



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13.02.1998

COM(1998) 79 final

96/0052 (COD)

OPINION OF THE COMMISSION

pursuant to Article 189 b (2) (d) of the EC Treaty,
on the European Parliament's amendments
to the Council's common position regarding the

proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DECISION

**creating a network for the epidemiological surveillance
and control of communicable diseases
in the European Community**

AMENDING THE PROPOSAL OF THE COMMISSION

pursuant to Article 189 a (2) of the EC Treaty

COMMISSION OPINION, delivered conforming to Article 189b (2) (d) of the EC-Treaty, on the European Parliament amendments to the Council common position relating to the proposal for a European Parliament and Council Decision creating a network for the epidemiological surveillance and control of communicable diseases in the European Community, amending the Commission proposal

conforming to Article 189a (2) of the EC-Treaty

The draft Decision is based on Articles 3(o) and 129 of the Treaty establishing the European Community which define the responsibilities of the Community with regard to public health. Pursuant to Council Resolution No 92/C 326/1 of 13 November 1992 on the surveillance and control of communicable diseases in Europe, the Commission prepared, with the help of a group of experts, a rapid inventory of existing cooperation in this field between Member States or institutions. Following a thorough analysis of the situation in conjunction with European specialists, the Commission was able to draw some important conclusions, which are set out in communication COM(96) 78 of 7 March 1996 and can be summarised as follows: faced with an increasingly urgent and universally recognised need to set up and organise European cooperation for the prevention of communicable diseases, cooperation between the authorities and experts from the various national institutions responsible for the surveillance and control of communicable diseases needs to be formalised in order to identify public health problems and to establish priorities for action at European level.

The only way that this can be done is by setting up a European network for the epidemiological surveillance and control of communicable diseases involving all the Member States bar none. This is what the Commission proposal sets out to do, in line with the Council's conclusions No 94/C 15/04 of 13 December 1993 on this matter.

The system proposed is a universal, gradual and pragmatic one which creates obligations for the Member States and makes it possible to take action on the epidemiological front and achieve the following specific and quantifiable aims:

- to set up a system for close cooperation and effective consultation and coordination between the Member States in the field of surveillance and control of both routine and emergency situations with a view to preventing and controlling a certain number of serious communicable diseases in Europe which make it necessary to take measures to protect the population;
- to establish a list of diseases and/or groups of diseases which should be covered by a Community-level warning and surveillance system;
- to draw up a common definition of cases, especially in clinical terms, and, as far as possible, to determine the microbiological agent responsible;
- to determine the nature and type of data and information to be collected under the epidemiological surveillance arrangements;
- to establish epidemiological and microbiological surveillance methods;
- to define the protective measures to be taken, particularly in emergency situations;
- to provide information, recommendations and guides to good practice for the public.

The Economic and Social Committee (ECOSOC) adopted its opinion on the proposal for a Decision on 25 September 1996 (Doc. CES 1068/96).

It warmly welcomes the Commission's plan to form, on the basis of Article 129 of the Treaty establishing the European Community, a network for the surveillance and control of communicable diseases which places specific obligations on the Member States in this

area. However, the Economic and Social Committee put forward some proposals for improving the system which can be summarised as follows:

- if necessary, co-funding by the Community should be provided for to form the network;
- the arrangements should be examined to see whether the range of diseases listed in the Annex is sufficient and whether the breakdown of ailments according to the categories of measures to be taken is suitable;
- care should be taken to ensure that the activities undertaken in the Member States are comparable and that the information collected and to be processed is presented in the same way at Community level;
- all the institutions concerned in the Member States should have direct and permanent access to all the information accumulated in this way.

The Committee of the Regions (COR) adopted its opinion on 13 June 1996 (Doc. CdR 157/96).

It is entirely in favour of the Commission's proposal to create a general network involving specific obligations on the part of the Member States with regard to the surveillance and control of communicable diseases, but would have liked local and regional authorities to be represented in the committee which is to assist the Commission in running the network and the regional centres in the Member States to be integrated into the network. The Committee would also like to see formal cooperation arrangements between the network and the relevant international organisations and third countries and, finally, specific Community funding to ensure that the network runs smoothly.

The European Parliament at the vote on 13 November 1996, adopted at the first reading 17 amendments, 12 of which the Commission accepted in their entirety (Nos 9, 13, 14, 16 and 17) or in part (Nos 1, 2, 4, 5, 6, 12 and 15).

The amendments which the Commission did not accept are as follows:

- No 3 (the amendment did not conform with the wording of the EC Treaty);
- Nos 7, 10, 11 (additions without legal effect);
- No 8 (unacceptable financial and political consequences).

Of the amendments the Commission rejected, No 8 is the most important because it would have completely altered the proposal for a Decision and would have had major financial and political consequences for those Member States which were not in favour of it. The other amendments which were rejected were additions which had no legal effect and which were either covered by other provisions (Nos 10 and 11) or implicit (No 7).

In the light of the opinion delivered by the European Parliament at the first reading on 13 November 1996, the Commission presented an amended proposal for a decision in accordance with Article 189a, paragraph 2 of the EC Treaty. The amended text incorporates the amendments by the Parliament which the Commission deemed acceptable, either changing the wording in the interests of clarity or simply adopting it unchanged. The sole aim of the amendments is to make it easier to understand how the future surveillance and control network is to operate.

At its meeting on 5 June 1997, the Council reached unanimous agreement on a text to be adopted in the form of a common position. The Commission was against this text. On 22 July 1997, the Council adopted its common position.

The Council did not adopt all the amendments proposed by the European Parliament which the Commission had incorporated in its modified proposal. In view of the importance that the Parliament attaches to these amendments, the Commission has no alternative but to enter a reservation at their not being included in the Council's common position.

The common position incorporates the main elements judged necessary from the point of view of public health or the surveillance of communicable diseases in the Commission's amended proposal. However, it has several legal and technical shortcomings and does not fulfil the main aim pursued by the Commission's proposal, which is to set up a network intended to respond, at Community level, effectively and in a coordinated fashion to epidemics or outbreaks of communicable diseases in a Community without internal borders.

For the above reasons, the Commission has entered a general reservation regarding this common position.

The Commission's specific reservations apply to:

- Recital 26, which specifies that the Community must shoulder the costs of running the network which comprise the "Community share"; this will create unsuitable conditions for the network and, at the same time, if funds for existing programmes are used it might seriously disrupt them;

- Article 2(3): in order to achieve its aims, the system must comprise not only the exchange of information but also the prevention and control activities mentioned in Article 2(2). The words "prevention" and "control" must therefore be inserted after "exchange of information";

- Article 3(d), Article 4, paragraph 1, and Article 8: to set up the network and the exchange of information required, the Member States must designate not only the structures or authorities under Article 1, second paragraph, but also those under Article 1, third paragraph;

- Article 5, paragraph 2 and the first sentence of paragraph 3 lay down vague and contradictory requirements and paragraph 3 should provide for the transmission of information on the application of protective measures implemented by Member States in the past (rather than those applied or introduced specifically on an outbreak of disease or in an emergency situation and which are covered by both paragraphs 2 and 3, which could lead to confusion);

- Article 5, paragraph 3, second sentence: this description of the measures which could be proposed at Community level when epidemics or outbreaks of communicable diseases occur is unacceptable and the way in which such measures could be adopted is expressed in terms of intergovernmental cooperation which are inappropriate. What is more, it is in complete contradiction with paragraph 5, as this involves a Community procedure, namely the procedure under Article 6 (comitology). It is also in contradiction with Article 5, paragraph 4, second sentence;

- Article 5, paragraph 4, second sentence: this text is unacceptable because it aims to prevent Community measures being adopted to protect against communicable diseases,

which is possible under Article 129 of the Treaty as long as the measures do not lead to harmonisation;

- Article 13, paragraph 1 concerns the Commission's obligation to submit a report every two years (a period of five years was agreed with the European Parliament and was incorporated in the Commission's amended proposal): a report every two years is quite unrealistic and is an unjustifiable administrative burden which serves no apparent purpose;

- Article 13, paragraph 2: the obligation placed on the Commission to submit proposals to adapt the Decision if necessary undermines its right of initiative;

- the Annex: it is inaccurate to describe the Annex as indicative; it is indicative as regards the choice of diseases subject to detailed surveillance and declaration measures but it is obligatory as regards the communication of outbreaks/emergencies as provided for in Article 4.

In conclusion, the Commission is unable to accept this common position and enters the following general reservation:

"The Commission points out that the common position adopted by the Council does not enable a comprehensive and effective response to be mounted when there is an outbreak of a communicable disease and it restricts the scope and the added value of the Community network for the surveillance and control of diseases. The Commission therefore reserves judgement whilst awaiting the European Parliament's examination of this proposal for a decision at the second reading".

On the 14th of January 1998, the European Parliament adopted 22 amendments to the common position. The opinion of the Commission concerning each of these amendments is given in the annex.

The Commission points out that in accordance with Article 189b(3) of the Treaty if, within three months of receiving the Parliament amendments, the Council, acting by a qualified majority, approves all of the amendments, it shall amend its position accordingly and adopt the act in question; however, the Council shall act unanimously on the amendments on which the Commission has delivered a negative opinion. If the Council does not approve the act in question, the President of the Council, in agreement with the President of the European Parliament, shall forthwith convene a meeting of the Conciliation Committee.

ANNEX

Amendment 1: Commission opinion: rejected.

The situation is so diverse that one cannot talk about "shortcomings in structures". It would be wiser to refer to "increasing needs". The common position has largely taken over the text of the Commission's amended proposal.

Amendment 2: Commission opinion: accepted.

At the first reading the Commission did not want to accept a specific reference to the WHO, but the Council adopted the European Parliament's wording. The addition at the end of the sentence does not run counter to the spirit of the proposal. It also stresses the need for standardised definitions.

Amendment 3: Commission opinion: rejected.

The Council adopted the text of the Commission's amended proposal in its common position. The amendment must be rejected because the fact that a methodology is previously established does not guarantee that it is suitable. The term "suitable" is more appropriate.

Amendment 4: Commission opinion: accepted.

This recital has been simplified to leave the type of funding open, stipulating that the funds will come from the Community. It also pre-empts the objection that the funds will be obtained from resources for programmes with different aims which have already been adopted.

Amendment 5, article 1 (first and third paragraphs): Commission opinion: rejected.

The early warning system is understood to be part of surveillance.

Amendment 5, article 1, last paragraph: Commission opinion: rejected.

The term "Eurocentres" does not properly describe these structures, whose activities are mainly geared towards national surveillance. The setting up of a central organisation is not in line with the method of forming the current European networks (Enternet, euroTB, Earss, etc.) and there is no need for it. On the contrary, it is likely to precipitate objections from the Council.

Amendment 6: Commission opinion: accepted.

Amendment 7: Commission opinion: accepted.

The wording is clearer than the Council's in as far as it leaves the Commission free to propose measures via the comitology procedure (under Article 6) in order to prepare realistic and technically sound criteria. Recital 8 must also be amended (to delete the words "in the light, *inter alia*, of their estimated cost-effectiveness") to make it compatible with this amendment.

Amendment 8: Commission opinion: accepted.

Amendment 9: Commission opinion: accepted.

Amendment 10: Commission opinion: accepted.

This point was in the Commission's original and amended proposals and was deleted by the Council.

Amendment 11: Commission opinion: accepted.

The proposed amendment is in line with the reservation entered by the Commission, i.e. that the structures and/or authorities are involved in both surveillance and control (Article 1, paragraph 3).

Amendment 12: Commission opinion: accepted.

This is an improvement, as a Member State cannot give notice of a problem without saying what control measures have been applied.

Amendment 13: Commission opinion: accepted.

Amendment 14: Commission opinion: partially accepted.

This provision was introduced by the Council. The "as far as possible" diminishes the effect of the text and hence cooperation between the Member States and with the Commission. This amendment also allows the Commission to reformulate Recital 24 and Article 5(3) which contradict Article 5(2) and do not properly describe the measures which could be proposed at Community level (see the specific reservations entered by the Commission, indents 4 and 5).

Amendment 15: Commission opinion: accepted.

The wording indicates the need for coordination, which is one of the fundamentals of the Commission proposal, without excluding the possibility of introducing measures at Community level (see the specific reservations entered by the Commission, indents 5 and 6).

Amendment 16: Commission opinion: rejected.

The procedure under paragraph 4 must be mentioned.

Amendment 17: Commission opinion: rejected.

The fact of having two representatives could be interpreted as having one from the surveillance centre (surveillance) and the other from the supervisory authority (control).

Amendment 18: Commission opinion: partially accepted.

No, as far as "general measures" are concerned, yes, as regards "may lay down".

Amendment 19: Commission opinion: accepted.

Amendment 20: Commission opinion: accepted.

In its common position the Council mentions only the surveillance structures referred to in the second paragraph of Article 1, whereas a reference should be made to the response and control structures referred to in the third paragraph of Article 1.

Amendment 21: Commission opinion: partially accepted.

The wording "the network shall be subject to" is awkward. It would be better to rephrase it as follows: "a periodic assessment of the network shall be carried out ...".

Amendment 22: Commission opinion: accepted.

This is a classification, not an indicative list. There must be arrangements for proposing changes to the classification via the comitology procedure (under Article 6).

AMENDED PROPOSAL

**FOR A EUROPEAN PARLIAMENT AND COUNCIL DECISION
CREATING A NETWORK FOR THE EPIDEMIOLOGICAL SURVEILLANCE
AND CONTROL OF COMMUNICABLE DISEASES IN THE EUROPEAN
COMMUNITY**

(presented by the Commission pursuant to Article 189 a (2)
of the EC-Treaty)

<u>COUNCIL COMMON POSITION</u>	<u>AMENDED PROPOSAL</u>
<p>THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,</p> <p>Having regard to the Treaty establishing the European Community, and in particular Article 129 thereof,</p> <p>Having regard to the proposal from the Commission¹,</p> <p>Having regard to the opinion of the Economic and Social Committee²,</p> <p>Having regard to the opinion of the Committee of the Regions³,</p> <p>Acting in accordance with the procedure laid down in Article 189b of the Treaty⁴</p> <p>1 - Whereas the prevention of diseases, in particular of the major health scourges, is a priority for Community action, requiring a global approach coordinated between Member States,</p> <p>2 - Whereas the European Parliament, in its Resolution on public health policy after Maastricht⁵, invited the Commission to set up a transfrontier network to devise working definitions of notifiable diseases, to collect, update, analyse and disseminate Member State data on such diseases and to work with national and international agencies on these matters;</p> <p>3 - Whereas in its resolution of 2 June 1994⁶ on the framework for Community action in the field of public health the Council agreed that priority should be given at present to communicable diseases in particular;</p> <p>4 - Whereas in its conclusions of 13 December 1993⁷, the Council considered that there was a need to develop at Community level a network for the surveillance and control of communicable diseases, the main purpose of which would be to collect and coordinate information from monitoring networks in the Member States;</p>	

¹ OJ No C 123, 26.4.1996, p. 10.

² OJ No C 30, 30.01.1997, p. 1.

³ OJ No C 337, 11.11.1996, p. 67.

⁴ Opinion of the European Parliament of 13 November 1996 (OJ C 362.2.12.1996, p. 111), Council common position of 22 July 1997 and Decision of the European Parliament of ... (not yet published in the Official Journal).

⁵ OJ No C 329, 6.12.1993, p. 375.

⁶ OJ C 165, 17.6.1994, p. 1.

⁷ OJ No C 15, 18.1.1994, p. 6.

5 - Whereas in those same conclusions the Council requested the Commission to devote special attention, in its proposals relating to the framework for action in the field of public health, to setting up an epidemiological network in the Community, taking account of current proceedings and mechanisms existing at Community and at Member States level, and ensuring the comparability and compatibility of data;

6 - Whereas in their resolution of 13 November 1992 on the monitoring and surveillance of communicable diseases⁸ the Council and the Ministers for Health, meeting within the Council, underlined the desirability of improving, within the Community, the coverage and effectiveness of existing networks between Member States for the surveillance of communicable diseases (including data-processing networks), and also the desirability of maintaining, establishing or strengthening coordination between them for monitoring outbreaks of communicable diseases, where such action could add to the value of existing measures;

7 - Whereas in that same resolution, the Council and the Ministers for Health, meeting within the Council, underlined the value of collecting data from the Member States on a limited number of rare and serious diseases which require large samples for epidemiological study;

8 - Whereas in that same resolution the Council and the Ministers for Health, meeting within the Council invited the Commission to examine the desirability of giving priority to certain suitable proposals relating to the control and surveillance of communicable diseases, in the light, *inter alia*, of their estimated cost-effectiveness;

9 - Whereas, in accordance with the principle of subsidiarity, any new measure taken in an area which does not fall within the exclusive competence of the Community, such as the epidemiological surveillance and control of communicable diseases, may be taken by the Community only if, by reason of the scale or effects of the proposed action, the objectives of the proposed action can be better achieved by the Community than by the Member States;

⁸ OJ No C 326, 11.12.1992, p. 1.

10 - Whereas the constantly growing information needs of the structures and/or authorities responsible in the Member States for the epidemiological surveillance of communicable diseases make it necessary to establish, at Community level, a permanent network to respond to those needs;

11 - Whereas measures to be taken in the health field must take into account other actions undertaken by the Community in the field of public health or which have an impact on public health;

12 - Whereas the measures to be taken under this Decision are adopted excluding any harmonization of the laws and regulations of the Member States;

13 - Whereas Decision 647/96/EC of the European Parliament and of the Council of 29 March 1996 adopting a programme of Community action on the prevention of AIDS and certain other communicable diseases within the framework for action in the field of public health (1996 to 2000)⁹ envisages a number of Community actions for the creation and development of networks for the control and surveillance of certain communicable diseases, the early detection of such diseases, and promotion of the training of field epidemiologists;

14 - Whereas cooperation with the competent international organisations, particularly the World Health Organization, in particular with regard to disease classification, must be fostered;

15 - Whereas cooperation with third countries, in particular in the case of the appearance or resurgence of serious communicable diseases, must be supported;

16 - Whereas the recent appearance or resurgence of serious communicable diseases has demonstrated that when an emergency situation occurs all relevant data and information must be communicated swiftly to the Commission in an agreed form of presentation, using appropriate methods;

17 - Whereas, in order to ensure protection of the population in an emergency, Member States must exchange relevant data and information immediately via the Community network;

14 - Whereas cooperation with the competent international organizations, particularly the World Health Organization, notably with regard to disease classification, must be fostered, as well as the use of appropriate language and technology;

⁹ OJ No L 95, 16.4.1996, p. 16.

18 - Whereas Council Directive 92/117/EEC of 17.12.92 concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications¹⁰ applies equally to information concerning zoonoses which affect human beings; where that same Directive provides for a system for collecting and transmitting information on specified zoonoses and zoonotic agents,

19 - Whereas the setting up of a network for the epidemiological surveillance and control of communicable diseases at Community level necessarily presupposes compliance with the legal provisions concerning the protection of individuals with regard to the processing of personal data and the introduction of arrangements to guarantee the confidentiality and security of such data; whereas in this connection the European Parliament and the Council adopted Directive 95/46/EC¹¹;

20 - Whereas the Community projects in the field of the telematic interchange of data between administrations (IDA)¹² and the G7 projects should be closely coordinated with the implementation of the Community actions relating to the epidemiological surveillance and control of communicable diseases;

21 - Whereas consideration must be given to the efforts deployed with a view to encouraging international cooperation in this field, particularly as part of a joint plan of action with the United States;

22 - Whereas it is important, in an emergency situation, that the competent national structures and/or authorities should strengthen their cooperation, in particular with regard to the identification of biological samples;

23 - Whereas any Community procedures which may be set up for the rapid exchange of information do not affect the Member States' rights and obligations under bilateral or multilateral agreements and conventions;

¹⁰ OJ No L 62, 15.3.1993, p. 38.

¹¹ OJ No L 281, 23.11.1995, p. 31.

¹² OJ No L 269, 11.11.1995, p.23.

24 - Whereas a procedure needs to be established to promote coordination between the Member States concerning the measures they may decide to take to control the spread of communicable diseases; whereas the adoption and implementation of these measures fall within the exclusive competence of the Member States;

25 - Whereas it is important that the Commission should implement the Community network in close cooperation with the Member States; whereas a procedure therefore needs to be established to ensure the Member States' full participation in this implementation;

26 - Whereas the costs which may result from the operation of the network at Community level should be met from Community resources; whereas relevant Community programmes and initiatives, including those in the context of public health action as well as, in particular, the framework programme for statistical information, projects in the field of telematic interchange of data between administrations, and the framework programme for research and technological development, especially the telematics applications of the latter, might provide the necessary financial means;

27 - Whereas the costs which may result from the operation of the network at national level will have to be financed by the Member States themselves, unless Community provisions provide otherwise;

28 - Whereas a *modus vivendi* between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the Treaty was concluded on 20 December 1994,

HAVE DECIDED AS FOLLOWS:

Article 1

The objective of this Decision is to set up a network at Community level to promote cooperation and coordination between the Member States, with the assistance of the Commission, with a view to improving the prevention and control, in the Community, of the categories of communicable diseases specified in the Annex. This network shall be used for:

24 - Whereas procedures need to be established to ensure consultation and coordination between the Member States concerning the measures to be taken in order to control the spread of communicable diseases;

26 - Whereas the costs which may result from the operation of the network at Community level should be met from Community resources;

- the epidemiological surveillance of these diseases, and

- a response system for the prevention and control of these diseases.

As regards epidemiological surveillance, the network shall be established by bringing into permanent communication with one another, through all appropriate technical means, the Commission and those structures and/or authorities which, at the level of each Member State and under the responsibility of that Member State, are competent at national level and are charged with collecting information relating to the epidemiological surveillance of communicable diseases, and by establishing procedures for the dissemination of the relevant surveillance data at Community level.

As regards the response system, this network shall be formed by bringing into permanent communication with one another, through appropriate means, the Commission and the competent public health authorities in each Member State responsible for determining the measures which may be required to protect public health.

Article 2

For the purposes of this Decision, the following terms shall have the following meanings:

1 - *epidemiological surveillance*: the ongoing systematic collection, analysis, interpretation and dissemination of health data, including epidemiological studies, concerning the categories of communicable diseases set out in the Annex, in particular relating to the pattern of spread of such diseases over time and space and analysis of the risk factors for contracting such diseases, for the purpose of enabling appropriate preventive measures and counter-measures to be taken;

2 - *prevention and control of communicable diseases*: the range of measures, including epidemiological investigations, taken by the competent public health authorities in the Member States to prevent and stop the spread of communicable diseases;

1 - *epidemiological surveillance*: the ongoing systematic collection, analysis, interpretation and dissemination of comparable and compatible health data, including epidemiological studies, concerning the categories of communicable diseases set out in the Annex, in particular relating to the pattern of spread of such diseases over time and space and analysis of the risk factors for contracting such diseases, for the purpose of enabling appropriate preventive measures and counter-measures to be taken;

3 - *Community network*: network for the epidemiological surveillance and control of communicable diseases, namely the system by which the necessary information for carrying out the activities referred to in points 1 and 2 is exchanged.

Article 3

With a view to the effective operation of the Community network with regard to epidemiological surveillance and to achieving uniform information within this framework, the following shall be determined in accordance with the procedure laid down in Article 6:

a) the communicable diseases to be gradually covered by the Community network, having regard to the categories set out in the Annex and the existing collaborative networks for disease surveillance that can be readily built upon and on the basis of selection criteria such as:

- value added at the level of the Community and the Member States,
- potential threat to public health,
- potential threat to Community policies,
- need to develop an early warning system,
- possibilities for improving knowledge about the disease concerned,
- resources available;

b) case definitions;

c) the nature and type of data and information to be collected and transmitted by the structures and/or authorities referred to in the second paragraph of Article 1 in the field of epidemiological surveillance;

d) epidemiological and microbiological surveillance methods;

e) the appropriate technical means and the procedures by which the data will be disseminated and analyzed at Community level.

a) the communicable diseases covered by the Community network, having regard to the categories set out in the Annex and the existing collaborative networks for disease surveillance that can be built upon;

b) case definitions, in particular the clinical definition and, whenever possible, the microbiological characterization of the agent responsible;

f) the protective measures to be taken, in particular at external frontiers, notably in emergency situations;

g) information, recommendations and guides of good practice for the public;

Article 4

Each structure and/or authority referred to in the second paragraph of Article 1 shall communicate to the Community network:

- a) information regarding the appearance or resurgence of cases of communicable diseases as referred to in Article 3 (a) in the Member States to which the structure and/or authority belongs;
- b) any relevant information concerning the progression of epidemic situations for which it has responsibility for information collection;
- c) information on unusual epidemic phenomena or new communicable diseases of unknown origin;
- d) any relevant information in its possession;
 - on cases of communicable diseases covered by the categories set out in the Annex,
 - on new communicable diseases of unknown origin in third countries;
- e) information concerning existing and proposed mechanisms and procedures for the prevention and control of communicable diseases, in particular in emergency situations;
- f) any relevant considerations which could help Member States to coordinate their efforts for the prevention and control of communicable diseases, including any counter-measures implemented.

Article 5

1. Member States shall, on the basis of the information available through the Community network, consult each other in liaison with the Commission with a view to coordinating their efforts for the prevention and control of communicable diseases.

Each structure and/or authority referred to in Article 1 shall communicate to the Community network:

- a) information regarding the appearance of cases of communicable diseases as referred to in Article 3(a) in the Member States to which the structure and/or authority belongs, together with information on control measures applied;

Article 4bis

The Community network shall without delay forward the information referred to in Articles 3 and 4 to the appropriate authorities of all the Member States. It shall forward to the appropriate authorities of the Member States any information of which it is aware on the subject of any state of emergency arising from the appearance or resurgence of serious communicable diseases within the territory of the European Community or originating in third countries.

2. Where a Member State intends to adopt measures for the control of communicable diseases, it shall, before adopting those measures, inform and, to the extent possible, depending on the urgency of the situation, consult the other Member States and the Commission on the nature and scope of those measures, through the Community network.

3. Where a Member State has to adopt, as a matter of urgency, control measures in response to the appearance or resurgence of communicable diseases, it shall as soon as possible inform through the Community network the other Member States and the Commission.

In duly justified specific cases, appropriate prevention and protection measures, adopted by mutual agreement amongst Member States in conjunction with the Commission, may be taken by the Member States which so desire.

4. Member States shall, on the basis of their consultations and the information provided, coordinate amongst themselves in liaison with the Commission with regard to the intended or adopted measures. The measures shall, however, remain entirely the responsibility of the Member States.

5. Procedures concerning the information and consultation referred to in paragraph 1, 2 and 3 and procedures concerning the coordination referred to in paragraphs 1 and 4 shall be established in accordance with the procedure laid down in Article 6.

Article 6

1. For the purpose of implementing this Decision, the Commission shall be assisted by a committee composed of two representatives of each of the Member States and chaired by the representative of the Commission.

2 - Where a Member State intends to adopt measures for the control of communicable diseases, it shall, before adopting those measures, inform and, depending on the urgency of the situation, consult the other Member States and the Commission on the nature and scope of those measures, through the Community network;

3 - Where a Member State applies, as a matter of urgency or in accordance with pre-determined plans or procedures, control measures in response to the appearance or resurgence of communicable diseases, it shall immediately inform through the Community network the other Member States and the Commission.

In duly justified cases, appropriate preventive measures may be adopted, excluding any harmonisation of the laws and regulations of the Members States, in accordance with the procedure laid down in Article 6.

4 - Member States shall, on the basis of their consultations and the information provided, coordinate amongst themselves in liaison with the Commission with regard to the intended or adopted measures.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman shall lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

b) If the measures envisaged 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 relating to the measures to be taken. The Council shall act by a qualified majority

If, within three months of the matter being referred to it the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 7

The Annex shall be amended or supplemented in accordance with the procedure laid down in Article 6.

Article 8

Each Member State shall designate, within six months following the entry into force of this Decision, the structures and/or authorities referred to in the second paragraph of Article 1 and shall notify the Commission and the other Member States thereof.

Article 9

For the purposes of this Decision, the competent authorities of the Member States and the Commission shall foster cooperation with third countries and international organizations competent in the field of public health, in particular the World Health Organizations.

Article 10

This Decision shall apply without prejudice to Directives 92/117/EEC and 95/46/EC.

2 - The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Annex may be amended or supplemented in accordance with the procedure laid down in Article 6.

Each Member State shall designate, within six months following the entry into force of this Decision, the structures and/or authorities referred to in Article 1 and shall notify the Commission and the other Member States thereof.

Article 11

1. This Decision shall not affect the right of the Member States to maintain or introduce other arrangements, procedures and measures, for their national systems for the epidemiological surveillance and control of communicable diseases.

2. This Decision shall not affect Member States' rights and obligations deriving from existing or future bilateral or multilateral agreements or conventions in the field covered by this Decision.

Article 12

The Commission, with the help of the Member States, shall ensure that there is consistency and complementarity between this Decision and the relevant Community programmes and initiatives, including those in the context of public health action as well as, in particular, the framework programme for statistical information, projects in the field of telematic interchange of data between administrations and the framework programme for research and technological development, especially the telematics applications of the latter programme.

Article 13

1. The Commission shall submit a report on the operation of the Community network to the European Parliament and the Council every two years.

The first report shall be submitted two years after the entry into force of this Decision.

2. The second report to be submitted by the Commission shall, in particular, identify those elements of the Community network which should be improved or adapted. It shall also include any proposal that the Commission considers necessary for the amendment or adaptation of this Decision.

Article 14

This Decision shall enter into force on ... (*).

Article 15

This Decision is addressed to the Member States.

Done at

For the European Parliament
The President

For the Council
The President

An evaluation of the Community network shall be carried out by the Commission every five years, paying particular attention to its structural capacity and effective use of resources, and the Commission shall submit a report to the European Parliament and the Council.

<p>ANNEX</p> <p>Categories of communicable diseases</p> <p>Indicative list</p> <ul style="list-style-type: none"> - Diseases preventable by vaccination, - sexually-transmitted diseases, - viral hepatitis, - food-borne diseases, - water-borne diseases and diseases of environmental origin, - nosocomial infections, - other diseases transmissible by non-conventional agents (including Creutzfeldt-Jakob's disease), - diseases covered by the international health regulations (yellow fever, cholera and plague), - other diseases (rabies, typhus fever, viral haemorrhagic fevers, malaria and any other as yet unclassified serious epidemic disease, etc. 	<p>ANNEX</p> <p>Categories of communicable diseases</p> <ul style="list-style-type: none"> - Diseases preventable by vaccination, - sexually-transmitted diseases, - viral hepatitis, - food-borne diseases, - water-borne diseases and diseases of environmental origin, - nosocomial infections, - other diseases transmissible by non-conventional agents (including Creutzfeldt-Jakob's disease), - diseases covered by the international health regulations (yellow fever, cholera and plague), - other diseases (rabies, typhus fever, viral haemorrhagic fevers, malaria and any other as yet unclassified serious epidemic disease, etc.
---	---

ISSN 0254-1475

COM(98) 79 final

DOCUMENTS

EN

05 15 06 01

Catalogue number : CB-CO-98-082-EN-C

ISBN 92-78-31053-0

Office for Official Publications of the European Communities

L-2985 Luxembourg