



COMMISSION OF THE EUROPEAN COMMUNITIES

Corrigendum
COM (97) 31 final/2
3 February 1997

Brussels, 03.02.1997
COM(97) 31 final

96/ 0052 (COD)

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)

EXPLANATORY MEMORANDUM

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

- 1 The initial proposal for a European Parliament and Council Decision was adopted on 7 March 1996.
- 2 The Economic and Social Committee¹ and the Committee of the Regions² have delivered favourable opinions on this initial proposal from the Commission.
- 3 In the light of the opinion delivered by the European Parliament at first reading on 13 November 1996, an amended proposal for a Decision has been submitted by the Commission in accordance with Article 189a, paragraph 2, of the EC Treaty. The amended text incorporates those of the Parliament's amendments which the Commission considered acceptable, either with changes to the wording in order to ensure clarity or exactly as transmitted by Parliament. The objective of these amendments is merely to improve comprehension and the mode of operation of the future surveillance and control network.
- 4 At the vote of 19 November 1996, the European Parliament adopted 17 amendments. The Commission considers 12 of these to be acceptable, either in their entirety (Nos 9, 13, 14, 16 and 17) or in part (Nos 1, 2, 4, 5, 6, 12 and 16).
- 5 The amendments which were not acceptable to the Commission are as follows:
 - No 3 (inconsistent with the wording of the EC Treaty)
 - Nos 7, 10 and 11 (additions with no legal significance)
 - No 8 (unacceptable financial and political consequences).

¹ Opinion delivered on 25 September 1996 (Doc. CES 1068/96)

² Opinion delivered on 13 June 1996 (Doc. CdR 157/96)

<u>COM (96) 78 final</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>1 - Whereas the prevention of diseases, and in particular of the major health scourges, is a priority for Community action, requiring a global and coordinated approach between Member States,</p> <p>2 - Whereas the European Parliament, in its Resolution on public health policy after Maastricht⁴, invited the Commission to set up a trans-frontier network to devise working definitions of notifiable diseases, to collect, update, analyse and disseminate Member State data on notifiable diseases and to work with national and international agencies on these matters,</p> <p>3 - Whereas in its resolution of 2 June 1994 on the framework for Community action in the field of public health⁵ 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 1993⁶, the Council considers that there is 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 ...

³ OJ No ...

⁴ OJ No C 329, 6.12.1993, p. 375.

⁵ OJ No C 165, 17.6.1994, p. 1.

⁶ OJ No C 15, 18.1.1994, p. 6.

5 - Whereas in these same conclusions the Council requests the Commission to devote special attention, in its proposals relating to the framework for action in the field of public health¹, to setting up an epidemiological network in the Community, taking account of current proceedings and mechanisms existing at Community level and that of Member States, and ensuring the comparability and compatibility of data;

6 - Whereas in their resolution of 13 November 1992², the Council and the Ministers for Health meeting within the Council underline the desirability of improving, within the Community, the coverage and effectiveness of existing networks between Member States (including data-processing networks), and 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 this same resolution, the Council and the Ministers for Health meeting within the Council underline 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 this same resolution, the Council and the Ministers for Health meeting within the Council invite 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 one or more Member States;

¹ COM(93) 559 final, 24.11.1993.

² OJ No C 326, 11.12.1992, p. 1.

<p>10 - Whereas measures 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;</p> <p>11 - Whereas European Parliament and Council Decision 647/96/EC 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 health¹ 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;</p> <p>12 - Whereas cooperation with the competent international organisations, notably with regard to disease classification, must be fostered;</p> <p>13 - Whereas cooperation with third countries, notably in the case of the emergence or resurgence of serious communicable diseases, must be supported;</p> <p>14 - Whereas the emergence or recent resurgence of serious communicable diseases has demonstrated that when an emergency situation occurs all relevant information must be communicated swiftly to the Commission in an agreed form of presentation;</p> <p>15 - Whereas the introduction of specific Community arrangements will help to ensure that all Member States are swiftly informed in the event of such an emergency situation, so that the protection of the population can be ensured;</p>	<p><u>9a - Whereas the constantly growing needs of the structures which, in the Member States, are responsible for the epidemiological surveillance of communicable diseases make it necessary to establish, at Community level, a permanent structure to respond to those needs;</u></p> <p>10 - Whereas measures <u>to be taken</u> 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;</p> <p>14 - Whereas the emergence or recent resurgence of serious communicable diseases has demonstrated that when an emergency situation occurs all relevant <u>data</u> and information must be communicated swiftly to the Commission in an agreed form of presentation <u>and using appropriate methods;</u></p> <p>15 - <u>Whereas in order to ensure protection of the population in an emergency, the Community network must be in a position to communicate relevant data and information to all Member States without delay;</u></p>
--	--

¹ OJ No L 95, 16.4.1996, p. 16.

16 - Whereas the provisions of Council Directive 92/117/EEC¹ of 17.12.93 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 intoxications apply equally to information concerning zoonoses which affect human beings, and whereas the same directive provides for a system for collecting and transmitting information on specified zoonoses and zoonotic agents,

17 - Whereas the setting up of a network for the epidemiological surveillance and control of communicable diseases at Community level necessarily presupposes observance of 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 and information; whereas in this connection the European Parliament and the Council adopted Directive 95/46/EC on 24 October 1995,

18 - Whereas the Community projects in the field of the telematic interchange of data between administrations (IDA)² 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;

19 - Whereas it is important, in an emergency situation, that the competent national structures should strengthen their cooperation, notably with regard to the identification of biological samples;

20 - Whereas these Community arrangements for the rapid exchange of information do not affect the Member States' rights and obligations under Treaties or bilateral and multilateral conventions;

18a - Whereas consideration must be given to the efforts deployed with a view to encouraging international cooperation in this field, particularly as part of the joint plan of action with the United States aiming at establishing a global early warning system and response network for communicable diseases;

¹ OJ No L 62, 15.3.1993, p. 38.

² OJ No L 269, 11.11.1995, p.23.

21 - 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;

22 - Whereas an agreement on a *modus vivendi* between the European Parliament, the Council and the Commission concerning measures for the implementation of acts adopted under the procedure laid down in Article 189b of the Treaty was reached on 20 December 1991,

HAVE DECIDED AS FOLLOWS:

Article 1

A general network for the epidemiological surveillance and control of communicable diseases shall be set up in the European Community.

This Community network shall be formed by putting into permanent communication with one another, through all appropriate technical means, structures which, at the level of each member State and under the responsibility of the Member State, are charged with collecting information relating to epidemiological surveillance and coordinating control measures.

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 concerning communicable diseases, for the purpose of enabling appropriate counter-measures to be taken;

2 - *control of communicable diseases*: the range of measures taken by the competent public health authorities to stop the spread of communicable diseases, as well as epidemiological studies, in particular of the pattern of spread of such diseases over time and space and analysis of the risk factors for contracting such diseases, the results of which enable appropriate preventive measures to be devised.

Article 3

For every Member State, the epidemiological surveillance and control of communicable diseases at Community level shall apply to:

a) the appearance or resurgence on its territory of cases of serious and/or rare communicable diseases as listed in the Annex;

1 - *epidemiological surveillance*: the ongoing systematic collection, analysis, interpretation and dissemination of comparable and compatible health data concerning communicable diseases, for the purpose of enabling appropriate counter-measures to be taken;

- b) the importation onto its territory, from another Member State or a non-Community country, of cases of serious and/or rare communicable diseases as listed in the Annex.

Article 4

For the purposes of implementing this decision the Commission shall be assisted by a committee consisting of representatives from the Member States and chaired by a representative of the Commission.

The Commission representative shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on this 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.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee. If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion has been delivered, the Commission shall forthwith submit to the Council a proposal concerning 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 adopted measures, the Commission shall adopt the measures proposed and implement them immediately.

Article 5

The measures referred to in Article 4 concern in particular:

1 - case definitions, in particular the clinical definition and, where appropriate, the microbiological characterisation of the agent responsible;

2 - the nature and type of data and information to be collected by the structures referred to in Article 1 in the field of epidemiological surveillance;

The Commission representative shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on this 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 Commission shall adopt the measures envisaged where they are in accordance with the opinion of the committee. If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion has been delivered, the Commission shall without delay submit to the Council a proposal concerning 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 measures proposed shall be adopted by the Commission.

1 - case definitions, in particular the clinical definition and, wherever possible, the microbiological characterisation of the agent responsible;

<p><u>Article 7</u></p> <p>Each Member State shall appoint, within six months following the entry into force of this decision, the structure or structures referred to in Article 1, and shall notify the Commission thereof.</p> <p><u>Article 8</u></p> <p>The Commission may amend or supplement the Annex in accordance with the procedure provided for in Article 4.</p> <p><u>Article 9</u></p> <p>This decision shall apply without prejudice to Council Directive 92/117/EEC 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 intoxications, and shall take account of the information collection and transmission procedure provided for in that directive.</p> <p><u>Article 10</u></p> <p>This decision shall apply without prejudice to European Parliament and Council Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and to Council Decision 95/468/EC on a Community contribution for telematic interchange of data between administrations in the Community (IDA).</p> <p><u>Article 11</u></p> <p>This decision shall not affect Member States' reciprocal rights and obligations deriving from existing or future bilateral or multilateral agreements or conventions in the domain covered by the decision, and which are in line with the decision's subject, methods of implementation and objectives.</p> <p><u>Article 12</u></p> <p>This decision is addressed to the Member States and shall enter into force three months after the date of its publication in the Official Journal of the European Communities.</p> <p>Done at Brussels</p> <p>For the European Parliament For the Council The President The President</p>	<p>The Annex may be amended or supplemented in accordance with the procedure provided for in Article 4.</p>
---	---

ANNEX

The communicable diseases referred to in Article 3 are divided into groups of serious and/or rare disorders, namely:

- concerning paragraph a):

diseases requiring measures to be taken at local level and reported on periodically to the Member States' public health authorities in accordance with arrangements specific to each of these diseases and defined in accordance with Article 5, notably:

- 1 - diseases preventable by vaccination (tuberculosis, tetanus, poliomyelitis, diphtheria, meningitis, measles, mumps, rubella, influenza and influenza syndromes, etc.),
- 2 - sexually-transmitted diseases (hepatitis B, AIDS/HIV, chlamydia, etc.),
- 3 - viral hepatitis (including hepatitis C and other as yet unclassified categories of hepatitis),
- 4 - food-borne diseases (listeriosis, salmonellosis, etc.),
- 5 - water-borne diseases and diseases of environmental origin (legionellosis, etc.),
- 6 - nosocomial infections,
- 7 - other diseases transmissible by non-conventional agents (including Creutzfeldt-Jakob disease, etc.).

- concerning paragraph b):

the same diseases as under paragraph a), plus diseases requiring exceptional measures to be taken at national and international levels, such as:

- 1 - diseases covered by the International Health Regulations (yellow fever, cholera, plague)
- 2 - other diseases (smallpox, rabies, typhus fever, African haemorrhagic fevers, malaria and any other as yet unclassified serious epidemic disease, etc.).

ISSN 0254-1475

COM(97) 31 final

DOCUMENTS

EN

05 15

Catalogue number : CB-CO-97-028-EN-C

ISBN 92-78-15256-0

Office for Official Publications of the European Communities

L-2985 Luxembourg