COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.11.1996
COM(96) 581 final

95/0238 (COD)

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

proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DECISION

adopting a programme of Community action on health monitoring in the context of the framework for action in the field of public health (1997-2001)

AMENDING THE PROPOSAL OF THE COMMISSION
pursuant to Article 189 a (2) of the EC Treaty

The entry into force of the Treaty of the European Union conferred upon the Community particular competence with regard to public health. In order to attain the health protection objectives set out in Articles 3(o) and 129 of the Treaty establishing the European Community, the Commission set out in its Communication COM(93)559 final a framework for action in the field of public health.

In initiating action under Article 129, the Community has to address itself to preventing disease and protecting health. A prerequisite for such action is knowledge about existing problems, their nature, and their extent. It is therefore necessary to measure the changes in health as well as the impact of policies, programmes, and actions, both in the Member States and at the Community level, in order to ascertain that actions attain their objectives and actually lead to the improvements intended. Appropriate measures to monitor health and its determinants, as well as a capacity for the monitoring and evaluation of actions are therefore needed. Based on the criteria laid down in the above-mentioned Commission communication, health data and indicators have been identified as essential means to the acquisition of such knowledge and capacity, and, therefore, as a priority for Community action.

The Commission has therefore proposed a programme of Community action on health monitoring[1] with the aim to contribute to the development of a high-quality, policy-oriented health monitoring system for the European Community. This aim is intended to be achieved 1) by establishing a set of health indicators, 2) by developing a network for the collection and dissemination of the data needed for the indicators; and 3) by developing the capacity to undertake analyses of the data.

The Economic and Social Committee (ECOSOC) adopted its opinion on 27 March 1996[2].

In general, the opinion is very favourable towards the proposed health monitoring programme. The ECOSOC warmly welcomes and endorses it, emphasising the importance of establishing and maintaining health indicators. It stresses the Commission's cooperation with the World Health Organization, the Organization for Economic Cooperation and Development, and the European Monitoring Centre for Drugs and Drug Addiction.

The ECOSOC proposes that the proposed list of domains and headings for potential health indicators, which appear in Annex A of the Communication which accompanies the proposal, be annexed to the latter. Finally, it draws attention to the size of the appropriations of the programme which it feels should be increased because of the importance of the subject matter.

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[1] OJ No. C 338/4, 16/12/1995; COM(95)449 final

[2] OJ No. C 174/3, 17/6/1996, p. 3

The Committee of the Regions (COR) adopted its opinion on 18 January 1996[3].

The COR has no objections to the general objectives of the proposed programme, but it insists that the COR and the local and regional authorities be given a significant role in the implementation of the programme. It also notes that the programme could be used for setting up minimum standards of health in all Member States in the future.

The COR is concerned that the budget is too low to permit the cooperation that will be needed with other agencies, local and regional authorities, etc.

The COR proposes to reduce the proposed Committee to one (1) representative per Member State instead of the proposed two (2) representatives per Member States. In addition, it would like to have additional Committee members drawn from regional bodies such as the COR, the NOMESKO (the Nordic Committee for Medical Statistics) and others.

The European Parliament adopted its opinion following the first reading on 17 April 1996[4], containing 44 amendments to the original Commission proposal. The amendments adopted are intended to modify or supplement the proposal for a Decision on a number of points:

- the implementation arrangements for the programme: comitology and budget;

- general aspects relating to the scope of the programme (including the establishment of a European Health Observatory, and the setting of health targets by Member States);

- further information on certain measures, through rewording or additions to the text, including an Annex (II), containing a list of potential domains in which the health indicators may be established.

The Commission accepted 28 amendments of the 44 proposed by the Parliament, either in full or in part.

On 13 May 1996 the Commission adopted an amended proposal taking account of the aforementioned Parliament amendments[5],

On 14 May 1996 the Council unanimously adopted a common position with a view to adopting the Decision in question.

The Commission was unable to accept this common position and expressed reservations concerning the following points:

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[3] OJ No. C 129/50, 2/5/1996, p. 50
[4] Doc. PE 215.742/fin.
[5] Com(96) 222 final

- **Article 3 (Budget)**: The common position adopted by the Council makes provisions for a budget of 13 MECU for the programme over a period of five years between 1 January 1997 and 31 December 2001. In its proposal, the Commission had proposed a total of 13.8 MECU for the period 1997-2001. The Commission considers that its proposal respects the ceilings under Rubric 3 of the Financial Perspective and is relatively modest given the scale of the new programme and its importance. The Commission has therefore asked that a statement be inserted in the Council minutes reserving its position on the budget, which it considers insufficient.

- **Article 5 (Comitology)**: The Council wants to introduce a "mixed" comitology procedure for the implementation of the programme. Under this procedure, which is similar to that set up for the other public health programmes (AIDS, Cancer, and Health Promotion), there would be 9 matters which fall under the Committee's "management" competence, and others falling within its "advisory" competence. The Commission has entered a reservation concerning this approach, which it finds overly bureaucratic and onerous, preferring a purely advisory committee which could cover explicitly, but not limited to, some of the areas of activity envisaged by the Council.

- **Article 7(3) (Evaluation)**: The Council wanted the Commission to make proposals concerning the continuation of the programme. The Commission regrets the reference to evaluations forming the basis for making recommendations concerning the continuation of the programme, as this may not be desirable or appropriate in relation to the right of initiative of the Commission. Accordingly, the Commission has entered a reservation on Article 7(3) into the Council minutes.

- **Recital 26, Article 5(g), Annex I (objective A and action A.3)**: The Commission regrets the deletion of the words "progressively harmonised data" in recital 26, and the reference to making data merely "comparable" rather than "progressively harmonised" in Art. 5(g), and objective A and action A.3 of Annex I, and, in view of the second reading of the European Parliament, reserves its position on this matter. A reservation on this matter has been entered into the Council minutes.

Furthermore, the Council did not adopt most of the amendments proposed by European Parliament which the Commission had introduced in its amended proposal. Given the importance attached by Parliament to these amendments, the Commission could only express its reservation at their non-inclusion in the Council's common position and made a statement to be entered in the minutes to this effect.

On 23 October 1996 the European Parliament[6], adopted 19 amendments to the Council common position. The Commission's opinion concerning each of these amendments is given in the Annex.

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

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[6] Doc. PE 218.544/fin.

ANNEX[7]

Amendment 1: Commission opinion: partially accepted.
The Commission can only accept this amendment partially because a recital should refer to a legal text (e.g., resolution, conclusion, recommendation) and not to "a conciliation meeting".

Amendment 2: Commission opinion: partially accepted.
The Commission can only accept this amendment partially because the word "comparable" results in limiting the data to be collected by the system to only those which are comparable. This is not desirable as most data currently are not comparable. We should not await the production by Member States of Comparable data in order to develop health indicators. Furthermore, it is important to emphasise that the system includes the collection of health data. Finally, the network may already be in existence and need therefore not be established anew.

Amendments 3: Commission opinion: rejected
Support for Member States specific activities is outside the scope of the health monitoring programme. Furthermore, the subsidiarity principle would indicate that establishment and improvement of Member State databases is the purview of Member States.

Amendment 4: Commission opinion: rejected.
The Commission rejected this amendment because this is an important recital. There are no apparent reasons for its deletion.

Amendments 5: Commission opinion: rejected.
Text should be aligned to the wording of Article 129.

Amendment 6: Commission opinion: partially accepted.
The Commission can only accept this amendment partially because not all data will require joint development of definitions, etc. It is therefore misleading to use this wording. Furthermore, as currently worded, the amendment does not make sense.

Amendments 7: Commission opinion: accepted.
The wording of this amendment is that of the original Commission proposal.

Amendment 8: Commission opinion: rejected.
The margin contained in Rubric 3 of the budget, under which this programme falls, does not allow for such an increase.

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[7] The numbering of the amendments corresponds to the numbering of the Recommendation for second reading - Doc. PE 218.544/fin.

Amendment 9: Commission opinion: accepted.
The Commission can fully accept this amendment because the wording is consistent with that of the three other public health programmes as agreed in the conciliation meeting in December 1996.

Amendment 10: Commission opinion: partially accepted.
Part 1 is accepted only partially because the exact formulation contained in the comitology decision of 1987 should be followed. The Committee representation should be analogous to that of the other health programmes (which have 2 representatives per Member States). Part 2-4 are fully accepted because the wording is that of the original Commission proposal.

Amendments 11: Commission opinion: rejected.
The text should be aligned to the wording of Article 129, which does not impose any legal obligation to cooperate with non-governmental organisations.

Amendment 12: Commission opinion: rejected.
This amendment is rejected because the dates for the duration of the programme depend on its adoption. It is therefore inappropriate to specify the specific dates for the interim and final reports because they may not end up corresponding to the half-way point and the end of the programme, respectively.

Amendments 13: Commission opinion: accepted.
The wording is that of the original Commission proposal.

Amendment 14: Commission opinion: rejected.
This amendment is rejected because the first part of the amendment limits the routine collection of data to comparable data, which is too restrictive, as it prevents supporting the activities necessary to improve the comparability of the data. The second part implies an obligation to harmonise national data which may require harmonisation of legal provisions something which cannot be done under Article 129.

Amendments 15: Commission opinion: rejected.
Support for Member States specific activities is outside the scope of the health monitoring programme. Furthermore, the subsidiarity principle would indicate that establishment and improvement of Member State databases is the purview of Member States. Finally, this programme is not an instrument for disbursing funds to the Member States. Such action would not correspond to any objective, nor would it provide any added value.

Amendment 16: Commission opinion: partially accepted.
It is not the Commission which always undertakes such activities directly. However, it will seek to ensure that these activities are initiated as well as supported.

Amendments 17: Commission opinion: accepted.
The wording is that of the Commission's amended proposal.

Amendment 18: Commission opinion: partially accepted.
Analyses are contained in reports. Information materials are important even if they may not be reports or contain analyses. Furthermore, health systems are considered part of the determinants of health, and cost-effectiveness analysis of health systems is outside the scope of the programme.

Amendment 19: Commission opinion: accepted.
It is appropriate to support wide dissemination of reports and information materials prepared under the programme.

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 (1997-2001)

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

Council Common Position	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 (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 referred to in Article 189b of the Treaty,	
(1) OJ N° C 338, 16.12.1995, p. 4 (2) OJ No C 174, 17.6.1996, p. 3 (3) OJ N° C 129, 2.5.1996, p. 50	

Council Common Position	Amended Proposal
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 insofar as the Community contributes to it by encouraging cooperation between the Member States and, if necessary, by lending support to their action;	1. Whereas, pursuant to Article 3 (o) of the Treaty, Community action must include a contribution of the Community towards the attainment of a high level of health protection; whereas Article 129 expressly provides for Community competence in this field, 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 relevant international organisations.
2. Whereas the Council, in its resolution of 27 May 1993 on future action in the field of public health (1), considered that improved collection, analysis and distribution of health data, as well as an improvement 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 (2), 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;	3. Whereas the European Parliament, in its report on public health policy after Maastricht, 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 on health;
4. Whereas the Commission, in its communication of 24 November 1993 on the framework for action in the field of public health, 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; 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 N° C 174, 25.6.1993, p. 1 (2) OJ N° C 329, 6.12.1993, p. 375	

Council Common Position	Amended Proposal
5. Whereas in its Resolution of 2 June 1994 on the framework for action in the field of Community health (1), the Council 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, 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; 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; 7. 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; 8. 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; 9. 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 (2), 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; (1) OJ N° C 165, 17.6.1994, p. 1 (2) OJ N° L 219, 28.8.1993, p. 1	

Council Common Position	Amended Proposal
10. 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 (1994-1998) (1), 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;	—
11. 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;	
12. 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, 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 and the collection of health data, a network for transmission and sharing of health data and indicators, and building capacity for analysis and dissemination of health information;
13. 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;	13. Whereas available options and possibilities for developing the various parts of a Community health monitoring system, including that of 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;
14. Whereas Community health data and indicators should draw from existing 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;	
(1) OJ N° L 361, 31.12.1994, p. 40	

Council Common Position	Amended Proposal
15. Whereas the situation with regard to the collection of data varies from one Member State to another;	
16. Whereas a Community health monitoring system would benefit from the establishment of a telematics network for the collection and distribution of Community health data and indicators;	16. 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;
17. Whereas the Community health monitoring system should be capable of producing data for the preparation of regular reports on health status in the European Community, analyses of trends and health problems, and should help produce and disseminate health information;	
18. 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 their confidentiality, such as the provisions laid down 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) n° 1588/90 of 11 June 1990 on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities (2);	
19. Whereas a multiannual programme should be launched within 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;	
20. 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;	20. Whereas, in accordance with the principle of subsidiarity, action on matters not under 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 may be better carried out at Community level;
(1) OJ N° L 281, 23.11.1995, p. 31 (2) OJ N° L 151, 15.6.1990, p. 1; Regulation amended by the 1994 Act of accession.	

Council Common Position	Amended Proposal
21. 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 be coordinated with and take account of relevant research activities under the Community's Framework Programme for Research and Technological Development; whereas the projects on telematics applications in the health field under the Community's RTD Framework 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 telematics 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 European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the European Environment Agency, should be taken into account;	
22. Whereas cooperation with the competent international organizations and with non-member countries should be strengthened;	22. Whereas cooperation in this area with the competent international organisations and with <u>third</u> countries should <u>be fostered;</u>
23. 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 further developed;	
24. Whereas it is important that the Commission should ensure implementation of this programme in close cooperation with the Member States;	

Council Common Position	Amended Proposal
25. Whereas a "modus vivendi" (1) 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;	
26. Whereas data is insufficiently comparable at present and unnecessary duplication of effort should be avoided by the joint development of comparison and conversion methods, criteria and techniques, suitable 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;	26. Whereas data <u>are</u> insufficiently comparable at present and there should be joint development of <u>methodologies, comparison and conversion</u> criteria and techniques, <u>progressively harmonized</u> data collection tools such as survey, questionnaires or parts thereof, and content specifications for health information to be shared using in particular a telematics network;
27.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;	
28. 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 of the European Parliament, the Council and the Commission of 6 March 1995 (2) , for the budgetary authority during the annual budgetary procedure;	
29. Whereas this programme should run for five years in order to allow sufficient time for actions to be implemented to achieve the objectives set,	
(1) OJ N° C 102, 4.4.1996, p. 1 (2) OJ N° C 102, 4.4.1996, p. 4	

Council Common Position	Amended Proposal
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.	1. A programme of Community action on health monitoring, hereinafter refereed 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 objective of the programme shall be to contribute to the establishment of a Community health-monitoring system which helps 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 high-quality 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 relevant international organisations.	
3. The actions to be implemented under the programme and their specific objectives are set out in Annex 1 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.	

Council Common Position	Amended Proposal
A non-exhaustive list of areas in which health indicators could 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 the 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 million. 2. The annual appropriations shall be authorized by the budgetary authority within the limits of the financial perspective.	1. The financial resources for implementation of this programme for the period referred to in Article 1 shall be ECU 13.8 million.
Article 4 Consistency and complementarity The Commission, with the assistance of 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, covering those that are situated 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, 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.

Council Common Position	Amended Proposal
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.	1. The Commission shall be assisted by a committee of an advisory nature, hereinafter referred to as 'the Committee', composed of two members per Member State 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 concerning:	2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken concerning in particular :
(a) the Committee's rules of procedure;	(a) the Committee's rules of procedure;
(b) an annual work programme indicating the priorities for action;	(b) an annual work programme laying down the priorities for action;
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);	(c) arrangements, criteria and procedures for selecting and financing projects under the programme, including those involving co-operation 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;	(d) the evaluation procedure;
(e) the arrangements for dissemination and transfer of results;	(e) the arrangements applicable to the reporting, conversion and harmonisation of data;
(f) the arrangements for cooperating with the institutions and organizations referred to in Article 2 (2);	(f) the arrangements for the definition and selection of indicators;
(g) the provisions applicable to reporting the data conversion thereof and other methods for making the data comparable in order to achieve the objective referred to in Article 1(2);	(g) the arrangements for the content specifications necessary for the setting up and operation of the networks;
(h) the provisions for the definition and selection of indicators;	Deleted
(i) the provisions for the content specifications necessary for setting up and operation of the relevant networks;	Deleted

Council Common Position	Amended Proposal
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.	Deleted
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 be communicated by the Commission to the Council forthwith. 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.	Deleted
3. In addition, the Commission may consult the Committee on any other matter concerning the implementation of this programme, including the arrangements for coordination with the other programmes and initiatives referred to Article 4.	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 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 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

Council Common Position	Amended Proposal
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.	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:	4. The representative of the Commission shall keep the Committee regularly informed of :
- financial assistance granted under the programme (amounts, duration, breakdown, and beneficiaries);	- financial assistance granted under the programme (amounts, duration, breakdown, and recipients;
- 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.	- 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 programme, with a view to ensure the consistency and complementarity required under 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, the Organization for Economic Cooperation and Development and the International Labour Organization, shall be encouraged and implemented in accordance with the procedure laid down in Article 5.	1. In the course of implementing this programme, cooperation with third countries and with international organisations competent in the field of public health, in particular the World Health Organization and the Organization for Economic Cooperation and Development, shall be fostered and implemented in accordance with 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.	

Council Common Position	Amended Proposal
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 halfway through the programme and a final report on completion thereof. 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 this programme.	Deleted
Done at Brussels, For the European Parliament The President For the Council The President	

Council Common Position	Amended Proposal
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 health data and for making such data comparable, in accordance with the objective referred to Article 1 (2).	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, in accordance with the objective referred to in Article 1(2).
1. Carrying out an 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, and for providing Member States with common measures for making comparisons. A non-exhaustive list of the areas in which health indicators could be established is set out in Annex II.	2. Creation of a set of Community health indicators, including a sub-set of core indicators for the monitoring of Community programmes and 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. A non-exhaustive list of the areas in which health indicators could be established is set out in Annex II.
3. Development of the routine collection data and of methods for making health data comparable, in order to achieve the objective referred to in Article 1 (2), including support for the drawing up data dictionaries and the establishment of appropriate conversion methods and rules.	3. Development of the routine collection of comparable and/or progressively harmonised data in the Member States, including support for the elaboration of data dictionaries, and the establishment of appropriate conversion methods and rules.

Council Common Position	Amended Proposal
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.	4. Contributing to the collection of comparable data by supporting the <u>elaboration</u> of surveys including Community-wide surveys in support of Community policies, or modules of <u>agreed forms of words for</u> questions in existing surveys.
5. Fostering cooperation with international organizations competent in the field of Community 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.	5. <u>Foster</u> co-operation with international organization competent in the field of <u>European</u> 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. Encouragement and 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.	
	6a.(new) <u>Carrying out feasibility studies on the possibility of setting up a permanent body (the European Observatory) responsible for monitoring and evaluation health data and indicators in the Community area</u>.
B. DEVELOPMENT OF A COMMUNITY-WIDE NETWORK FOR SHARING HEALTH DATA <u>Objective</u> 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.	
7. Encouragement 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 access, retrieval, confidentiality and security for the different types of information to be included in the system.	

Council Common Position	Amended Proposal
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.	
8. Encouragement and support for the development of capacity for analyses by enhancing existing capabilities and for feasibility studies for possible new structures of 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.
9. 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 such impact.	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 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.	10. Support for the drafting, preparation and production of reports and other information material on health status and trends, health determinants and the impact on health of other policies. 10a. (new) Support for the dissemination of reports and information material to the Member States, international organizations, professionals and bodies in the health sector and the general public.

Council Common Position	Amended Proposal
Annex II	Annex II
Non-exhaustive list of areas in which health indicators may be established	Non-exhaustive list of areas in which health indicators may be established
A. Health status	A. Health status
1. Life expectancy: - life expectancy at certain ages, - health expectancies,	1. Life expectancy: - life expectancy at certain ages, - health expectancies,
2. Mortality: - overall, - causes of death, - diseases-specific survival rates,	2. Mortality: - overall, - causes of death, - diseases-specific survival rates,
3. Morbidity: - disease-specific, morbidity, - co-morbidity,	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.	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	5. Anthropometric characteristics
B. Life style and health habits	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	1. Tobacco consumption 2. Alcohol consumption 3. Illegal drug consumption 4. Physical activities 5. Diet 6. Sexual behaviour 7. Other

Council Common Position	Amended Proposal
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.	C. Living and working conditions 1. Employment/unemployment: - occupation. 2. Work environment: - accidents, - exposure to carcinogenic and other dangerous substances, - occupational <u>health</u>. 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.	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.

Council Common Position	Amended Proposal
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. Marital status 4. Region of residence 5. Education 6. Income 7. Population subgroups 8. Health insurance status F. Miscellaneous 1. Product safety 2. Others	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. 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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