II

(Preparatory Acts)

COMMISSION

Amended proposal for a European Parliament and Council Decision adopting a programme of Community action on health monitoring in the context of the framework for action in the field of public health [1]

(96/C 214/05)

(Text with EEA relevance)

COM(96) 222 final — 95/0238(COD)

(Submitted by the Commission pursuant to Article 189a (2) of the EC Treaty on 15 May 1996)

[1] OJ No C 338, 16. 12. 1995, p. 4.

ORIGINAL PROPOSAL	AMENDED PROPOSAL
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,	
Having regard to the opinion of the Economic and Social Committee,	
Having regard to the opinion of the Committee of the Regions,	
Acting in according with the procedures referred to in Article 189b of the Treaty,	
1. Whereas in accordance with point (o) of Article 3 of the Treaty, Community action must include a contribution of the Community towards the achievement of a high level of health protection; whereas Article 129 expressly provides for Community competence in this field, in particular by encouraging cooperation between the Member States and, if necessary, lending support to their action;	
2. Whereas the Council, in its resolution [1] of 27 May 1993 on future action in the field of public health, considered that improved collection, analysis and distribution of health data, as well as an improvement in the quality and comparibility of available data, are essential for the preparation of future programmes;	

[1] OJ No C 174, 25. 6. 1993, p. 1.

ORIGINAL PROPOSAL	AMENDED PROPOSAL
3. Whereas, the European Parliament, in its report on public health policy after Maastricht (1), has 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 and analyse trends and assess the effects of public health policies, as well as the impact of other policies;	3. Whereas, the European Parliament, in its resolution on public health policy after Maastricht (1), has 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 it called on the Commission to collect and examine health data from the Member States in order to assess the effects of public health policies, as well as the impact of other policies, on the state of health in the European Community.
4. Whereas the Commission, in its communication of 24 November 1993 on the framework for action in the field of public health (2), identified 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; and 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;	
5. Whereas in its resolution of 2 June 1994, the Council (3) indicated that the collection of health data should be accorded priority and invited the Commission to present relevant proposals; 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, estimations 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;	
6. Whereas health monitoring at the 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;	

(1) OJ No C 329, 6. 12. 1993, p. 375.
(2) COM(93) 559 final.
(3) OJ No C 165, 17. 6. 1994, p. 1.

(1) OJ No C 329, 6. 12. 1993, p. 375.

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	6a (new). Whereas on the basis, *inter alia*, of knowledge of the facts of 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;
7. Whereas health monitoring, in this context, encompasses the establishment of Community health indicators, the collection, dissemination, and analysis of Community health data and indicators;	
8. Whereas in its Decision on the framework programme for priority actions in the field of statistical information 1993 to 1997 the Council (1) has identified under the heading 'health and safety' analysis of mortality and morbidity by cause as one of the fields of priority actions under the sectoral programmes for social policy, for economic and social cohesion and consumer protection;	
9. Whereas the Council (2) in its Decision 94/914/CEE of 15 December 1994 adopting a specific programme on research and technological development, including demonstration, in the field of biomedicine and health (1994 to 1998) identified a specific research task on coordination and comparison of European health data, including nutritional data, from the Member States, and whereas this was taken up in the relevant research work programme;	
10. 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;	

(1) OJ No L 219, 28. 8. 1993, p. 1.
(2) OJ No L 361, 31. 12. 1994, p. 40.

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11. Whereas, in order to give full effect to requirements and expectations in this area a Community health monitoring system should be developed, comprising the establishment of health indicators and the collection of health data, a network for transmission and sharing of health data and indicators, and a capacity for analysis and dissemination of health information;	
12. Whereas available options and possibilities for developing the various parts of a Community health monitoring system should be carefully assessed with respect to the desired performance, flexibility and the costs and benefits involved; whereas a Community health monitoring system should include the definition of sets of Community health indicators and the collection of the data necessary for the establishment of such indicators;	12. Whereas available options and possibilities for developing the various parts of a Community health monitoring system, including that if enhancing existing capabilities and/or setting up an observatory, should be examined with respect to the desired performance, and the costs and benefits involved; and whereas a flexible system is required which can incorporate features which are valuable at present while adapting to new requirements or other priorities; whereas a Community health monitoring system should include the definition of sets of Community health indicators and the collection of the data necessary for the establishment of such indicators;
13. Whereas, Community health data and indicators should draw from readily available European data and indicators, such as those held by Member States or transmitted by them to international organizations, so as to avoid unnecessary duplication of work;	13. Whereas Community health data and indicators should draw from existing European data and indicators, such as those held by Member States and/or transmitted by them to international organizations, so as to avoid unnecessary duplication;
	13a (new). Whereas the situation with regard to the collection of data varies from Member State to Member State;
14. Whereas a Community health monitoring system would benefit from the establishment of a network, the backbone of which relies on telematics, for the collection and distribution of Community health data and indicators;	14. Whereas the Community health monitoring system would benefit from being based on a network, the backbone of which relies on telematics, for the collection and distribution of Community health data and indicators;
15. Whereas a Community health monitoring system should be capable of encouraging and assisting in the production of analyses, trends, and health problems throughout the Community, and in the availability and dissemination of health information;	15. Whereas the health monitoring system should provide material for regular reports on health status in the European Community, analyses of trends, and health problems, and assist in the availability and dissemination of health information;
	15a (new). Whereas importance must be attached to cooperation in the field of health and occupational health and safety, from which a picture of the prevalence of occupational diseases and accidents at work can be built up;

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16. Whereas overriding considerations in the development of a Community health monitoring system are the respect of legislative provisions on data protection, and the implementation of appropriate confidentiality and security arrangements;	16. Whereas it is necessary to ensure the respect of legislative provisions on data protection, and the implementation of appropriate confidentiality and security arrangements;
17. Whereas a multiannual programme should be launched within the context of the framework for action in the field of public health, in order to permit the development of a Community health monitoring system and of appropriate mechanisms for its evaluation;	
18. Whereas, by reason of its scale and effects, Community action in support of health monitoring enables the desired objectives to be reached more effectively;	
19. Whereas policies and programmes formulated and implemented at Community level, in particular those undertaken in the context of 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 be coordinated with and 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 Framework must be closely 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 G-7 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 EMCDDA and the European Environment Agency, should be taken into account;	
20. Whereas cooperation in this area with the competent international organizations and with third countries should be fostered;	
	20a (previously recital 23) Whereas, from an operational point of view, the investments made in the past both in terms of the development of Community networks and cooperation with international organization competent in this field should be safeguarded and further developed;

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21. Whereas it is important that the Commission ensure implementation of the programme in close cooperation with the Member States;	21. Whereas it is important that the Commission implement this programme in close cooperation with the Member States;
22. Whereas an agreement on a 'modus vivendi' between the European Parliament, the Council and the Commission concerning measures implementing acts adopted in accordance with the procedure laid down in Article 189b of the EC Treaty was reached on 20 December 1994;	
23. Whereas, from an operational point of view, the investments made in the past both in terms of the development of Community networks and cooperation with international organizations competent in this field should be safeguarded and further developed;	23. Deleted
24. Whereas unnecessary duplication of effort should be avoided by the joint development of methodologies, comparison and conversion criteria and techniques, progressively harmonized data collection tools such as surveys, questionnaires or parts thereof, and content specifications for health information to be shared using in particular a telematics network;	24. Whereas at present data are insufficiently comparable, and unnecessary dupulication of effort should be avoided by the joint development of methodologies, comparison and conversion criteria and techniques, progresssively harmonized data collection tools such as surveys, questionnaires or parts thereof, and content specifications for health information to be shared using in particular a telematics network;
25. Whereas, in order to increase the value and impact of the programme, a continuous assessment of the measures undertaken should be carried out, with particular regard to their effectiveness and the achievement of objectives both at national and Community level and, where appropriate, the necessary adjustments should be made;	
26. Whereas this Decision lays down, for the entire duration of the programme, a financial framework constituting the principal point of reference, within the meaning of point 1 of the declaration of the European Parliament, the Council and Commission of 6 March 1995, for the budgetary authority during the annual budgetary procedure;	
27. Whereas this programme must be of five-year duration in order to allow sufficient time for actions to be implemented to achieve the objectives set,	

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HAVE DECIDED AS FOLLOWS:	
Article 1	
Establishment of the programme	
1. A programme of Community action on health monitoring, hereinafter referred to as 'this programme', is hereby adopted for the period 1 January 1997 to 31 December 2001 within the framework for action in the field of public health.	
2. The aim of this programme is to establish a Community health monitoring system which allows the measuring of health status, trends and determinants throughout the Community, facilitates the planning, monitoring, and evaluation of Community programmes and actions, and provides Member States with appropriate health information to make comparisons and to support their national health policies.	
3. The actions to be implemented under this programme and their specific objectives are set out in the Annex under the headings:	3. The actions to be implemented under this programme and their specific objectives are set out in Annex I under the headings:
A. Establishment of Community health indicators	
B. Development of a Community-wide network for sharing health data	
C. Analyses and reporting	
Article 2	
Implementation	
1. The Commission shall ensure implementation, in close cooperation with the Member States, of the actions set out in the Annex in accordance with Article 5.	1. The Commission shall ensure 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 institutions and organizations active in the field of health monitoring.	
Article 3	
Budget	
1. The total appropriation for implementation of this programme for the period referred to in Article 1 shall be ECU 13,8 million.	
2. The annual appropriations shall be established by the budgetary authority in accordance with the financial perspectives.	

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Article 4 **Consistency and complementarity**	
The Commission and the Member States shall ensure that there is consistency and complementarity between actions to be implemented under this programme and other relevant Community programmes and initiatives, including the framework programme for statistical information, the projects in the field of telematic interchange of data between administrations, and the framework programme for research and technological development and in particular the telematics applications of the latter.	The Commission shall ensure that there is consistency and complementarity between actions to be implemented under this programme and other relevant Community programmes and initiatives, including the framework programme for statistical information, the projects in the field of telematic interchange of data between administrations, and the framework programme for research and technological development and in particular the telematics applications of the latter.
Article 5 **Committee**	
1. The Commission shall be assisted by a committee composed of two members designated by each Member State and chaired by a representative of the Commission, hereinafter referred to as 'the committee'.	1. The Commission shall be assisted by a committee of an advisory nature, composed of two members designated by each Member State and chaired by a representative of the Commission, hereinafter referred to as 'the committee'.
2. The representative of the Commission shall submit to the committee draft measures concerning, in particular:	
(a) the committee's rules of procedure;	
(b) an annual work programme indicating the priorities for action;	
(c) the arrangements, criteria, and procedures for selecting and financing projects under this programme, including those involving cooperation with international organizations competent in the field of public health and participation of the countries mentioned in Article 6 (2);	
(d) the evaluation procedure;	
(e) the arrangements for reporting, conversion, and harmonization of the data;	
(f) the arrangements for the definition and selection of indicators;	
(g) the arrangements for the content specifications necessary for the development and operation of the relevant networks.	
3. In addition, the Commission may consult the committee on any other matter concerning the implementation of this programme.	

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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 chairperson 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 about:	
— financial assistance granted under this programme (amounts, duration, breakdown, and recipients),	
— Commission proposals or Community initiatives and the implementation of programmes in other policy areas which are relevant to the achievement of the objectives of this programmes, with a view to ensure the consistency and complementarity required under Article 4.	
Article 6	
International cooperation	
1. In the course of implementing this programme, cooperation with non-member countries and with international organizations competent in the field of public health, in particular the World Health Organization and the Organization for Economic Cooperation and Development shall be forstered and implemented in accordance with Article 5.	1. In the course of implementing this programme, cooperation with third countries and with international organizations competent in the field of public health, in particular the World Health Organization and the Organization for Economic Cooperation and Development, shall be forstered and implemented in accordance with Article 5.
2. This programme shall be open to participation by the associated countries of central and eastern Europe (CCEE), 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. This 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 EFTA countries, in accordance with procedures to be agreed with those countries.	

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Article 7	
Monitoring and evaluation	
1. The Community, 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 halfway through, and a final report on completion of this programme. It shall incorporate into these reports information on Community financing in the various fields of action and on complementarity with the other actions referred to in Article 4, as well as the results of the evaluations. It shall also send them to the Economic and Social Committee and the Committee of the Regions.	
ANNEX	*ANNEX I*
SPECIFIC OBJECTIVES AND ACTIONS	
A. ESTABLISHMENT OF COMMUNITY HEALTH INDICATORS	
Objective: to establish Community health indicators by a critical review of existing health data and indicators, and develop appropriate methods for the collection of comparable and progressively harmonized health data.	
1. Carrying out an identification, review and critical analysis of existing health indicators and data at the European and Member States' level in order to identify their relevance, quality and coverage with regard to the establishment of Community indicators.	
2. Creation of a set of Community health indicators, including a sub-set of core indicators for the monitoring of Community programmes actions in public health, and a sub-set of background indicators for the monitoring of other Community policies programmes and actions, and for providing Member States with common measures for making comparisons.	2. Creation of a set of Community health indicators, including a sub-set of core indicators for the monitoring of Community programmes actions in public health, and a sub-set of background indicators for the monitoring of other Community policies programmes and actions, and for providing Member States with common measures for making comparisons. Details of these indicators are given in Annex II to this programme.

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3. Development of the routine collection of comparable and/or progressively harmonized data in the Member States, including support for the elaboration of data dictionaries, and the establishment of appropriate conversion methods and rules.	
4. Contributing to the collection of comparable data by supporting the elaboration of surveys including Community-wide surveys in support of Community policies, or modules or agreed forms of words for questions in existing surveys.	
5. Foster cooperation with international organizations competent in the field of European health data and indicators and networks for the exchange of health data covering specific areas in public health, in order to enhance comparability of data.	
6. Support for the assessment of the feasibility and cost-effectiveness of developing standardized health resource statistics with the aim of including them in a future Community health monitoring system.	6. Assessment of the feasibility and cost-effectiveness of developing standardized health resource statistics with the aim of including them in the Community health monitoring system.
B. DEVELOPMENT OF A COMMUNITY-WIDE NETWORK FOR SHARING HEALTH DATA	
Objective: to enable the establishment of effective and reliable transfer and sharing of health data and indicators using telematic interchange of data as the principal means.	
7. Encourage and support the development of a network for 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 the access, retrieval, confidentiality and security for the different types of information to be included in the system.	7. Encouragement of and support for the development 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 the 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 support analyses and reporting on health status, trends, determinants, and the effect of policies on health.	
8. Encourage the development of a capacity for analyses, including comparative and predictive methodologies and tools, the testing of hypotheses and models and the evaluation of health scenarios and outcomes.	8. Encouragement of and support for the development of a capacity for analyses, 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.

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9. Support for the analysis and evaluation of the impact of Community actions and programmes in public health.	9. Support for the analysis, preparation, and dissemination of reports evaluating the impact of Community action and programmes in the field of public health.
10. Support for the production and dissemination of reports and other information material on health status and trends, health determinants and the impact on health of other policies.	10. Support for the preparation, production and dissemination of reports and other information material on health status and trends, health determinants and the impact on health of other policies.

ANNEX II

Non-exhaustive list of domains in which health indicators may be established under the Community health monitoring system

A. HEALTH STATUS

1. Life expectancy:
   - — life expectancy at certain ages,
   - — health expectancies.
2. Mortality:
   - — overall,
   - — causes of death,
   - — disease-specific survival.
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. Illicit drug consumption.

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4. Physical activities.

5. Diet.

6. Sexual behaviour.

7. Other health promotion-related activites.

C. LIVING AND WORKING CONDITIONS

1. Employment/unemployment:

— occupation.

2. Work environment:

— accidents,

— exposure to carcinogenic and other dangerous substances,

— occupational health.

3. Housing conditions.

4. Home and leisure activities:

— accidents at home,

— leisure.

5. Transport:

— automobile 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.

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	4. Consumption / uses:
	— in-patient care,
	— out-patient care,
	— pharmaceutical products.
	5. Health promotion and disease prevention.
	E. DEMOGRAPHIC AND OTHER SOCIAL FACTORS
	1. Gender.
	2. Age.
	3. Civil status.
	4. Region of residence.
	5. Education.
	6. Income.
	7. Population subgroups.
	8. Health insurance status.
	F. MISCELLANEOUS
	1. Product safety.
	2. Others.