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*(Acts whose publication is obligatory)***DECISION No 1400/97/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL****of 30 June 1997****adopting a programme of Community action on health monitoring within the framework for action in the field of public health (1997 to 2001)**

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 16 April 1997,

(1) Whereas, pursuant to Article 3 (o) of the Treaty, Community action must include a contribution towards the attainment of a high level of health protection; whereas Article 129 of the Treaty expressly provides for Community competence in this field in so far as the Community contributes to it by encouraging cooperation between the Member States and, if necessary, by lending support to their action;

(2) Whereas the Council, in its resolution of 27 May 1993 on future action in the field of public health ⁽⁵⁾, considered that improved collection, analysis and distribution of health data, as well as an improve-

ment in the quality and comparability of available data, are essential for the preparation of future programmes;

(3) Whereas the European Parliament, in its resolution on public health policy after Maastricht ⁽⁶⁾, stressed the importance of having sufficient and relevant information as a basis for the development of Community actions in the field of public health; whereas the European Parliament called on the Commission to collect and examine health data from Member States with a view to analysing the effects of public health policies on health status in the Community;

(4) Whereas it would be desirable to study the feasibility of establishing a permanent structure for the monitoring and evaluation of European Community health data and indicators;

(5) Whereas the Commission, in its communication of 24 November 1993 on the framework for action in the field of public health, regarded increased cooperation on standardization and collection of comparable/compatible data on health, and the promotion of systems of health monitoring and surveillance as a prerequisite for the establishment of a framework for supporting Member States' policies and programmes; whereas the area of health monitoring, including health data and indicators, has been identified as a priority area for proposals on multiannual Community programmes in the field of public health;

⁽¹⁾ OJ No C 338, 16. 12. 1995, p. 4, and OJ No C 214, 24. 7. 1996, p. 6.

⁽²⁾ OJ No C 174, 17. 6. 1996, p. 3.

⁽³⁾ OJ No C 129, 2. 5. 1996, p. 50.

⁽⁴⁾ Opinion of the European Parliament of 17 April 1996 (OJ No C 141, 13. 5. 1996, p. 94), Council Common Position of 18 June 1996 (OJ No C 220, 29. 7. 1996, p. 36) and Decision of the European Parliament of 23 October 1996 (OJ No C 347, 18. 11. 1996, p. 73). Decision of the Council of 5 June 1997 and Decision of the European Parliament of 10 June 1997.

⁽⁵⁾ OJ No C 174, 25. 6. 1993, p. 1.

⁽⁶⁾ OJ No C 329, 6. 12. 1993, p. 375.

⁽⁷⁾ OJ No C 165, 17. 6. 1994, p. 1.

- whereas the Council considered that data and indicators used should include measures relating to the quality of life of the population, accurate assessments of health needs, estimates of the avoidable deaths from the prevention of diseases, socio-economic factors in health among different population groups, and, where appropriate and if the Member States judge it necessary, health aid, medical practices, and the impact of reforms;
- (7) Whereas health monitoring at Community level is essential for the planning, monitoring and assessment of Community actions in the field of public health, and the monitoring and assessment of the health impact of other Community policies;
- (8) Whereas, on the basis in particular of knowledge of data relating to public health in Europe obtained by setting up a Community health monitoring system, it will be possible to monitor public health trends and define public health priorities and objectives;
- (9) Whereas health monitoring, for the purposes of this Decision, encompasses the establishment of Community health indicators and the collection, dissemination and analysis of Community health data and indicators;
- (10) Whereas in Decision 93/464/EEC of 22 July 1993 on the framework programme for priority actions in the field of statistical information 1993 to 1997⁽¹⁾, the Council identified under the heading 'Health and safety statistics' the analysis of mortality and morbidity by cause as one of the fields of priority actions under the sectoral programmes for social policy, economic and social cohesion and consumer protection;
- (11) Whereas in Decision 94/913/EC of 15 December 1994 adopting a specific programme of research and technological development, including demonstration, in the field of biomedicine and health (1994 to 1998)⁽²⁾, the Council identified a specific research task of coordination and comparison of European health data, including nutritional data, from the various Member States; whereas this was taken up in the relevant research work programme;
- (12) Whereas health monitoring at Community level should enable measurements of health status, trends and determinants to be carried out, facilitate the planning, monitoring and evaluation of Community programmes and actions, and provide Member States with health information supporting the development and evaluation of their health policies;
- (13) Whereas, in order fully to meet requirements and expectations in this area, a Community health monitoring system should be set up, involving the establishment of health indicators, the collection of the data, in particular those needed ultimately to arrive at comparable health indicators, the establishment of a network for transmission and sharing of health data and indicators, and the development of a capacity for analysis and dissemination of health information;
- (14) Whereas available options and possibilities for developing the various parts of a Community health monitoring system, including those making existing provisions more stringent, should be carefully examined with respect to the desired performance, flexibility and the costs and benefits involved; whereas a flexible system is required which can incorporate features which are deemed valuable at present while adapting to new requirements and other priorities; whereas such a system should include the definition of sets of Community health indicators and the collection of the data necessary for the establishment of such indicators;
- (15) Whereas Community health data and indicators should draw from existing European data and indicators, such as those held by Member States or forwarded by them to international organizations, so as to avoid unnecessary duplication of work;
- (16) Whereas the situation with regard to the collection of data varies from one Member State to another; whereas the Community may lend support to Member States' actions, including those related to data collection in the context of a Community health monitoring system, when such support would provide Community added value;
- (17) Whereas a Community health monitoring system could benefit from the establishment of a telematics network for the collection and distribution of Community health data and indicators;

⁽¹⁾ OJ No L 219, 28. 8. 1993, p. 1.

⁽²⁾ OJ No L 361, 31. 12. 1994, p. 40.

- (18) Whereas the Community health monitoring system should be capable of producing data for the preparation of regular reports on health status in the Community and analyses of trends and health problems, and of helping to produce and disseminate health information;
- (19) Whereas the setting up of a health monitoring system at Community level necessarily presupposes compliance with provisions concerning the protection of data and the introduction of measures to guarantee the confidentiality and security thereof, such as the provisions in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ⁽¹⁾ and in Council Regulation (Euratom, EEC) No 1588/90 of 11 June 1990 on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities ⁽²⁾;
- (20) Whereas a multiannual programme must be launched within the framework for action in the field of public health, in order to permit the setting up of the future Community health monitoring system and of appropriate mechanisms for the evaluation thereof;
- (21) Whereas, in accordance with the principle of subsidiarity, action on matters not falling within the exclusive competence of the Community, such as action on health monitoring, must be undertaken by the Community only if, by reason of their scale or effects, it can be better achieved by the Community;
- (22) Whereas policies and programmes formulated and implemented at Community level, in particular those undertaken within the framework for action in the field of public health, should be compatible with the targets and objectives of Community action on health monitoring; whereas the implementation of Community actions on health monitoring should take account of relevant research activities under the Community's framework programme for research and technological development; whereas projects on telematics applications in the health field under the Community's RTD programme must be coordinated with Community actions on health monitoring; whereas actions under the Community's framework programme for statistical information, the Community projects in the field of telematic interchange of data between administrations (IDA) and G7 health-related projects must be closely coordinated with the implementation of Community actions on health monitoring; whereas the work undertaken by the specialized European agencies, such as the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the European Environment Agency, should be taken into account;
- (23) Whereas cooperation should be strengthened with the competent international organizations, including the World Health Organization (WHO) and the Organization for Economic Cooperation and Development (OECD), and with non-member countries; whereas other bodies, such as non-governmental organizations, may also have a role to play;
- (24) Whereas, from an operational point of view, the investments made in the past in terms both of the development of Community networks and of cooperation with international organizations competent in this field should be safeguarded and developed;
- (25) Whereas it is important that the Commission should ensure implementation of this programme in close cooperation with the Member States;
- (26) Whereas a *modus vivendi* ⁽³⁾ 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;
- (27) Whereas data are insufficiently comparable at present and unnecessary duplication of effort should be avoided by the joint development of comparison and conversion definitions, methods, criteria and techniques, by the development of suitable data collection tools such as surveys, questionnaires or parts thereof, and by means of content specifications for health information to be shared using in particular a telematics network;

⁽¹⁾ OJ No L 281, 23. 11. 1995, p. 31.

⁽²⁾ OJ No L 151, 15. 6. 1990, p. 1. Regulation as amended by the 1994 Act of Accession.

⁽³⁾ OJ No C 102, 4. 4. 1996, p. 1.

- (28) Whereas, in order to increase the value and impact of the action programme, a continuous assessment of the measures undertaken should be carried out, with particular regard to their effectiveness and the achievement of objectives at both national and Community level, and, where appropriate, the necessary adjustments should be made;
- (29) Whereas this Decision lays down, for the entire duration of this programme, a financial framework constituting the principal point of reference, within the meaning of point 1 of the declaration by the European Parliament, the Council and the Commission of 6 March 1995⁽¹⁾, for the budgetary authority during the annual budgetary procedure;
- (30) Whereas this programme should run for five years in order to allow sufficient time for actions to be implemented to achieve the objectives set,

HAVE DECIDED AS FOLLOWS:

Article 1

Establishment of the programme

1. A programme of Community action on health monitoring, hereinafter referred to as 'the programme', shall be adopted for the period 1 January 1997 to 31 December 2001 within the framework for action in the field of public health.
2. The objective of the programme shall be to contribute to the establishment of a Community health monitoring system which makes it possible to:
 - (a) measure health status, trends and determinants throughout the Community;
 - (b) facilitate the planning, monitoring and evaluation of Community programmes and actions; and
 - (c) provide Member States with appropriate health information to make comparisons and to support their national health policies;

by encouraging cooperation between Member States and, if necessary, by supporting their action through promoting coordination of their policies and programmes in this field and encouraging cooperation with non-member countries and the competent international organizations.

3. The actions to be implemented under the programme and their specific objectives are set out in Annex I under the following headings:

- A. Establishment of Community health indicators;
- B. Development of a Community-wide network for sharing health data;
- C. Analyses and reporting.

A non-exhaustive list of areas in which health indicators may be established is set out in Annex II.

Article 2

Implementation

1. The Commission shall ensure the implementation, in close cooperation with the Member States, of the actions set out in Annex I, in accordance with Article 5.
2. The Commission shall cooperate with the institutions and organizations which are active in the field of health monitoring.

Article 3

Budget

1. The financial framework for the implementation of the programme for the period referred to in Article 1 shall be ECU 13,8 million.
2. The annual appropriations shall be authorized by the budgetary authority within the limits of the financial perspective.

Article 4

Consistency and complementarity

The Commission shall ensure that there is consistency and complementarity between actions to be implemented under the programme and the other relevant Community programmes and initiatives, both those in the context of public-health action and, 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, in particular the telematics applications of the latter.

Article 5

Committee

1. The Commission shall be assisted by a committee consisting of two members designated by each Member State and chaired by a representative of the Commission.
2. The representative of the Commission shall submit to the committee a draft of the measures to be taken concerning:
 - (a) the committee's rules of procedure;
 - (b) an annual work programme indicating the priorities for action;

⁽¹⁾ OJ No C 102, 4. 4. 1996, p. 4.

- (c) the arrangements, criteria and procedures for selecting and financing projects under the programme, including those involving cooperation with international organizations competent in the field of public health and participation of the countries referred to in Article 6 (2);
- (d) the evaluation procedure;
- (e) the arrangements for dissemination and transfer of results;
- (f) the arrangements for cooperating with the institutions and organizations referred to in Article 2 (2);
- (g) the provisions applicable to reporting of the data, conversion thereof and other methods for making the data comparable in order to achieve the objective referred to in Article 1 (2);
- (h) the provisions for the definition and selection of indicators;
- (i) the provisions for the content specifications necessary for the setting up and operation of the networks.

The committee shall deliver its opinion on the draft measures referred to above 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 measures which shall apply immediately. However, if these measures are not in accordance with the opinion of the committee, they shall forthwith be communicated by the Commission to the Council. In that event:

- the Commission shall defer application of the measures which it has decided upon for a period of two months from the date of such communication,
- the Council, acting by a qualified majority, may take a different decision within the time limit laid down in the first indent.

3. In addition, the Commission may consult the committee on any other matter concerning the implementation of the programme.

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, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its opinion recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

4. The representative of the Commission shall keep the committee regularly informed of:

- financial assistance granted under the programme (amount, duration, breakdown and beneficiaries),
- Commission proposals or Community initiatives and the implementation of programmes in other areas which are of direct relevance to achievement of the objectives of the programme, with a view to ensuring the consistency and complementarity referred to in Article 4.

Article 6

International cooperation

1. In the course of implementing the programme, cooperation with non-member countries and with international organizations competent in the field of public health, in particular the World Health Organization (WHO), the Organization for Economic Cooperation and Development (OECD) and the International Labour Organization (ILO), and with other organizations competent in the field of health monitoring shall be encouraged and implemented in accordance with the procedure laid down in Article 5.

2. The programme shall be open to participation by the associated countries of Central and Eastern Europe (ACCEE) in accordance with the conditions laid down in the Additional Protocols to the Association Agreements relating to participation in Community programmes, to be concluded with those countries. The programme shall be open to participation by Cyprus and Malta on the basis of additional appropriations in accordance with the same rules as those applied to the European Free Trade Association (EFTA) countries, in accordance with procedures to be agreed with those countries.

Article 7

Monitoring and evaluation

1. The Commission, taking into account the reports drawn up by the Member States and with the participation, where necessary, of independent experts, shall ensure that an evaluation is made of the actions undertaken.

2. The Commission shall submit to the European Parliament and the Council an interim report by 30 June 2000 and a final report on completion of the programme, and in any case not later than 30 June 2003. The Commission shall incorporate into these reports information on Community financing in the various fields of action and on complementarity with the other programmes and initiatives referred to in Article 4, as well as the results of the evaluation referred to in paragraph 1. It shall also send the reports to the Economic and Social Committee and the Committee of the Regions.

3. On the basis of the evaluations referred to in paragraph 1, the Commission may, if appropriate, make relevant proposals with a view to the continuation of the programme.

Done at Luxembourg, 30 June 1997.

For the European Parliament

The President

J. M. GIL-ROBLES

For the Council

The President

A. NUIS

ANNEX I

SPECIFIC OBJECTIVES AND ACTIONS

A. ESTABLISHMENT OF COMMUNITY HEALTH INDICATORS

Objective

To establish comparable Community health indicators by means of a critical review of existing health data and indicators, by developing methodologies for obtaining comparable health data and indicators, and by developing appropriate methods for the collection of the progressively comparable health data needed to establish these indicators.

1. Identification, review and critical analysis of existing health indicators and data at European level and at Member State level, taking as a basis data validated by the Member States in order to determine their relevance, quality and coverage with regard to the establishment of Community health indicators.
2. Identification of a set of Community health indicators, including a subset of core indicators for the monitoring of Community programmes and actions in public health and a subset of background indicators for the monitoring of other Community policies, programmes and actions, for providing Member States with common measurements for making comparisons. A non-exhaustive list of the areas in which health indicators may be established is set out in Annex II.
3. Development of and support for the routine collection of health data to be made comparable by the drawing up of data dictionaries, the establishment of appropriate conversion methods and rules, and other methods to achieve the objective referred to in Article 1 (2).
4. Contributing to the collection of comparable data by supporting the preparation of surveys, including Community-wide surveys in support of the framing of Community policies, or drawing up agreed specimen modules or questionnaires for use in existing surveys.
5. Fostering cooperation with international organizations competent in the field of Community health data and indicators and fostering networks for the exchange of health data covering specific areas in public health, in order to enhance comparability of data.
6. Encouragement and support for the assessment of the feasibility and cost-effectiveness of compiling standardized health resource statistics with the aim of including them in the Community health monitoring system to be established.
7. Support for continuation of the feasibility study in progress into the possibility of establishing a permanent structure for the monitoring and evaluation of Community health data and indicators.

B. DEVELOPMENT OF A COMMUNITY-WIDE NETWORK FOR SHARING HEALTH DATA

Objective

To enable the establishment of an effective and reliable system for the transfer and sharing of health data and indicators using telematic interchange of data as the principal means.

8. Encouragement and support for the establishment of a network for transferring and sharing health data, mainly using telematic interchanges and a system of distributed databases, in particular by the establishment of data specifications and of procedures with regard to access, retrieval, confidentiality and security for the different types of information to be included in the system.

C. ANALYSES AND REPORTING**Objective**

To develop methods and tools necessary for analysis and reporting and to support analyses and reporting on health status, trends and determinants and on the effect of policies on health.

9. Encouragement and support for the development of capacity for analyses by enhancing existing capabilities and for feasibility studies for possible new structures, comparative and predictive methodologies and tools, the testing of hypotheses and models and the evaluation of health scenarios and outcomes.
 10. Support for the analysis of the impact of Community actions and programmes in the field of public health, and for drawing up and disseminating reports evaluating that impact.
 11. Support for the preparation, drafting and dissemination of reports, analyses and other information in order to help to make comparisons on the subject of health status and trends, health determinants, and the effect of policies on health.
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ANNEX II

NON-EXHAUSTIVE LIST OF AREAS IN WHICH HEALTH INDICATORS MAY BE ESTABLISHED

A. Health status

1. Life expectancy:
 - life expectancy at certain ages,
 - health expectancies.
2. Mortality:
 - overall,
 - causes of death,
 - disease-specific survival rates.
3. Morbidity:
 - disease-specific morbidity,
 - co-morbidity.
4. Functioning and quality of life:
 - self-perceived health,
 - physical disability,
 - activity limitations,
 - functional status/ability,
 - health-related work loss,
 - mental health.
5. Anthropometric characteristics.

B. Life style and health habits

1. Tobacco consumption
2. Alcohol consumption
3. Illegal drug consumption
4. Physical activities
5. Diet
6. Sex life
7. Other

C. Living and working conditions

1. Employment/unemployment:
 - occupation.
2. Work environment:
 - accidents,
 - exposure to carcinogenic and other dangerous substances,
 - occupational diseases.
3. Housing conditions.
4. Home and leisure activities:
 - accidents at home,
 - leisure.
5. Transport:
 - car accidents.
6. External environment:
 - air pollution,
 - water pollution,
 - other types of pollution,
 - radiation,
 - exposure to carcinogenic and other dangerous substances outside the work environment.

D. Health protection

1. Sources of financing.
2. Facilities/manpower:
 - health resource utilization,
 - health care personnel.
3. Cost/expenditure:
 - in-patient care,
 - out-patient care,
 - pharmaceutical products.
4. Consumption/uses:
 - in-patient care,
 - out-patient care,
 - pharmaceutical products.
5. Health promotion and disease prevention.

E. Demographic and social factors

1. Gender
2. Age
3. Marital status
4. Region of residence
5. Education
6. Income
7. Population subgroups
8. Health insurance status

F. Miscellaneous

1. Product safety
 2. Others
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