted to other species, i.e. other animals and man, but if it does it is a dead end, that is to say, it is a self limiting disease in other species because the infected animal usually dies without propagating infection. This is the only type of rabies (bat rabies excepted) which occurs in the E.E.C., this fact is of vital importance when one considers control/eradication procedures.

Distribution in Europe

The current epidemic of rabies appeared at the Russian-Polish borders in the 1930's. It has since been progressing annually at the rate of 30 to 40 km in a westerly direction. It arrived in Eastern Germany in 1947, Austria and Czechoslovakia 1948, Western Germany 1950, Hungary 1954, Denmark 1964, Belgium and Luxemburg 1966, Switzerland 1967, France 1968, the Netherlands 1974 and Italy and Yugoslavia in 1977.

With the exception of U.K., Ireland and Portugal (last case in 1984), all other Member States may be considered infected or at risk.

It is difficult to estimate the exact amount of rabies that occurs because due to the nature of the disease there is massive under-reporting. Some idea of the prevalence of rabies may be had from the following table (1).

Effects of rabies

The presence of rabies not alone inhibits the free movement of dogs and cats, but also of people because of the requirement for quarantine in some Member States of accompanying companion animals. Thus holiday makers who might wish to bring their pets with them are prohibited from doing so in certain instances. For example, not alone can a French citizen not go on holidays accompanied by his pet to the U.K. (because of quarantine restrictions) but also a U.K. citizen is inhibited from going to France if he is accompanied by his companion animal, because the animal would have to be quarantined for 6 months on return. Quarantine is not alone upsetting to the owners and animals themselves, it is also expensive.

The presence of rabies has environmental repercussions in so far as it militates against a closer association of man and animals.
The presence of rabies is costly, as is demonstrated by the following examples:

A) France

Cost of vaccination of domestic animals	=	189 million French francs
Cost of diagnosis, vaccine control and research	=	5 million French francs
Cost of human post exposure vaccination	=	6 million French francs
TOTAL	=	200 million French francs (per year)

B) Belgium

Cost of vaccination of domestic animals	=	149 million Belg. francs
Cost of human vaccination	=	5 million Belg. francs
Fox killing premiums	=	12 million Belg. francs
Cost of diagnosis		0.5 million Belg. francs
TOTAL	=	166.5 million Belg. francs (per year)

TABLE I

EUR EUROPE 1987 RABIES CASES 1. 1.87 - 31.12.87

LOCATION CODE	NAME	DOMESTIC ANIMALS							WILD ANIMALS						HUMAN CASES	TOTAL
		DOG	CAT	CATTLE	HORSE	SHEEP GOAT	OTHERS	TOTAL	FOX	BADGER	OTHER MUSTEL	DEER	OTHERS	TOTAL		
AUT	AUSTRIA	3	20	44	2	19	-	88	1722	100	54	75	3	1954		2042
BEL	BELGIUM	6	18	43	3	18	1	88	140	3	9	2	-	154		242
BUL	BULGARIA *							0						0		0
CZE	CZECHOSLOVAKIA	27	63	15	-	5	-	110	1605	7	38	19	4	1673		1783
ODR	GERMAN DEM. REPUBLIC	66	95	70	9	107	1	368	1187	21	58	52	7	1325		1693
DEN	DENMARK							0	-	-	-	-	48	48		48
DEU	FED.REP. OF GERMANY	34	98	160	21	69	1	383	3013	75	120	188	13	3409		3792
FIN	FINLAND *							0						0		0
FRA	FRANCE	37	76	98	16	121	-	348	1640	13	37	23	7	1720		2068
GBR	UNITED KINGDOM 1)							0						0	1	1
GRE	GREECE	1	-	-	-	-	-	1						0		1
HUN	HUNGARY	49	67	53	1	5	8	183	1263	1	4	14	1	1283		1466
IRE	IRELAND *							0						0		0
ISL	ICELAND *							0						0		0
ITA	ITALY *							0						0		0
LUX	LUXEMBOURG	-	2	6	-	1	-	9	14	-	-	-	-	14		23
NET	NETHERLANDS							0	-	-	-	-	86	86		86
NOR	NORWAY							0	-	-	-	1	-	1		1
POL	POLAND	52	75	79	1	16	7	230	1209	18	56	67	106	1456		1686
POR	PORTUGAL *							0						0		0
ROM	ROMANIA	5	6	6	2	5	-	24	21	-	-	-	1	22		46
SPA	SPAIN 2)	5	2	-	-	-	-	7	-	-	-	-	2	2		9
SWE	SWEDEN *							0						0		0
SWI	SWITZERLAND + LIECHT	1	2	4	1	1	-	9	85	1	3	1	-	90		99
TUR	TURKEY	695	84	155	9	26	10	979	3	-	-	1	22	26		1005
YUG	YUGOSLAVIA	11	16	2	-	2	-	31	559	2	-	3	4	568		599
TOTAL		1011	624	735	65	395	28	2858	12461	241	379	446	304	13831	1	16690
PER CENT		6.1	3.7	4.4	0.4	2.4	0.2	17.1	74.7	1.4	2.3	2.7	1.8	82.9	0.0	100.0

* NO CASES. 1) IMPORTED FROM INDIA. 2) 7 CASES IN NORTH AFRICA, 2 BAT CASES IN THE MAINLAND.

Control measures in the EEC

1. Non-infected Member States (UK and Ireland).
   All animals potentially susceptible to rabies are quarantined for a period of six months. Since 1928 there have been 28 animals which have died from rabies in quarantine in the UK (26 dogs, 1 cat and 1 leopard). There was 1 case of rabies in quarantine in the last 10 years. The last case of rabies in the UK occurred in 1969, in fact there were two cases in dogs and both occurred after the animals had been released from quarantine. Previous to this the last case was in 1922. The last case of rabies in Ireland was in 1903.

2. Member States in which there are occasional cases of rabies or are at risk of becoming infected. The name of the M/S is followed by the date of the last reported case in brackets. Denmark (1982), The Netherlands (1986), Portugal (1984), Italy (1988), Greece (1986) and Spain (1985). In the case of Spain only the mainland and islands are being considered.

   If a case of rabies happens control measures involve a combination or all of the following; vaccination of dogs and cats in the infected area, movement control (leash laws), sequestration of strays or their destruction. Vaccination of foxes and/or methods to reduce their density.

3. Member States in which rabies is endemic (Belgium, France, Germany, Luxembourg).

   The fox is the main species to be infected. Control measures are mainly based on a reduction of the fox population by various methods such as shooting, gassing, poisoning and trapping. Dogs and cats are usually vaccinated annually in the infected areas.

New developments

The use of oral immunisation of foxes has been studied since the early 1970s. Under a brilliant Swiss scientist, Prof. Franz Steck, trials were set up in the late 1970s to evaluate the efficacy and safety of oral immunisation using a Swiss manufactured SAD vaccine dispersed in chicken head baits and containing a marker to evaluate the rate of vaccine uptake in foxes. The objective of the trial was to create immune belts in non-infected areas and to eradicate rabies in infected zones. The results were remarkable in that the spread of rabies was inhibited and there was a dramatic fall in the number of cases in infected areas. No deleterious side effects were observed. Prof. Steck was tragically killed when a helicopter from which he was sowing baits hit a pylon and crashed. Results from Switzerland are given in Table 2. The following is the situation.

TABLE 2

SWITZERLAND

	1975	1980	1982	1985	1986	1987*
Number of outbreaks in Switzerland	1635	1194	994	301	120	63
no.of baits used Cumulative(000's)	0	21	62	490	770	930

* up to end of August 1987

Federal Republic of Germany

Field trials aiming at the large scale reduction of rabies in non-alpine territories were started in Germany in 1983.
Developmental steps between 1983 and 1985 included:

1. Development of the SAD B19 vaccine (Tübingen) with;
   - excellent temperature stability under field and storage conditions;
   - improved immunogenicity (10^7TCID/ml);
   - improved safety for target and non-target animals(no case of vaccinal death observed after distribution of more than 5.2 million doses in the field);
   - proven immunogenicity in other rabies vector species such as dog, jackal, racoon and racoon dog.

2. Development of monoclonal antibodies for differential diagnosis (field virus vs. vaccine virus).

3. Development of machine-made bait (Tübingen fox bait) which for the first time enabled mass application of vaccine in the field and which substantially increased the efficacy of the vaccine for foxes and other wildlife species.

4. Development and testing of strategies for immunization using fox densities and different types of rabies epidemics.
5. Development of new schemes for organizing field campaigns.(first time use of private hunters for bait distribution in the field at no cost).

6. Laboratory evaluation of control foxes for bait uptake and seroconversion.

RESULTS.

Field trials were conducted in 8 "Bundesländer" of the Federal Republic of Germany.

During the initial phase from 1983-85 a total of 476 000 chickenhead baits were prepared for field use.

Since autumn of 1985, the new "Tübingen bait" was used exclusively. Within a two year period more than 3.6 million doses were used in the field covering 134 453km^2 of German territory.

Laboratory examination of more than 5 000 foxes showed that 73% (range 60%-90%) had taken a bait, and that 72% (range 58%-96%) were effectively immunized against rabies. This was sufficient to provoke a dramatic drop in the number of reported rabies cases. By 1987, territories that were almost free of rabies totalled over 50 000 km^2.

SAFETY.

SAD strains have been examined in the laboratory and in the field with the following results:

a) Laboratory. Several species of animals (fox - both adult and juvenile, marten, badger, wild boar, domestic pig, domestic dog, raccoon dog, raccoon and jackal) have been given oral doses at a rate of between 10^6 and 10^8 TCID/ml. None of these animals developed rabies and in fact all of them became immunized. Palhogenicity has been demonstrated in mice which have been given an oral dose of 7.5 10^5.

b) Field. About 5.2 mill. doses have been used to date and about 50 ooo animals from the vaccination zones have been examined including more than 3 000 rodents, 7 800 foxes, 5856 rabid foxes tested by monoclonal antibody, and more than 30 000 additional rabies suspect animals. No case of vaccine induced rabies was detected. No virus neither vaccinial or wild was isolated from 216 small mammals which were analysed during the Belgian project. There are reports of a cat developing rabies after eating a bait in the Swiss project, however, it appears that the cat was immuno-suppressed due to cortisone therapy for some other condition. The risks involved in using live mutant vaccines are as follows:

- the possible establishment of the vaccine virus in a non-fox reservoir,
- the possible creation of cases of vaccine induced rabies.

From laboratory results it appears that there is a risk of setting up rabies in wild mice however, from field results it appears that even if this is occurring in individual cases there is no evidence that the virus is cycling.

TABLE 3

VACCINATION AREAS	km^2	RABIES CASES PER YEAR					
		1975	1980	1982	1985	1986	1987
Baden-Württemberg	12191	618	1061	612	1285	396	42
Bayern	25775	869	742	653	328	248	45
Hessen	7629	410	247	630	615	164	30
Niedersachsen	3742	53	60	130	22	16	1
Nordrhein-Westfalen	5124	357	327	81	433	76	32
Rheinland-Pfalz	3039	177	117	179	72	3	1
Schleswig-Holstein	15678	207	67	32	3	0	0
TOTALS	73178	2691	2621	2317	2758	903	151
Frequency of cases per 100 km^2		3.68	3.58	3.17	3.77	1.23	0.21

NON-VACCINATION AREAS	km^2	RABIES CASES PER YEAR					
		1975	1980	1982	1985	1986	1987
Baden-Württemberg	23560	494	904	1127	578	690	524
Bayern	44771	777	1001	369	968	984	861
Hessen	13483	566	545	979	623	604	475
Niedersachsen	43688	649	554	307	575	488	110
Nordrhein-Westfalen	28933	420	108	671	750	1045	382
Rheinland-Pfalz	16798	203	601	708	555	444	306
Saarland	2567	19	271	72	53	96	45
Hamburg	748	0	0	0	0	1	0
Bremen	404	3	0	1	1	0	0
Berlin	480	44	0	1	2	0	0
TOTAL	175432	3175	3984	4235	4105	4352	2703
Frequency of cases per 100 km^2		1.81	2.27	2.41	2.34	2.48	1.54

Italy

Rabies existed in Italy up to 1973, it was associated with dogs and other domestic animals. It was eradicated by vaccinating all domestic dogs in the national territory during 1969 and 1970, subsequently some at risk provinces were vaccinated between 1971 and 1975.

In February 1977 rabies occurred in the Bolzano province having arrived from Austria via the Krimml pass. By 1985 there were 7 provinces infected (Udine, Trento, Bergamo, Bolzano, Como, Sondrio and Aosta). A field trial was started in 1985 using 77 000 doses of SAD B19 vaccine dispersed in chicken head baits in an area of 2100 km^2. The number of baits laid per km^2 varied according to the altitude, 15 to 20 baits below 900m, 9-12 below 1200m and 5 to 7 baits below 1700m. It should be remarked that the Italian project is an example of a campaign mounted in an alpine region which differs fundamentally from other areas in relation to fox densities, geographical features and bait dispersion.

Following two vaccination campaigns per year for two years (1984 and 1985), no more cases of rabies were recorded since mid 1986. Unfortunately a case of rabies was reported in the Autumn of 1988, it is thought that this resulted from infection crossing the Yugoslavian border.

TABLE 4

CASES:

1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987*
99	250	79	12	367	345	448	354	122	0	0

* Until Nov. 1987

In 1984 a meeting was held in the Commission premises (under the framework of agricultural research) to discuss the possibility of cooperation to eradicate rabies at the European level. From this and subsequent meetings that were held both within and without the Commission a field trial was designed which would take place in the autumn of 1986 and the spring and autumn of 1987 involving all of the territory of Luxembourg and adjoining areas of Belgium, France and Germany (about 18 000km^2). The trial was carried out and whilst it maybe too early to give definite results the indications are that there were no deleterious effects and this was accompanied by a drop in reported cases. Baits (Tübingen) were dispersed at the rate of 15 per km^2 and the uptake rate was: Autumn 1986 - 58.4%, Spring 1987 - 63.7% and Autumn 1987 - 65.8%. On examination of foxes there was about 75% rate of sero conversion.

Luxembourg

The first case of rabies occurred in 1966 and cases have occurred every year since with the exception of 1971 and 1972. There have been a high percentage of cases in bovines (55 in 1967, 73 in 1982). The situation is outlined in Table 5. The cases that occurred in 1987 were close to the border.

TABLE 5

CASES:

1966	1969	1971	1974	1977	1980	1981	1982	1983	1984	1985
28	12	-	43	34	25	86	205	106	64	67

1986	1987*
138	21

Until 15 Oct. 1987

Belgium

About 2100 km2 were utilised for bait dispersion during autumn of 1986 and spring and autumn of 1987, the area was increased by 750 km2 for the Oct. 1987 campaign. The baited area was in the East of Belgium, along the border with Luxembourg. There seems to be a lower uptake of bait in the spring, about 50% uptake in 1986 but more recently this has gone up to 66% as indicated by the presence of tetracycline in the bones of examined foxs. There was no isolation of vaccine virus in small mammamls. Up to the end of October 1987 there have been 24 cases in the area and most of these were due to reinfection from the outside, before vaccination took place there were nearly 300 cases (1985).

France

In 1986-87 a small scale project took place in three Departments (Moselle, Meurthe Moselle and Doubs). There were 29.000 baits distributed on 1 200 km^2 in Moselle and Meurthe Moselle. After the first campaign there were 6 reported cases of rabies, after the second there were two cases and there have been no cases reported in the area up to the end of October 1987. Another project took place in 1987 in the Department of Doubs (130km^2) on the Swiss border. After the second bait distribution no more rabies cases were reported in the vaccinated area.

Austria

A field trial in Vorarlberg was started in the spring of 1986 in a 2000km^2 border area with Germany and Switzerland. After two bi-annual vaccinations no more rabies cases were recorded. Vorarlberg has been free from rabies since October 1986.

Costs

The cost of the Tubingen vaccine plus bait (delivered) is about 1 ECU (2DM). The cost of distribution and collection of the vaccine is nil as this service was largely provided by the hunters. The cost of examination of specimens, i.e. foxes for vaccine uptake and mammals for vaccine leaks, is also largely nil because this was carried out by institutes that were already providing this service anyway (some small transportation cost might be involved). The total cost of the Luxembourg project was 7 million Lux. francs.

Cost benefit analysis

The following may serve as an example:

In France there are currently about 30 Departments infected or at risk with rabies. As has been pointed out earlier in this report, the total National cost is in the order of 200 million French francs per year which is equal to an annual cost of 1200FF per km^2 per year (200 million FF divided by the area of the 30 concerned Departments).

Cost of eradication of rabies:
Cost of bait = 7FF
at 15 baits per km^2 = 105 FF per km^2.
Total cost (2 vaccination campaigns) + dispersion costs = 315 FF per year/km^2

This is an exaggerated figure because all of the infected area would not need to be vaccinated because there are pockets where the disease does not exist because of low fox densities, etc.

The future

Further research is currently being conducted in France and Belgium both in the laboratory and in the field, to evaluate the advantages of new candidate vaccines of lower pathogenicity. Such vaccines are obtained either from selection of SAD mutants (with monoclonal antibodies or from recombinant DNA technology).

Conclusions:

Results of large-scale field trials in Austria, Federal Republic of Germany, Italy and Switzerland suggest that the elimination of wildlife rabies can be achieved in a cost-effective way by oral vaccination campaigns.

Laboratory research between 1973 and 1978 and field trials since 1978 have not indicated a risk of reversion of the virus to virulence, nor an epidemiological significance of residual pathogenicity of the SAD virus strains used in the Berne (Switzerland) and the Tübingen (FRG) B19 vaccines. Three cases of vaccine-induced rabies, believed to be due to immunosuppresion, were registered after field use of 1 million doses of the SAD Berne vaccine. No case of vaccinal rabies has so far been observed after field application of 2.4 million doses of the SAD B19 vaccine.

Despite this, evidence presented at the meeting suggests that vaccination using the Berne and Tübingen vaccine strains by the oral route is safe in the field, feasible and practical.

The Commission is therefore of the opinion that it is technically feasible to eradicate rabies from the EEC. This view is supported by the European Parliament (see Parliamentary Report on woodland rabies, Rapporteur: Mrs V. Squarcialupi). The Commission is also of the opinion that the eradication of rabies is desirable because of the threat of rabies to human health, the effect an absence of rabies would have on the environment, the freeing of trade in dogs and cats and also because of the need to complete the internal market.

The Commission therefore proposes to provide financial aid for the creation of large scale pilot projects for the eradication of rabies, with priority being given to cross border projects.

Additional proposals are also attached for the harmonisation of the requirements for dogs and cats on short stay visits in a Member State from other Member States without prejudicing the quarantine requirements of some Member States.

Proposal for a

Council Regulation (EEC)

instituting a certificate for dogs and cats

on visits of less than one year in the Member States

and introducing Community measures to set up pilot projects

for the control and eradication of rabies

Proposal for a

COUNCIL REGULATION (EEC)

instituting a certificate for dogs and cats on visits of less than one year in the Member States and introducing Community measures to set up pilot projects for the control and eradication of rabies

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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 the certificate which accompanies dogs and cats on short stay visits from one Member State to another has not heretofore been harmonised and whereas this situation and increases the risk of spread of rabies in the animal population;

Whereas it is necessary, as a preliminary step to completion of the internal market, to harmonise this certificate whose validity shall be applicable for just over three years, thus contributing to the free movement of dogs and cats, reducing the risk of the spread of rabies not alone amongst dogs and cats but to other agricultural species as well and giving a wider choice of destination to their accompanying owners;

Whereas it would be unreasonable to require certain Member States to withdraw their quarantine provisions in respect of rabies at this stage in the light of their freedom from this disease and its widespread dissemination in certain other Member States;

Whereas it will be necessary to review the measures applicable in this sector so that they apply not only to short stay visits but also to transit and trade in dogs and cats, particularly in the light of the measures necessary for the completion of the internal market;

Whereas the continued presence of rabies in certain areas of the Community presents obstacles to the freedom of movement of companion animals and other agricultural species, owing to quarantine restriction in some Member States, whereas it would be premature to require the dismantlement of quarantine restriction owing to the risk of spread of rabies;

Whereas rabies is a serious source of loss and disruption to the agricultural community;

Whereas the continued presence of rabies has impact on the environment in so far as it inhibits a closer association of man and animals and also constitutes a costly danger for human and animal health;

Whereas it is therefore necessary to stimulate the creation of large-scale pilot projects for the control and eradication of rabies, and to that end to provide for Community financial aid;

Whereas it is necessary for facilities to be provided for the planning and the examination of the results of such pilot projects, particularly in cross-border areas and whereas it is also necessary to establish a Community procedure between the Commission and Member States for the implementation of such plans for pilot projects; whereas it is necessary that a small grant be made to national hunters organizations for preservation and conservation work in those Member States where hunters have given, free of charge, their time for bait dispersion;

Whereas the Commission should submit to the Council a report on the results achieved:

Whereas it is necessary to make provisions in the certificate for other treatments such as for echinococcosis that may be required prior to entry into particular Member States,

HAS ADOPTED THIS REGULATION:

CHAPTER I

Article 1

Dogs and cats which are on visits of less than one year to a Member State other than those which apply quarantine must be accompanied by a certificate conforming to the specimen in Annex I, which shall be drawn up in at least the language of the originating Member State.

Article 2

Before 31 December 1990 the Commission shall submit to the Council proposals concerning the definitive arrangements for the completion of the internal market in respect of dogs and cats.

The Council shall take a decision on these proposals before 1 July 1991.

Article 3

Member States shall admit onto their territory dogs and cats which are accompanied by the certificate as in Annex I, without prejudice to additional requirements which may be necessary in relation to quarantine for rabies in some Member States.

CHAPTER II

Article 4

A Community measure is hereby established to create large-scale pilot projects for the eradication of rabies from the wild life of the Community using vaccines for the oral immunisation of foxes.

CHAPTER III

Technical provisions relating to the creation of pilot projects for rabies eradication.

Article 5

Rabies shall be a compulsorily notifiable disease in all species.

Article 6

For the purpose of this Regulation, Member States which are infected with rabies shall draw up plans to create large-scale pilot projects for the oral immunisation of foxes.

Article 7

The minimum area for a pilot project shall be 6000 km^2 or the total national area of the State infected with rabies. Priority shall be given to plans which involve cross-border cooperation.

Article 8

1. The pilot projects shall take into account natural and administrative boundaries, the prevalence of rabies as well as the epidemiological situation. The pilot projects will cater for at least two and possibly three vaccination campaigns in any one pilot project zone. The vaccination campaigns may be carried out twice a year in the spring and autumn or annually in the spring or autumn.Vaccination may be carried out annually in protective belts adjacent to borders to avoid reinfection.

The choice of vaccine and baits to be used shall be laid down in accordance with the procedure set out in Article 18.

2. Baits are to be dispersed at approximately 15 per km^2 or less according to altitude. They are to be dispersed evenly with gloved hands in predetermined positions indicated on a grid map (scale 1 : 25,000); they must be invisible for humans and animals and protected from direct sunlight by a covering of leaves or grass. Other methods of distribution may be adopted.

Article 9

The plan referred to in Article 6 must indicate the following

- the bodies in charge of the technical organisation;
- a description of the area;
- arrangements for dissemination of information to persons concerned such as medical and veterinary practitioners, various ministries, hunting associations, schools in the pilot project area, police and mayors etc.;
- arrangements for dispatching wild and domestic animals that are suspected of suffering from rabies to a central diagnostic laboratory;
- arrangements for sending foxes killed during hunting, in the post vaccinal period, for testing for tetracycline incorporation and antibody formation
- arrangements for trapping small mammals in the zone during the first month following vaccination in order to be examined for rabies virus.

Article 10

Community financial aid shall be available for small-scale conservation and preservation actions carried out in pilot project areas where hunters have been used for bait dispersion. The plans for such actions shall be submitted to the Commission by the Federation of Hunting Associations of the EEC.

Article 11

The Commission, after examination of the proposed conservation and preservation actions and any amendments thereto, shall approve them in accordance with the procedure laid down in Article 18.

CHAPTER IV

Common and Financial provisions

Article 12

1. Member States shall forward to the Commission the pilot projects provided for in Article 6 and the information required under Articles 8 and 9 and Annex II, prior to their implementation, not later than six months after the entry into force of this Regulation, and annually thereafter. The pilot projects provided for in Article 6 shall be forwarded annually to the Commission by Member States and prior to their implementation in the case of Member States which have not yet drawn up pilot projects.

2. The Commission shall examine the pilot projects forwarded in accordance with paragraph 1 for the purpose of determining whether, in terms of conformity with this Regulation and having regard to the objectives thereof, the conditions for financial contribution by the Community are met. Within four months following the receipt of any pilot projects the Commission shall, after examination of the proposed pilot projects and any amendments thereto, approve them in accordance with the procedure laid down in Article 18.

3. Provisions will be made for coordinating Member States pilot projects.

4. On the dates fixed by the Commission in its decision of approval, as referred to in paragraph 2, Member States shall bring into force the laws, regulations or administrative provisions required to implement the pilot projects for the control and eradication of rabies.

Article 13

1. Community financial aid shall be given for the measures provided for in this Regulation.

2. Expenditure incurred by the Member States in connection with measures adopted pursuant to the pilot projects approved in accordance with Article 18 shall qualify for Community aid within the limits fixed in Articles 14 and 15.

Article 14

1. The estimated amount of aid to be charged to the Community budget for the period laid down in paragraph 2 shall be 9.3 Million ECU.

2. This measure shall be applicable for three years.

Article 15

1. Community financial aid shall be available for the following:
   - the purchase of anti-rabies oral vaccine plus bait for use in foxes,
   - the funding of small-scale preservation and conservation actions carried out in regions where hunters have been used for dispersing bait free of charge.

2. The Community shall reimburse to the Member States
   - 0.5 ECU for each vaccine plus bait dispersed within a pilot project area in the context of the measures provided for in this Regulation and complying with the special technical provisions referred to in Chapter III.
   - expenditure incurred in carrying out small-scale conservation and preservation actions in pilot project areas where hunters have been used for dispersing bait free of charge, up to a maximum of 10 000 ECU per pilot project area per year, for a maximum period of three years.

3. Articles 8 and 9 of Council Regulation No 729/70/EEC (1) shall apply 'mutatis mutandis'.

4. Detailed rules for the implemetation of this Article shall be adopted in accordance with the procedure laid down in Article 18.

Article 16

The Commission shall make regular on-the-spot checks to verify from a veterinary viewpoint whether the plans are being applied.

Member States shall take the necessary steps to facilitate these checks and shall in particular ensure that the experts are supplied at their request with all information and documentation needed for assessing the execution of the pilot projects.

The provisions for implementing this Article, especially as regards the frequency and method of carrying out the checks referred to in the first subparagraph, the rules governing the appointment of official veterinarians and the procedure which they must follow when drawing up their report, shall be laid down according to the procedure laid down in Article 18.

Article 17

The Commission shall be assisted by the Standing Veterinary Committee ("the Committee") set up by the Council Decision of 15 October 1968.

Article 18

1. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on such measures within a time-limit to be set by the Chairman according to the urgency of the questiones under consideration. Opinions shall be delivered by the majority specified in Article 148(2) of the Treaty in the case of decisions to be adopted by the Council following a proposal from the Commission. Within the Committee the votes of the Member States shall be weighted as provided for in the said Article 148. The Chairman shall not vote.

(1) OJ No L 94, 28.4.1970, p.13.

2. The Commission shall adopt the measures where they are in accordance with the Committee's opinion.

3. Where the proposed measures are not in accordance with the Committee's opinion or if the Committee fails to deliver an opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council adopt the measures by a qualified majority.

   If, after a period of three months after the matter was referred to it, the Council has not acted, the Commission shall adopt the proposed measures.

Article 19

When the pilot projects have been executed, the Commission shall submit a general report to the Council on the results obtained, with a proposal for further harmonization of national preventive measures, should this be necessary.

Article 20

This Regulation shall enter into force on the thirtieth day following that of its publication in the Official Journal of the European Communities.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Council
The President

Annex I

Rabies vaccination and health certificate for dogs and cats on visits of less than 1 year in the Member States (1).

1. Valid from .....to..... (2)
2. Name and address of owner .....
.....
3. Description .....
Dog/cat .....
Breed .....
Male/female .....
Age .....
Colour .....
coat type and marking .....
Tatoo N°(where present) .....

4. Health certification

I, the undersigned hereby declare that I have examined the above described animal and it did not show any symptoms of contagious diseases and it was clinically healthy on the day of examination (3).

5. Rabies vaccination		2nd vaccination	3rd vaccination
Vaccination date	.....	.....	.....
Type of rabies vaccine	.....	.....	.....
Manufacturing laboratory	.....	.....	.....
Batch N°	.....	.....	.....
Expiring date	.....	.....	.....

.....

Signature of Veterinarian

Name and address .....

(Printed) .....

.....

.....

Date .....

(1) This certificate does not prejudice the requirements for quarantine in some Member States. Dogs and cats will continue to be subject to a minimum of 6 months quarantine on entry into Ireland and the United Kingdom.

(2) This certificate is valid as follows: for three months for dogs and cats under three months of age; for those over three months of age from the 30th day until the end of the 12th month after the date of the first vaccination (2nd injection): in the case of revaccination within the validity period, for 12 months from the date of revaccination.

(3) Dogs and cats must be treated for tapeworms within 30 days prior to entry into Greece.

ANNEX II

GUIDELINES FOR A TIMETABLE FOR AN ORAL VACCINATION CAMPAIGN OF FOXES

Days prior to and after vaccination	activities
Immediately	- general planning - responsibilities - budget
- 100 to - 60	- information to governmental authorities (Health, Agriculture, Hunting and Forestry, Police) - assignment of duties and functions - freezer space for storage of baits - notification of vaccine manufacturing centre on vaccination date and number of baits and vaccines required
- 60 to - 14	- information to hunters and game wardens : assignment of duties: -information to local authorities
- 30 to - 10	- transportation of baits to place of storage (- 20°C)
- 7	- information to schools
- 4	- informtion to news media
- 1	- preparation of baits for distribution storage at +4°C
0/00	- issue of baits and maps to distribution teams; - distribution of baits
+1	- return of maps
+ 4, + 8, + 14	- control of baits for uptake in special control areas
+ 1 to + 20	- virological, serological and tetracycline testing - evaluation of information - inclusion of experience into future projects

Note: in cross border projects above arrangements will have to be coordinated with organising body in other country.

FINANCIAL STATEMENT concerning : A proposal for a Council Regulation introducing Community measures to set up pilot projects for the control and eradication of rabies (3 years programme)

1. Budget heading : IIIB Item : 380 Title : Specific Veterinary measures

2. Legal basis : Article 43 of the Treaty

3. Classification : ~~Compulsory expenditure~~/Non-compulsory expenditure

4. Purpose/description of the measure : To set up large scale pilot projects to control/ eradicate rabies in the Community by way of subventing the purchase of oral fox rabies vaccines

5. Method of calculation

5.1 Form of expenditure : Subsidising purchase of vaccines (up to 50%) plus small donation to hunters' organizations where hunters have dispersed

5.2 Community contribution : the vaccine for conservation and preservation projects. 0.5. ECU per dose of vaccine plus up to a maximum of 100 000ECU per year for conservation/preservation projects.

5.3 Calculation :

	Chargeable to the E.C.
Total cost of oral vaccine for rabies= 1 ECU	
Total n° of doses over 3 years = 18 mill cost = 18 mill ECU	9 mill ECU
+ 300 000 ECU for hunters who have dispersed baits for preservation/conservation purposes	0.3 mill ECU
	TOTAL : 9.3 mill ECU

6. Financial implication as regards operating appropriations

6.1 Schedule of commitment appropriations and payment appropriations (m ECU)

Year	C.A.	P.A.
19 89		3.1
19 90		3.1
19 91		3.1
19		
19		
following years		
Total		9.3

6.2 Financing during current year :

7. Observations : This project is necessary to complete the internal market