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► **B** **DECISION NO 2119/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**
of 24 September 1998
setting up a network for the epidemiological surveillance and control of communicable diseases in
the Community

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**DECISION NO 2119/98/EC OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL**

of 24 September 1998

**setting up a network for the epidemiological surveillance and
control of communicable diseases in the Community**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE
EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and
in particular Article 129 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the Economic and Social
Committee ⁽²⁾,

Having regard to the opinion of the Committee of the Regions ⁽³⁾,

Acting in accordance with the procedure laid down in Article 189b of
the Treaty ⁽⁴⁾, in the light of the joint text approved by the Conciliation
Committee on 27 May 1998,

- (1) Whereas the prevention of disease, in particular of the major
health scourges, is a priority for Community action, requiring a
global approach coordinated between Member States;
- (2) Whereas the European Parliament, in its resolution on public
health policy after Maastricht ⁽⁵⁾, invited the Commission to set
up a transfrontier network to devise working definitions of noti-
fiable diseases, to collect, update, analyse and disseminate
Member States data on such diseases and to work with national
and international agencies on these matters;
- (3) Whereas in its resolution of 2 June 1994 ⁽⁶⁾ 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;
- (4) Whereas in its conclusions of 13 December 1993 ⁽⁷⁾ 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;
- (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 the current proceedings and mechanisms existing at
Community and at Member State level, and ensuring the
comparability and compatibility of data;
- (6) Whereas in their resolution of 13 November 1992 on the moni-
toring and surveillance of communicable diseases ⁽⁸⁾ the Council
and the Ministers for Health, meeting within the Council, under-
lined the desirability of improving, within the Community, the

⁽¹⁾ OJ C 123, 26. 4. 1996, p. 10 and
OJ C 103, 2. 4. 1997, p. 11.

⁽²⁾ OJ C 30, 30. 1. 1997, p. 1.

⁽³⁾ OJ 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 (OJ C 284, 19. 9.
1997, p. 10) and Decision of the European Parliament of 14 January 1998
(OJ C 34, 2. 2. 98, p. 70). Decision of the European Parliament of 15 July
1998 (OJ C 292, 21. 9. 1998). Council Decision of 20 July 1998.

⁽⁵⁾ OJ C 329, 6. 12. 1993, p. 375.

⁽⁶⁾ OJ C 165, 17. 6. 1994, p. 1.

⁽⁷⁾ OJ C 15, 18. 1. 1994, p. 6.

⁽⁸⁾ OJ C 326, 11. 12. 1992, p. 1.

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- 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;
 - (10) Whereas the varying levels and needs of epidemiological surveillance of communicable diseases in the Member States make it necessary to establish a permanent network at Community level;
 - (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 harmonisation 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) ⁽¹⁾ 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 Organisation, notably with regard to disease classification, must be fostered, as well as the use of appropriate language and technology;
 - (15) Whereas cooperation with non-member 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 necessary information and data gathered in accordance with an agreed methodology must be communicated swiftly to the Commission;
 - (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; whereas

⁽¹⁾ OJ L 95, 16. 4. 1996, p. 16.

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- priority must be given at all times to the protection of public health;
- (18) Whereas Council Directive 92/117/EEC of 17 December 1992 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 ⁽¹⁾ applies equally to information concerning zoonoses which affect human beings; whereas 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/EC ⁽²⁾;
 - (20) Whereas the Community projects in the field of the telematic interchange of data between administrations (IDA) ⁽³⁾ 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;
 - (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 and/or from relevant Community programmes;
 - (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

⁽¹⁾ OJ L 62, 15. 3. 1993, p. 38.

⁽²⁾ OJ L 281, 23. 11. 1995, p. 31.

⁽³⁾ OJ L 269, 11. 11. 1995, p. 23.

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down in Article 189b of the Treaty ⁽¹⁾ was concluded on 20 December 1994,

HAVE ADOPTED THIS DECISION:

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:

- the epidemiological surveillance of these diseases, and
- an early warning and 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 early warning and 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.

The Commission shall provide for the coordination of the network in collaboration with the Member States.

Article 2

For the purpose 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;
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 7:

- (a) the communicable diseases to be progressively covered by the Community network;

⁽¹⁾ OJ C 102, 4. 4. 1996, p. 1.

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- (b) the criteria for selection of these diseases, having regard to the categories set out in the Annex and the existing collaborative networks for disease surveillance that can be built on;
- (c) case definitions, in particular clinical and microbiological characteristics;
- (d) 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 and the ways in which such data are to be made comparable and compatible;
- (e) epidemiological and microbiological surveillance methods;
- (f) guidelines on the protective measures to be taken, in particular at external frontiers of the Member States, notably in emergency situations;
- (g) guidelines on information and guides to good practice for the public;
- (h) the appropriate technical means and the procedures by which the data will be disseminated and analysed at Community level.

Article 4

Each structure and/or authority referred to in the second paragraph or in the third paragraph, whichever is appropriate 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 State to which the structure and/or authority belongs, together with information on control measures applied;
- (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 non-member 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

The Commission shall make available the information referred to in Article 3 to all the structures and authorities referred to in Article 1. Each structure/authority shall ensure that the information which they communicate to the network, pursuant to Article 4, is promptly forwarded to all other participating structures/authorities and the Commission.

Article 6

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

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Member State in question shall also consult other Member States and the Commission through the Community network on the nature and scope of intended measures unless the need to protect public health is so urgent that consultation proves impossible.

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 among 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 among themselves in liaison with the Commission with regard to the measures which they have adopted, or intend to adopt at national level.

5. Procedures concerning the information and consultation referred to in paragraphs 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 7.

Article 7

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

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.

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 8

The Annex may be amended or supplemented in accordance with the procedure laid down in Article 7.

Article 9

Each Member State shall designate, within six months of the entry into force of this Decision, the structures and/or authorities referred to in the second and third paragraphs of Article 1 and shall notify the Commission and the other Member States thereof. The structures and/or authorities which have been so designated shall be described in public by the Member States as forming part of the Community network established by this Decision.

Article 10

For the purposes of this Decision, the competent authorities of the Member States and the Commission shall foster cooperation with non-

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member countries and international organisations competent in the field of public health, in particular the World Health Organisation.

Article 11

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

Article 12

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 13

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 14

1. The Commission shall submit regular reports evaluating the operation of the Community network to the European Parliament and the Council.

2. The first report, which shall be submitted within three years after the entry into force of this Decision 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.

3. The Commission shall conduct an evaluation of the Community network every five years thereafter, paying particular attention to its structural capacity and effective use of resources, and shall submit a report to the European Parliament and the Council.

Article 15

This Decision shall enter into force on 3 January 1999.

Article 16

This Decision is addressed to the Member States.

▼B*ANNEX***LIST INDICATING CATEGORIES OF COMMUNICABLE DISEASES**

- 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)

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- Other diseases (rabies, typhus, viral haemorrhagic fevers, malaria and any other as yet unclassified serious epidemic disease, including diseases that are caused by agents specifically engineered for the purpose of maximising morbidity and/or mortality upon deliberate release, etc.).