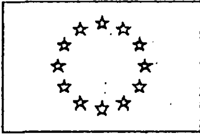

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 16.10.1995
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95/0238 (COD)

COMMUNICATION FROM THE COMMISSION

concerning a Community action programme on health monitoring in the context of the framework for action in the field of public health

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

(presented by the Commission)

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I. INTRODUCTION

1. By virtue of Articles 3(o) and 129 of the Treaty establishing the European Community, the Community has for the first time been given an explicit legal basis for undertaking action in the field of public health. The role of the Community is to contribute towards ensuring a high level of human health protection, directing actions towards the prevention of diseases, in particular by encouraging cooperation between Member States and, if necessary, lending support to their action, and by promoting coordination of their policies and programmes.

2. In its communication of 24 November 1993[1] on the framework for Community action in the field of public health, the Commission defined a framework for Community action in order to attain the objectives on health protection laid down in Articles 3(o) and 129. The role of the Community is identified as underpinning the efforts of the Member States in the public health field, assisting in the formulation and implementation of objectives and strategies, and contributing to the provision of a high-level health protection across the Community, setting as a target the best results already obtained in a given area anywhere in the Community.

3. 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.

4. Health data and indicators have also been singled out by the Council[2], the European Parliament[3], and the Economic and Social Committee[4] as an important area for Community action in public health. A long series of resolutions, conclusions, and opinions by these institutions culminated in June 1994 in the adoption of a Council resolution on the framework for future action in the field of public health, which identified health data and indicators as an area to which priority should be assigned and on which the Commission was invited to present proposals[5].

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[1] COM (93) 559 final

[2] OJ No. C 174, 25.6.1993, p.1.

[3] OJ No. C 329, 6.12.1993, p. 375

[4] 6 May 1994, ENVI/379

[5] OJ No. C 165, 17.6.1994, p.1

5. The efforts of the Commission in this area concentrated on identifying the needs of the Community and the Member States, and on determining how to obtain the maximum effect from the involvement of the Community while fully respecting the principle of subsidiarity. To this end, the Commission has, with the assistance of Member States' representatives, conducted a review of existing health data and indicators at the Community level, their sources, coverage, and importance, and obtained valuable advice and recommendations.

6. In this communication, health monitoring covers the following three elements:

   - collection of health data at the Community level and development of Community health indicators. This includes the development of mechanisms for Community data collection, including surveys, as well as the development of agreed definitions and methodologies for Community health indicators.

   - building a capacity for analysis of data obtained from the monitoring of developments in health, disease, other health problems, and health determinants. This includes analysis of the distribution of diseases and disability in human populations and of the factors which influence that distribution.

   - dissemination of information on health and its determinants to enable the Community as well as the Member States to establish priorities, review policies and actions, and assist them in deciding on allocation of resources.

7. Health monitoring is not meant to cover disease surveillance for control purposes which is undertaken with the aim of rapidly deciding on counter-measures and actions to be taken by the competent authorities in order to address acute health problems and control often rapidly evolving situations, especially in the area of communicable diseases. However, disease surveillance systems may provide appropriate input to an overall health monitoring system, especially as regards the incidence and prevalence of specific diseases.

8. Health monitoring at the Community level would cover the areas of public health in which the Commission has already proposed a number of action programmes covering cancer[6], health promotion, information, education, and training[7], drug dependence[8], and AIDS and certain other communicable diseases[9], and would draw from the results of pertinent actions undertaken under these programmes. Moreover, Community health monitoring should also serve to assess the impact on health of Community programmes and other Community policies and also provide a means for comparisons between Member States and between the European Community and other parts of the world.

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[6] OJ No C 139, 21.5.1994, p. 12

[7] OJ No C 252, 9.9.1994, p. 3

[8] OJ No C 257, 14.9.1994, p. 4

[9] OJ No C 333, 29.11.1994 and COM(94), p. 413

9. Whether the impact of the actions taken at the Community and national levels can be properly monitored and evaluated depends, inter alia, on the pertinence and quality of the indicators available. The aim of the action programme proposed in this document therefore is to develop a high-quality, policy-oriented health monitoring system to support the Community and Member States in health policy-making and evaluation. The starting point for such a system is, of course, what already exists in Member States, and what is transmitted by them to international organisations, notably the World Health Organization (WHO) and the Organization for Economic Cooperation and Development (OECD). Based on this, a careful selection has to be made of indicators covering agreed areas of interest, supplemented by new ones as appropriate, and a system developed for the purpose of underpinning the collection of data and making them available to the Member States and the Community.

10. To be able to meet expectations in this area and yield the maximum added value, a Community health monitoring system would have to consist not only of carefully selected Community health data and indicators but also of a network for the collection and dissemination of Community data, mainly using the possibilities offered by telematics. In addition, an integral part of such a system will be the capacity to contribute to the analysis of health and health-related information, to respond to information requests and test hypotheses, and to disseminate, where appropriate, the results of these analyses. An over-riding consideration in all of the work involved is the respect of data protection legislation requirements, and the implementation of appropriate confidentiality and security arrangements.

II. A REVIEW OF EFFORTS ON EUROPEAN HEALTH DATA AND INDICATORS

11. The search for objective measures of the health status of a population has a long tradition in public health and may be traced back to the foundation of demography in the second half of the 17th century. For more than a century, infant mortality and life expectancy at birth have been widely accepted as valid measures of the level of health in a population. It is only a relatively recent development that a wider range of indicators has been introduced to complement the picture, coupled with epidemiological research.

12. This development has been brought about, inter alia, by a growing awareness within the health sector that, as a consequence of the rapid decline in previously important health scourges, in particular infectious diseases, such mortality-based measures could no longer be viewed as sufficient, and by the development and widespread adoption of quantitative measurements in the social sciences and in public health.

13. The growing use of indicators for the formulation, implementation, and evaluation of social policies and programmes has been promoted by the work of the United Nations, particularly its efforts, since the 1950s, to develop a Level of Living Index and design a system of social accounts. The social indicators programme of the OECD has also had substantial impact on the establishment of indicators in OECD countries.

14. As to health indicators, which are usually a constituent part of social indicators, the League of Nations, already in the 1930s, published a comprehensive review of "indices of health".

After the second world war, many initiatives on health indicators were undertaken, especially in the United States.

15. Internationally, the systematic use of health indicators and policy-oriented health information has been promoted by the WHO since the early eighties. In its Health For All strategy, a significant role has been assigned to the monitoring and evaluation of regional, national, and global health strategies. A minimal list of global indicators has subsequently been introduced. In 1984, the WHO's Regional Office for Europe has added to this list regional indicators tailored to the specific needs and priorities in Europe. Countries have been invited to use additional national indicators in keeping with their own needs and capabilities[10]. On the basis of these indicators, WHO regularly undertakes monitoring exercises in order to measure progress in relation to the Health For All targets and to assess its priorities.

16. The OECD has also carried out valuable work on health indicators, especially in relation to indicators on the provision of health care. This work is to some extent complementary to the work of WHO. Finally, a number of specialised European institutions and networks, like the International Agency of Research on Cancer (IARC) in Lyon and the European Centre for the Epidemiological Monitoring of AIDS in Paris, have contributed to the production of valuable health information at the European level, with support from the Community, particularly in relation to relevant programmes and actions in the field of public health.

17. In the first Biomedical and Health research programme (1990-1994), within the third RTD framework programme, research on health systems allowed the setting up of specific disease-related databases and valuable European networks for health data exchange.

18. The Statistical Office of the European Communities (Eurostat) has also collected statistical data on health and health-related issues for a number of years. In particular, a number of health indicators have been selected as part of the global framework for social indicators and social statistics.

19. Significant international experience has already been gathered in the field of health information and the use of health indicators. The Community has played a role in this process, but its involvement needs to be stepped up if an appropriate contribution to ensuring a high-level of health protection is to be made.

III. THE EUROPEAN COMMUNITY AND HEALTH MONITORING

A. A NEW ROLE FOR THE COMMUNITY

20. Member States are becoming more closely interdependent in many areas. In the area of economic integration, this takes place at a fast pace, but also in other areas, such as free circulation, the environment, professional education and research and social provisions, in particular health and safety at work, common approaches to existing problems are

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[10] HANSLUWKA, H.E., "Measuring health of populations-Indicators and Indications," *Social Sciences and Medicine*, 1985, Vol. 20, No. 12, pp. 1207-1224.

increasingly being sought and implemented. The impact of the Community is, in this respect, preponderant.

21. Health is no exception to this. Not only do health problems cross borders, but they appear to be growing more alike in each country. Moreover, European cooperation on health has made important strides and attempts are increasingly being made to find common solutions and to step up the exchange of expertise and the sharing of experience. As a result of such internationalisation, interest in other countries' problems and policies has grown and international comparisons are becoming an important tool in national and Community health policy-making. The Member States of the European Community have over the last decade steadily increased their cooperation in the public health field to cover a wide range of areas, and the Community has played an increasingly important role in this process, especially after the coming into force of the Treaty on the European Union.

22. Community actions implementing Article 129 of the Treaty establishing the European Community must have as objective to make a contribution towards ensuring a high level of human health protection, focus on the prevention of diseases, promote coordination of Member States' policies and programmes and foster cooperation with third countries and international organisations competent in the sphere of public health. The elaboration of such actions in a way that maximises the Community's contribution, and the assessment of these actions to determine whether they have accomplished their objectives, presupposes the existence of quantitative measures and of a system which permits the measurement of the changes in health and its determinants, and the impact on health of policies, programmes, and actions at the level of Member States as well as the Community.

B. RECENT COMMUNITY INITIATIVES IN HEALTH INFORMATION

23. In a number of documents, in particular in the Report on Public Health Policy after Maastricht[11], the European Parliament 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.

24. In the resolution adopted with the report, the European Parliament called on the Commission to establish a European epidemiological investigation unit to collect and examine health data from Member States and to begin work on a "State of Health in the Community" report which will analyse trends and assess the effects of public health policies, as well as the impact of other policies on health. Moreover, it requested the Commission to collect, analyse and disseminate Member State data on notifiable diseases and to work with national and international agencies in these matters.

25. The Commission, in its Communication of 24 November 1993 on the framework for action in the field of public health, identified increased cooperation on standardisation and collection of comparable data on health, and the promotion of systems of monitoring and surveillance, as a prerequisite for the establishment of a framework for supporting and adding value to Member States' policies and programmes, in compliance with the principle of subsidiarity.

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[11] OJ No. C329, 6.12.93, p.375

26. In its resolution of 2 June 1994 on the framework for Community action in the field of public health, the Council stressed the importance of the development of Community health information and indicated 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 on 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.

27. In December 1993, the High-Level Committee on Health, which advises the Commission on health matters and comprises senior representatives of the Health Ministries of the Member States, set up a working party on health data and indicators to assist in the development of a Community health monitoring system. The working party was charged with the following tasks:

- to assess the validity and comparability of health data available in the Community.

- to assess the feasibility of uniform basic data sets for the purpose of monitoring health status and formulating and measuring the impact of prevention policies.

- to examine the conversion of existing health data into effective health indicators for specific measures.

- to define possible actions for further co-operation at Community level in this field.

28. On the basis of the report of the Working Party, which included a comprehensive review of definitions and sources of the available indicators at the European level collected by Eurostat, WHO, and OECD, the High Level Committee adopted a number of recommendations, the main elements of which are as follows:

- sets of Community core and background indicators are necessary as instruments at Community level as well as for national health policy-making;

- the available health data are very diverse as far as comparability and validity are concerned;

- with the necessary resources becoming available, substantial progress can be achieved within a 5-to-10-year period on making uniform basic data sets at Community level to measure health status and the impact of public health policies;

- in some areas the available data can be converted into usable specific indicators. In other areas, however, data do not exist or are inadequate to establish specific indicators of an acceptable quality.

29. The report of the Working Party and the recommendations of the High Level Committee have been used extensively in the preparation of the present communication and the Commission proposals in the field of health monitoring.

C. OTHER COMMUNITY POLICIES AND AREAS OF ACTION

30. Community policies and actions in areas outside public health often have direct and indirect health impacts. In its report on the integration of health protection requirements in Community policies[12], the Commission presented an overview of programmes, actions and instruments having an impact on health.

31. In the area of social policy, health information is mainly linked to questions relative to the follow-up of Member States's policies regarding social protection, particularly with respect to the risk of illness. In its recommendation[13] on convergence of social policies aiming at guiding the policies of the Member States, the Council set, inter alia, the following objectives:

    - to ensure that people legally residing in the Member States have access to necessary health care as well as to measures aimed at disease prevention;

    - to maintain, and if necessary, develop a health care system that is adapted to the changing needs of the population.

32 The Commission closely follows the developments in this area and analyzes and reports on the convergence or divergence of social policies. Regarding health systems, the monitoring of measures taken to try to keep costs reasonable and to evaluate performance also requires the evaluation of the consequences that they may have on the quality of services provided and the equality of access to care.

33 In the area of health and safety at work, sustained efforts have been made at the Community level to obtain harmonised data concerning occupational diseases (EODS) and accidents at work (ESAW). The process which was followed involved the development of similar criteria and methodology for recording statistics in all Member States. When these are put into effect, they are expected to produce a more accurate picture of the extent of occupational diseases and injuries.

34. Within the statistical framework programme 1993-1997, laid down by the Council in its decision 93/464/EEC[14], Eurostat produces statistical data in areas, such as health and safety, employment, living conditions and social protection, as fields of priority action under the sectoral programmes for social policy, for economic and social cohesion and consumer protection. Community statistics in areas such as environment, industry, national accounts and transport are also collected under the statistical framework programme. In addition, Eurostat collects data on certain other social indicators which are of interest to public health. In 1994, a Community Household Panel Survey (ECHP) was launched, covering, inter alia,

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12 COM(95) 196, 29.5.1995

13 Council Recommendation 92/442/EEC, OJ No L 245, 26.8.1992, p. 49

14 OJ No. L 219, 28.8.1993, p.1

demographics, income, labour force participation, education, housing, and certain health aspects.

35. In the area of Trans-European networks, the Commission proposal for a Council Decision on support for the telematic interchange of data between administrations in the Community (IDA)[15] foresees three projects in the field of health, namely CARE (two projects : early warning system and pharmacovigilance) and REITOX (European Information Network on Drugs and Drug Addiction which will link with the European Monitoring Centre for Drugs and Drug Addiction). The two CARE projects retained in IDA are spin-offs of earlier efforts on the European Nervous System (ENS-CARE). Under current IDA plans, CARE-Early warning system (CARE-EWS) work and the work on a pharmacovigilance network, to which the European Medicines Evaluation Agency will be linked, will concentrate over the next two years on further development of the pilot systems between national administrations and the passage to exploitation phase, while strictly adhering to the general system architecture foreseen for IDA.

36. In the area of research and technological development, activities under the third RTD framework programme included research on quality of care, avoidable deaths (deaths that could be avoided by prevention), a European stroke database (EUROSTROKE), harmonisation of health expectancy calculations in Europe, comparison and harmonisation of denominator data for primary health care research in Member States of the European Community, and the establishment of a European Clearing House on Health Outcomes. Concerning equality of access to care according to the level of income, research has been carried out on comparing health care consumption and morbidity for certain groups of individuals (the COMAC Project), the future development of which would benefit from the existence, at the Community level, of indicators on the relationship between income and morbidity. Under Area 6 of the Biomedical and Health research programme[16] (BIOMED 2) within the 4th RTD framework programme, research will focus initially on methodologies linked to health data on demographic changes, methods of evaluating the effectiveness of prevention strategies, and assessment of the socio-economic impact and performance measurement of health policy initiatives including the development of health information systems. Finally, under the fourth RTD framework programme, activities initiated previously on health telematics (ENS-CARE), which involved pilot projects on electronic exchange of health data concerning communicable diseases, statistics, poison control and pharmacovigilance, are to be pursued in certain selected areas.

37. The environment plays an important role in the health of citizens. Appropriate and accurate information on the state of the environment and on emissions and waste disposal into its compartments is indispensible. There is a need, in particular, for data on the concentration of pollutants in the environment in order to estimate the impact of such pollutants on public health. Examples of such data include data on air quality in urban and rural areas and on concentration of dangerous substances in the soil and ground water, in particular from the

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[15] OJ No C 105, 16.4.1993

[16] Council Decision 94/913/EEC of 15 December 1994, OJ No L 361 of 31.12.1994, p. 40

use of pesticides. Moreover, data on the effects on humans from the incorporation of pollutants, and on the pathways for such incorporation are required if sound interventions are to be made. The European Environment Agency has, in its 5-year Work Programme, a project on "Threats to Human Health" which involves an analysis of the current situation and information/data bank linking with the WHO.

38. In the area of transport, the need for information is firstly linked to the problem of achieving accessible public transport for everybody, which requires in turn information on the patterns and geographical distribution of various types of disability, mobility-restricting illnesses, and age-specific health factors, and secondly to road accidents, for which the Council decided to establish a Community database[1], the development of which will serve as a basis for the improvement of information at Community level in this field.

39. As regards consumer protection, efforts to organise and coordinate the collection of data on home and leisure accidents is being pursued in the context of the programme EHLASS[2].

40. The Commission has also recognised the importance of a level playing field of data protection rules as being a necessary pre-requisite to the free exchange of data. In 1990, it proposed a framework directive on the protection of individuals with regard to the processing personal data, with the aim of ensuring the free morvement of such data. This directive, which includes specific provisions on health data, has been adopted on 24.7.95 by the Council and the Parliament. The Commission has also committed itself to applying the principles of this directive to its own data processing.

41. With regard to the Community Agricultural Policy, three information systems (ADNS, ANIMO and SHIFT) are being developed using telematics as essential tools in the Community veterinary control strategy.

42. Finally, in the area of drugs, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) has as its main task to furnish "overall information...on the drug and drug addiction phenomenon". This will involve providing the Community and its Member States with "objective, reliable and comparable information at [the] European level concerning drugs and drug addiction and their consequences". Moreover, through the European information network on drugs and drug addiction (REITOX) data will be collected which will be used, inter alia, in the preparation of a yearly report on the state of the drugs problem.

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[1] OJ No L 329 of 30.12.93, p.63

[2] OJ No. L 331 of 21.12.94

IV. THE PURPOSES AND PRINCIPLES OF A COMMUNITY-WIDE HEALTH MONITORING SYSTEM

43. Health information has been identified in Article 129 as a specific area of action; moreover, as explained above, it has been recognised, in the form of health data and indicators, as a fundamental instrument in the Community policy-making process, and an essential part of a health monitoring system which will be required to serve the following purposes:

- to monitor health and health determinants throughout the Community, and permit comparisons with third countries;

- to facilitate planning, monitoring, implementation, and evaluation of Community programmes and actions;

- to provide Member States with high quality, comparative indicators and information which support and add value to their national health monitoring systems and contribute to the development of national health policies.

44. The development of a health monitoring system should be based on the following principles:

- the system should build on readily available European data and indicators, such as those held by Member States, international organisations, notably the WHO, the OECD, the EMCDDA and the European Environment Agency, European networks, and the Commission. In a first stage, these data will be used for health monitoring and policy appraisal purposes and should also serve as a basis for identifying the inevitable gaps in quality and ways to overcome them, as well as for developing new data and indicators that are considered necessary.

- any unnecessary duplication of work should be avoided. The work already being carried out by international organisations, European networks, and the Commission should be mutually complementary and congruent. On the one hand, existing work of relevance to the Community being carried out by Member States and the relevant international organisations should be consolidated and progressively harmonised, thus minimising the risk of wasteful overlap and competing demands on scarce resources. On the other hand, the health monitoring system should as a matter of priority cover areas of importance to Community programmes and policies which are not yet fully developed or are developed insufficiently.

- the system should not impose unnecessary burdens on Member States which already transmit health data to a number of international organisations, networks, and the Commission. Serving the needs of a Community health monitoring system should therefore not imply Member States having to duplicate work carried out in the context of existing international arrangements.

- available options and possibilities for developing the various parts of the system whether with respect to the choice of health indicators, the extent and quality of coverage, the means used, and the routine or ad hoc analyses to be undertaken, should be carefully assessed with respect to the costs and benefits involved;

- the system should be designed to have as much flexibility as possible so as to be capable of incorporating existing useful elements and of adapting to changes in coverage as well as to changes in the priorities for action, whilst maintaining its characteristics of comparability and progressive harmonisation. Furthermore, it is also important that the collection and distribution mechanisms for health data and indicators are equally flexible and do not demand undue administrative burdens.

45. In establishing a Community health monitoring system, it is important to ensure that the information which should be collected and disseminated is specified in close collaboration with the potential users and suppliers in Member States and at the Community level, and that data protection requirements are fully respected.

V. COMMUNITY HEALTH INDICATORS

46. On the basis of the needs of the proposed and planned programmes and actions in the field of public health, requirements stemming from other Commission policies, the needs of Member States, and the expected developments in health status and determinants, the Commission has selected a number of domains in which indicators would have to be established as part of the Community health monitoring system. These domains are listed in Annex A. It is important to note that data are already being collected in these domains but they have to be carefully assessed with a view to establishing relevant health indicators.

47. Community health indicators would consist of two types: core indicators and background indicators. Core indicators are considered to be those which are essential to Community public health programme actions, and to measuring health status as well as health determinants, e.g., alcohol and tobacco consumption. Background indicators are those linked indirectly to public health but which are nevertheless important for health policy purposes. They include indicators which concern other Community policies. They also include indicators which may be of particular use to Member States but are not essential for Community policy purposes.

48. The indicators, both core and background, to be used in the Community health monitoring system will be selected from those existing at the international level and already reviewed by the High-Level Committee on Health, and those existing at national level but deemed appropriate for Community use; moreover, new ones will have to be created, if necessary. This process will be carried out in close coordination with the Member States and, where appropriate, with the cooperation of international organisations competent in this area. Community indicators would have to be continually evaluated and updated in order to ensure that they fulfil the current needs of the Community and Member States. This may involve developing new indicators and/or reclassifying indicators from background to core, and vice versa.

49. Community indicators would consist of:

- indicators that provide both the Community and the Member States with an instrument for making comparisons between Member States and also facilitate coordination by and among the Member States themselves;

- indicators that facilitate the measurement of health status and major health determinants in the Community, including outcomes and use of resources.

50. Depending on the quality and availability of data needed, Community indicators will fall into the following categories:

- those for which good quality data are readily available in all Member States;

- those for which data are available in all Member States but for which the quality needs to be improved;

- those for which data are not currently available in the Community but which would have to be collected under the Community programme on health monitoring.

A. CORE INDICATORS

51. To support Community action in the field of public health a core set of basic indicators should be developed. These indicators would represent the basic information needed to monitor health status in the Community and would also reflect key public health priorities as defined in the Commission communication on the framework for action in the field of public health[1]. Over time, these indicators could be adapted to reflect changing priorities.

52. Consequently, the core indicators would be divided into the following two inter-related types:

- indicators for measuring health status and determinants of health in the Community;

- indicators for measuring the impact of Community policies and actions in public health.

B. BACKGROUND INDICATORS

53. Since priorities change over time, the health monitoring system should be sufficiently comprehensive and flexible to respond to shifting demands arising from emerging issues. As a means of obtaining the desired coverage and flexibility, a number of indicators, in addition to the core ones, should be established as background indicators. Such indicators are intended to provide both more in-depth information in the areas covered by the core indicators and to cover a wider range of areas.

54. The set of background indicators would include the following four types of indicators:

- indicators that provide additional information on issues raised by the core indicators, including the assessment of relations between health outcomes and health determinants;

- indicators that provide information regarding other Community policies;

- indicators that support public health policies in Member States;

- indicators that provide Member States with information for making comparisons in areas not covered by the core set of indicators.

C. ADDITIONAL INDICATORS

55. In areas where health data are of use only to national and/or regional authorities, coordination of definitions and collection methods will have to be promoted in order to achieve a higher degree of comparability between regions and Member States.

D. A HARMONISED SYSTEM OF STATISTICS ON HEALTH RESOURCES

56. In the light of the recommendations of the High-Level Committee on Health, which emphasised the assessment of the feasibility and cost-effectiveness of developing standardised health resource statistics, the Commission intends to give support to efforts aiming at incorporating such statistics into a future Community health monitoring system. This would provide an important input to the work currently being done at European level on the development of satellite national accounts for health.

VI. METHODOLOGY OF HEALTH DATA COLLECTION AT COMMUNITY LEVEL

57. In developing a Community health monitoring system, a methodology needs to be followed to ensure that the data obtained from the Member States are comparable, i.e., defined in the same manner and of similar (good) quality. In addition, the data must also be timely or they will lose much of their usefulness. Finally, the methodology employed must follow the principles set out in Chapter IV for the establishment of a Community health monitoring system.

58. Avoiding unnecessary duplication of Member States' data collection efforts points in particular to the need of building on existing national databases validated by Member States' authorities. Data held in these databases may have to be supplemented by specific surveys in order to collect data that are not available by other means or that are needed for specific analyses. Such a two-tier approach holds the promise of fast and cost-effective implementation. In addition, this approach ensures the maximum use of existing data and allows Member States to obtain improvements in the comparability and quality of their data. This approach creates, however, a number of methodological questions which must be addressed.

59. In particular, the comparability of existing data from Member States is currently inadequate, because Member States often define their health data and indicators differently. However, comparability may be improved in three ways:

   - creating data dictionaries which could serve to establish correspondences between data defined in different ways;

   - converting national data to Community network definitions according to a commonly agreed set of rules;

- harmonising the definition and collection methods of the health data collected in the Member States.

60. Data dictionaries serve to explain how different Member States define similar concepts. Thus, they provide a way to establish correspondences between data while retaining individual definitions. This approach is likely to be used when it is impossible to either convert or harmonise existing data. In addition, this method may also be employed while conversion and/or harmonisation methods are being developed.

61. Comparability may also be improved by devising and agreeing Community network definitions enabling Member States to convert their data accordingly. This approach improves comparability of data at Community level without requiring Member States to change the definitions they use for their internal purposes.

62. Harmonisation of national data definition and routine collection has the greatest potential for improving the comparability and quality of Community data.. However, in some cases harmonisation may require changes in statutory stipulations or long-established traditions and practices. For this reason, harmonisation is both a difficult and time- and resource consuming process and should therefore be carefully evaluated in each case to assess the costs and benefits involved. While harmonisation of existing data may be seen as a long-term goal, and is being pursued in several areas as mentioned in paragraphs 30 to 35, the need for progress to be made on developing the Community health monitoring system means that recourse should be made, in the short-term, to both data dictionaries and conversion processes.

63. Member States also collect health data through surveys, such as data on self-perceived health status which must be obtained directly from the population, or particular types of health care provider data. The advantages of the survey method are that data are collected at the same point in time and that it allows the establishment of interrelations between the different variables. Survey data could be made comparable by agreeing on the content of present or future health surveys or by agreeing modules or agreed forms of words for questions in existing surveys. Harmonisation in the case of surveys is likely to be less time- and resource consuming, in part because it is easier to harmonise survey questions/instruments and methodologies than elements in existing registries and national databases, which are sometimes linked to statutory requirements, and in part because work has already been initiated in this area.

64 In certain areas, survey information would have to be obtained from Member States which do not currently conduct health surveys. This could be done by developing supplements to other types of national surveys (e.g., labour force surveys, household surveys), which take account of the need for comparable data throughout the Community, or through Community-wide surveys, including EUROBAROMETER surveys.

65. In addition to the health information which can be obtained from Member States' sources, as described above, specific health information may be needed to address the needs of the Community which might require the conduct of specific Community-wide surveys.

66. In addition to determining the data collection method, the frequency with which the data must be collected must also be decided. Data needed for the core indicators should be collected on a regular basis (annually for most) and processed and transmitted rapidly in order to ensure the availability of the most recent data possible. Data needed for the background indicators, however, will be collected at such intervals as are necessary, depending on the nature of the indicator and the usage to which it will be put.

VII. SERVING THE COMMUNITY HEALTH MONITORING SYSTEM

67. As stated previously, European health data are currently collected by the WHO (causes of death), the WHO Regional Office for Europe in its Health for All database, the OECD (health resource data) and by Eurostat. Moreover, data on specific scourges are collected by centres like IARC in Lyon for cancer, the European Centre for the Epidemiological Monitoring of AIDS in Paris, and the EMCDDA in Lisbon for drugs and drug addiction.. In view of this, and in order not to impose unnecessary burdens on Member States, the Commission will take into account the work carried out for, and by, the various European-level operators in the domain of the production, processing, and dissemination of Community data, so as to obtain a judicious division of labour between the various servers of the Community health monitoring system.

68. In any case, a Community health monitoring system has to rely primarily on health data from Member States. At the same time, the system would have to be served by an efficient and cost-effective means for the transmission, sharing, and dissemination of Community health data.

69. There are various means to achieve availability and transfer of health data and indicators. To ensure, however, that the role of the constituent parts of the future Community system is preserved and played to full advantage as regards the means of processing, storage, and rapid transmission of data, these are best accomplished by means of an electronic network of distributed, or disseminated, databases. In such a network, data would be made available by independent data producers (i.e., national administrations and/or institutions under their auspices) in accordance with a set of commonly agreed rules covering data specifications.

70. A network of distributed databases has a number of advantages:

- it is future-oriented, flexible, and less costly compared to traditional collection methods;
- it reduces current duplication of data collection efforts at the international level;
- Member States only have to supply data once (i.e., to the network);
- it does not require a major new administrative structure;
- Member States will be responsible for entering the data into the system. The data can therefore be updated continually; and
- it offers the opportunity to be multilingual.

71. It should be emphasised that a network of distributed databases is desirable not only because of the technical advantages it offers, but also because it maintains the sound practice of doing the work as close as possible to the source. This would also ensure compliance with the principle of subsidiarity.

72. An electronic network of distributed health databases has over the last three years been developed to a pilot level through the ENS-CARE project, which received financial support from the Commission. The establishment of a network of this kind aiming at facilitating the telematic interchange of data between national administrations is the object of the IDA project, which includes health monitoring as one of several sectors to be covered.

73. A network of distributed databases would, therefore, be the preferred method for the purposes of the Community health monitoring system. As such it would have to build on the experience gathered so far from the interchange of certain comparable health data and indicators, and would rely on the infrastructure currently being developed under the IDA programme. The present programme would allow the content of the information in this system to be properly specified with respect to all data and indicators included in the Community health monitoring system. The Commission will encourage the Member States to participate and collaborate closely in the development of a network of distributed databases. Relevant international organisations will be invited to participate as appropriate.

VIII. ANALYSES

74. Measuring health status and health determinants is only a first step, under the Community health monitoring system to be put in place through this programme, towards contributing to ensuring a high level of health protection. To achieve maximum usefulness, the information contained in the system must be fully utilised. This will require a variety of analyses to be performed, some annually, some periodically, and others on an ad-hoc basis.

75. On an annual basis, it will be necessary to monitor a set of health indicators which together provide an overall picture of health in the Community. This will help in the elaboration of Community health status reports. In addition, it will be necessary to analyze indicators by population subgroups (e.g., sex- and age-group, residence, socio-economic status) in order to ascertain whether there are unacceptable differences across subgroups, and problem areas, and to make appropriate inputs to the planning of programmes and actions which address such problems.

76. The indicators will also have to be analyzed with respect to trends over time to determine whether or not the trends are reflecting the objectives desired by policy.

77. An important task will be to identify the major sources of mortality and morbidity in the Community. This will also include identifying variations in mortality and morbidity by region and population subgroup. Such identification will then have to be supplemented by analysis of the determinants of these sources of morbidity and mortality in order to develop effective policy tools. In this context, it may be necessary to identify and analyze national health policies that have been shown to be effective.

78. Analyses of the relationship between various health determinants will also be important and may require the fielding of ad-hoc surveys to obtain the necessary information if the latter is not routinely available. Whilst fully respecting data protection legislation requirements, as stated at the outset, it would be possible to use data at the level of the individual in order to validate, in the context of such analyses, existing and proposed health indicators. However, the data used should not be such as to make possible the identification of any particular individual.

79. Having valid indicators will also contribute to improving the information available for epidemiological studies of the major causes of mortality and morbidity. This will be of use not only in the design of new health policies but also in the evaluation of past and current policies.

80. The Community health monitoring system will also assist in the analysis of the health impact of other Community policies, as stated in the Commission communication on the framework for action in the field of public health, help in identifying conflicting requirements, and contribute in cost-benefit evaluations of particular programmes and actions.

81. The analyses described above will have to be carried out in a coordinated manner, requiring the contribution of and coordination with several actors, including specialised European agencies and centres, such as the EMCDDA and the European Environment Agency. This type of activity will require the further development of an appropriate administrative capacity at the Community level capable of conducting high-quality analysis and responding timely to diverse requests and queries.

IX. PROPOSED ACTIONS FOR A FIVE-YEAR PROGRAMME

82. The Commission believes that the work on establishing a Community health monitoring system covering three strands of action, namely the establishment of Community health indicators, the development of a Community-wide network for data collection and dissemination, and the capacity for and conduct of analyses, should be initiated by means of a five-year Community action programme. The actions involved are described below.

A. ESTABLISHMENT OF COMMUNITY HEALTH INDICATORS

83. A Community set of health indicators is proposed to be established, in the domains set out in Annex A, consisting of:

- a sub-set of core indicators for the monitoring of Community actions in public health, and

- a sub-set of background indicators for monitoring other Community policies and for providing Member States with a better means for making international comparisons.

84. The establishment of the indicators would involve both identification and analysis of existing indicators at Member State and European level, in particular as regards quality and coverage, as well as the selection and/or creation of specific Community indicators, and the development of definitions for these indicators.

85. The Community health indicators will be so selected as to provide the necessary instruments for:

- monitoring areas of Community priority;

- monitoring the impact of action programmes on specific health problems, e.g., AIDS and other communicable diseases, cancer, drugs, accidents, health promotion, rare diseases;

- monitoring developments in health status and its determinants in the Community.

86. The establishment of Community indicators would have to take account of:

- user needs and specifications;

- inventories of the data currently available in Member States;

- definition and methodologies of collection used in Member States, in the Community, and in relevant international organisations;

- proposals for definitions and quality norms, such as validity, reliability, and comparability.

87. The Commission intends to ensure that the set of Community indicators is kept under review to ensure that it is capable of responding, if required, to new priorities and changing needs.

88. The Commission will also support the assessment of the feasibility and cost-effectiveness of developing health resource statistics, including an examination of the possibility of using satellite national accounts as a framework.

B. DEVELOPMENT OF A COMMUNITY-WIDE NETWORK FOR DATA COLLECTION AND DISSEMINATION

89. In order to make Community health data and indicators readily available to Member States, the Commission intends, as the best means of health data collection and dissemination, to promote the establishment of a Community-wide network, the backbone of which relies on telematics, and which links the competent authorities in the Member States, and would assist, under this programme, in the content specifications for the network using distributed databases. The relevant work would take place in parallel with the effort under the IDA and the G-7 health projects. However, as the electronic network for interchange of data may not be fully operational in the early stages of the programme, other appropriate mechanisms may, as necessary, be considered as a stop gap for the purposes of data collection and dissemination.

C. ANALYSES

90. Each year, the Commission publishes a report on the health status of the Community. This health status report will draw, as appropriate, from the health data and indicators collected through the Community health monitoring system..

91. The Commission intends to draw on information generated through the system in analysing and reporting on selected health determinants (e.g., smoking, alcohol consumption) and comment, if appropriate, on the need for action. Similarly, the Commission intends to use data available through the system in analysing the impact on health of Community public health programmes and actions, as well as the impact of other policies.

92. Finally, the Commission intends to make available information material on matters arising out of this work which may serve the needs of Member States, international organisations, health professionals and bodies, interest groups, and the general public.

X. CONSULTATION, ASSESSMENT, AND REPORTS

A. CONSULTATION AND PARTICIPATION MECHANISMS

93. In seeking to establish a Community health monitoring system through an initial 5-year programme, the Commission will rely on close collaboration with the Member States in all questions relating to reporting, conversion, harmonisation, description of data and selection of specific indicators. Most of the data needed for the establishment of indicators relevant to a Community health monitoring system will have to be made available from Member States sources. Moreover, much of the work related to the harmonisation, conversion, and description of data must be carried out by the competent authorities in Member States.

94. In implementing the programme, the Commission intends to have recourse to a Committee made up of Member States experts, representing both users and producers of health information. In the domain of Community health and safety statistics, existing Committees, such as the Statistical Programme Committee[19], and the European Advisory Committee on statistical information in the economic and social spheres[20] (CEIES) will be associated to the work as appropriate. Furthermore, other existing Community committees, such as the EHLASS Committee[21], and the Programme committee of the Biomedical and Health research programme[22], will be associated to the work as appropriate.

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[19] Council Decision 89/382/EEC, OJ No L 181, 28.6.89, p. 47

[20] Council Decision 91/116/EEC, OJ No L 59, 6.3.91, p. 21

[21] Council Decision of 7 December 1994, OJ No L 331 21.12.94, p.1

[22] Council decision 94/382/ EC, OJ No L 361, 31.12.94, p 42

95. In view of the important role of the WHO and the OECD in the development of international health information, the Commission will maintain appropriate links with them. It also intends to foster cooperation in this field with other international organisations and with third countries.

96. Where appropriate, the Commission will encourage participation of professionals, non-governmental organisations engaged in health monitoring and European networks for the exchange of health data by drawing upon their experience in specific areas when initiating and implementing actions on the development of health data and indicators under the proposed programme.

B. EVALUATION REPORTS

97. Assessment of the programme will be provided in two reports:

- a mid-term report to the Council, the European Parliament, the Economic and Social Committee, and the Committee of the Regions. The purpose of the mid-term report is to ensure that the Community institutions and, through them, all the parties concerned, are kept fully informed on the progress of the actions undertaken in the context of this action plan. It will include information on the projects supported under the different actions.

- a final report on the implementation of the programme, which will include an evaluation of the actions undertaken, will be submitted to the above-mentioned institutions by the Commission after the completion of the programme.

C. GENERAL INFORMATION ACTIVITIES

98. In addition to the information activities contained in the programme, the Commission will ensure that the general public and all parties concerned have access to reports on the actions, studies, and assessments undertaken.

ANNEX A

Domains in which Health indicators may be established under a future 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

4. Physical activities

5. Diet

6. Sexual behaviour

7. Other health promotion-related activities

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 utilisation
   - 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 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

Proposal for a

<u>EUROPEAN PARLIAMENT AND COUNCIL DECISION</u> 95/0238 (COD)

adopting a programme of Community action on health monitoring in the context of the framework for action in the field of public health

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EXPLANATORY MEMORANDUM

1. In its Communication of 24 November 1993 on the framework for action in the field of public health, the Commission defined a framework for future Community action in order to attain the objectives on health protection laid down in Articles 3(o) and 129 of the Treaty establishing the European Community. The role of the Community is identified as underpinning the efforts of the Member States in the public health field, assisting in the formulation and implementation of objectives and strategies, and contributing to the provision of health protection across the Community, setting as target the best results already obtained in a given area anywhere in the Community.

2. 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 Community level. There is also a need to promote the sharing and dissemination of relevant information. Based on the criteria laid down in the above-mentioned Commission communication, health monitoring at Community level, and in particular health data and indicators, has been identified as an essential means for the acquisition and sharing of such knowledge, and, therefore, as a priority for Community action.

3. The European Parliament and the Council have also, in a number of resolutions, stressed the importance of having adequate and valid health data to map out health situations and trends, and to assist in the development of Community and Member States' actions in the field of public health. The European Parliament underlined, in particular, the need for collection and examination of health data from the Member States and the assessment of the effects of various policies on health. Similarly, the Council, has emphasised that it is necessary to have an accurate assessment of health needs, an estimation of avoidable deaths, and an evaluation the effects of socio-economic factors on health.

4. The efforts of the Commission in this area have concentrated so far on the needs of the Community and the Member States, and on identifying ways to obtain maximum value from the involvement of the Community. To this end, the Commission has consulted experts in this field and, with the assistance of Member States' representatives, conducted a review of existing health data and indicators at the Community level, their sources, coverage, and importance, and obtained advice and recommendations on the development of a Community action programme on health monitoring.

5. The overall aim of the proposed 5-year action programme is to develop a high-quality, policy-oriented health monitoring system. This system should allow the measurement of health status and health determinants throughout the Community. It should provide Member States with indicators and data for supporting their national health policies and should also facilitate the planning, monitoring, and evaluation of Community programmes and actions, in compliance with the principle of subsidiarity.

6. The Community health monitoring system would also involve the development of a network for the purpose of collection and dissemination of health data and indicators, in particular using the possibilities offered by telematics, and the development of a capacity to undertake the analysis of health data and the production of reports, reviews and other health information material.

7. The principles underlying the development of such a system include building on readily available European health data and indicators, such as those held by Member States, international organisations, and European networks, avoiding both any unnecessary duplication of work and the placing of unnecessary burdens on Member States which already transmit health data to a number of international organizations and networks, assessing the costs and benefits of developing the various parts of the system, and allowing as much flexibility as possible to permit adaptation whilst encouraging data comparability and progressive harmonisation.

8. The health indicators to be collected through the Community health monitoring system may be divided into two types: core indicators and background indicators. Core indicators are those indicators which are essential to Community health policy. These include data on health status as well as on health determinants, e.g., alcohol and tobacco consumption. Background indicators are those indicators which are linked indirectly to public health but which are nevertheless important for health policy purposes. As priorities are likely to change over time, the indicators to be collected (both core and background) will have to cover a wide range to permit a good understanding of the interplay of various factors impinging on health and enable anticipation of future problems.

9. The Commission attaches major importance to making Community health information readily available to Member States. Therefore, the Commission will, as the best means of health data collection and dissemination, promote the development of a Community-wide network using in particular, telematics, which would link the competent authorities in the Member States. Such a system would minimise the burden of data collection imposed on Member States, provide easy and timely adaptation and access to the information placed on it, and be more cost-effective compared to alternative collection methods.

10. Under the ENS-CARE programme of the third framework programme on Research and Technological Development, the infrastructure for such a system has already been developed in apilot project. This infrastructure is now being further developed under the project of telematic interchange of data between administrations (IDA) and under the Information Society health projects of the G-7 Member States. Under the proposed 5-year programme on health monitoring, the Commission will encourage the Member States to participate and collaborate closely in the content specifications of this system, which will use distributed databases as its backbone, and would promote participation of competent international organizations and third countries as appropriate.

11. The Community health monitoring system will provide an opportunity for a variety of analyses to be undertaken on a regular or on an ad hoc basis. These analyses could include health status and health trends reports, analyses of specific health problems and health determinants, and analyses of the health impacts of other policies. The dissemination of relevant information material will be supported.

12. Assessment of the action programme on health monitoring will be provided in two reports: A mid-term report reviewing progress and a final report on the implementation of the programme. These reports will incorporate information on Community financing in the various fields of action as well as the results of the evaluations and will be transmitted to the Council and the European Parliament, as well as to the Economic and Social Committee and the Committee of the Regions.

ADDENDUM
with respect to the principle of subsidiarity
to the explanatory memorandum of 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 fields of
public health.

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a. Quels sont les objectifs de l'action envisagée par rapport aux obligations pesant sur la Communauté?

In accordance with Article 129 of the Treaty establishing the European Community, the Commission is presenting proposals for adoption by the European Parliament and the Council of incentive measures, having as their objective to contribute towards ensuring a high level of human health protection by encouraging cooperation between the Member States, lending support to their action, promoting coordination of their policies and programmes, and fostering cooperation with third countries and the competent international organisations in the sphere of public health. The objective of the present proposal by the Commission is the development of a health monitoring system through a 5-year programme of action which, through the full participation of the Member States in its design and implementation, would permit their mutual cooperation and coordination in collecting, processing and sharing health data and indicators necessary for measuring the impact of health policies, health status and trends and health determinants, both at the Community and Member State level, thus permitting a better planning and implementation of their actions aiming at ensuring a high-level of human health protection.

b. L'action envisagée relève-t-elle d'une compétence exclusive de la Communauté ou d'une compétence partagée avec les Etats membres?

The proposed decision for a programme of action on health monitoring, pursuant to Article 129 of the E.C. Treaty, comes under the mixed competence of the Community and the Member States.

c. Quelle est la dimension communautaire du problème?

The situation at present is that neither the international organisations competent in the sphere of public health, nor the Community or the Member States possess appropriate and sufficient data and indicators about health status and the impact of health actions and policies.
The proposed programme sets up a series of mechanisms which will facilitate the gathering

and analysis of data at Community level and also be of assistance to Member States in information collection and evaluation of health data and indicators.

d. Quelle est la solution la plus efficace par comparaison entre les moyens de la Communauté et ceux des Etats membres?

The proposed programme of action involves the development of a health monitoring system using as a basis what already exists at the European level on health data and indicators, including those held by Member States. international organisations, and European networks,and building on it while avoiding any unnecessary duplication of work by carefully selecting and checking with the Member States the data and indicators needed, and by associating to this work the international organisations and networks to which the Member States already transmit data.

e. Quelle plus-value concrète apporte l'action envisagée de la Communauté et quel serait le coût de l'inaction?

The actions to be implemented under the proposed programme will yield added value in a number of ways.

1.They will facilitate the production of health data and indicators, not currently existing, which are valuable in the assessment of Community programmes and actions in the field of health.

2.They will assist in the development of more accurate. comparable and compatible health data and indicators at national level. This will enable better comparisons to be made and should make it easier for Member States to exchange and share important information.

3.They will lead to the establishment of a network for the exchange of data and indicators and this will be undertaken in the framework on the Community programme in the Interchange of Data between Administrations (IDA).

4 They will enable the production of comprehensive and detailed reports on health status and trends and on the impact of health policies. Existing reports on such matters are generally not of a high enough quality since the required data and indicators are not available. The programme is intended to support the production of these.

In the absence of the proposed programme of action and the development of the high-quality information and indicators that is its aim, neither the Community nor the Member States will have a fully adequate basis on which to plan future health policies and programmes and evaluate those which currently exist. Controlling the rising costs of health is a central issue across the Community. The absence of accurate information and indicators on health status and health activities makes it all the more difficult to address this issue, and to achieve a high level of health protection efficiently and effectively.

f. Quelles modalités d'action sont à la disposition de la Communauté?

The action envisaged in the area covered by the Commission proposals can only be undertaken by a European Parliament and Council decision adopting incentive measures, that is by the financial support of the activities contained in the 5-year programme.

g. Une réglementation uniforme est-elle nécessaire ou suffit-il d'une directive posant des objectifs généraux en renvoyant l'exécution au niveau des Etats membres?

There is no need for regulatory provisions in this matter; the actions envisaged by the proposed programme aim at the development of a health monitoring system which requires cooperation of the Member States and lending support to their action. According to Article 129, no harmonisation measures can be taken in this respect.

Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DECISION 95/0238 (COD)

adopting a programme of Community action on

health monitoring in the context of the

framework for action in the field of

public health

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 according with the procedures referred to in Article 189b of the Treaty,

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1 OJ No

2 OJ No

3 OJ No

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[4] 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;

3. Whereas, the European Parliament, in its report on public health policy after Maastricht[5], 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;

4. Whereas the Commission, in its Communication of 24 November 1993 on the framework for action in the field of public health[6], identified increased cooperation on standardisation and collection of comparable/compatible data on health, and the promotion of systems of

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[4] OJ No. C174, 25.6.1993, p.1

[5] OJ No. C329, 6.12.93, p.375

[6] COM(93) 559 final

health monitoring and surveillance as a prerequesite 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 multi-annual Community programmmes in the field of public health;

5. Whereas in its resolution of 2 June 1994[7], 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, 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;

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;

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[7] OJ No. C165, 17.6.94, p.1

8. Whereas in its Decision on the framework programme for priority actions in the field of statistical information 1993 to 1997 the Council[8] 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[9] in its Decision adopting a specific programme on research and technological development, including demonstration, in the field of biomedicine and health (1994-1998) 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;

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;

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8 OJ No. L 219, 28.8.93, p.1

9 OJ No L 361, 31.12.94, P.40

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;

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 organisations, so as to avoid unnecessary duplication of work;

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;

15. Whereas a Community health monitoring system should be capable of encouraging and assisting in the production of analyses of health status, trends, and health problems throughout the Community, and in the availability and dissemination of health information;

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;

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, 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 when, by reason of their scale or effects, it may be better carried out at Community level;

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 specialised 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 organisations and with third countries should be fostered;

21. Whereas it is important that the Commission ensure implementation of the 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 organisations competent in this field should be safeguarded and further developed;

24. Whereas unnecessary duplication of effort should be avoided by the joint development of methodologies, comparison and conversion criteria and techniques, progressively harmonised 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,

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 comparisions 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:

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.

2. The Commission shall cooperate with institutions and organisations 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.

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.

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".

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 organisations 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 harmonisation 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.

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 programme, 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 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. 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.

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.

Done at Brussels,

For the European Parliament	For the Council
The President	The President

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ANNEX

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 harmonised 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.

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.

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 co-operation 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 standardised health resource statistics with the aim of including them in a future 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 the 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.

9. Support for the analysis and evaluation of the impact of Community actions and programmes in 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.

FINANCIAL STATEMENT

1 TITLE OF OPERATION

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

2 BUDGET HEADING INVOLVED

B3-4306: Health data and indicators

3 LEGAL BASIS

Article 3(o) and Article 129 of the Treaty establishing the European Community.

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.

4 DESCRIPTION OF OPERATION

4.1 General objective

Implementation of a programme aiming at contributing to the establishment of a Community-wide health monitoring system, in particular by the development, availability and dissemination through a network of health data and indicators, and to the establishment of a capacity for analysis, evaluation, and comparisons. Both the European Parliament and the Council have stressed the importance of having sufficient and relevant information as a basis for the development of Community actions in the field of public health. The European Parliament has called on the Commission to collect and examine health data from the Member States and analyse trends and assess the effects of public health policies as well as the impact of other policies on health; and the Council has, in several acts, and most recently in its resolution from 2 June 1994 on the framework for Community action in the field of public health, stressed the importance of the development of Community health data and indicators.

The aim of the proposed action programme on health data and indicators is to contribute to the development of a high-quality, policy-oriented health monitoring system. This system should serve three purposes: 1) to enable measurement of health status, trends and determinants throughout the Community; 2) to facilitate the planning, monitoring, and evaluation of Community programmes and actions, and 3) to provide Member States with high quality, comparative health indicators and data which add value to their national health information systems and thus support the development of national health policies, whilst fully respecting the principle of subsidiarity.

Measurement of health status, trends and determinants will be made possible by the development of core and background Community health indicators, whereas the provision of information to

Member States will require the development of a mechanism for the collection and dissemination of Community health information.

<u>The method for achieving these objectives</u> consists of providing support for the establishment of mechanisms for collaboration among Member States, the Commission, and relevant international organisations in order to assess the quality and coverage of existing health data and indicators at the Community level and at the level of Member States and to define a set of core and background Community health indicators; providing support for the development of a network with agreed procedures and data specifications necessary for effective and reliable exchange of information using, as the principal means, an electronic network already under development as part of a wider Community project on interchange of data between administrations; and providing support for comparative analyses and reporting on health status and determinants and the impact of policies.

4.2 Period covered and arrangements for renewal or extension

- 5 years: 01.01.1997 to 31.12.2001
- Report on implementation to be transmitted to the Council and European Parliament during the third year of the programme indicating the need for any modifications, if any.
- Report to the Council and European Parliament after completion of the programme with conclusions on renewal or need for extension or revision of actions.

5 CLASSIFICATION OF EXPENDITURE OR REVENUE

Non-compulsory expenditure

Differentiated appropriations

6 TYPE OF EXPENDITURE OR REVENUE

Subsidy for joint financing with other sources in the public and/or private sector (not exceeding a certain percentage of the total cost of the proposed projects).

The level of funding granted depends on the scope of the measure to be financed and on the extent to which the action programme is reflected in the various activities planned.

Such funding will not exceed 70% of the total budget earmarked for the proposed projects except in the case of networks and work ordered and of direct use to the Commission, where the subsidy may amount to 100%.

7 FINANCIAL IMPACT

7.1 Method of calculating the total cost of operation (definition of unit cost)

The method of calculation is the result of experience acquired in previous activities related to health data and indicators such as the European System of accidents at work statistics (ESAW) and projects under ENS-CARE. The specific cost estimates are based on the assumption that half of the activities to be undertaken under this programme will require 100 percent funding while the other half will require 50 percent funding and that the activities to be undertaken will involve most or all Member States. A total amount rounded off to ECU 13.8 million during the period 1997-2001 is deemed necessary for these activities. The annual allocations will be decided in accordance with the normal budgetary procedures.

7.2 Itemized breakdown of cost (in ECU million)

Objective	Action Area	YEARS					
		1997	1998	1999	2000	2001	TOTAL 1997-2001
Community Health Data and Indicators		Indicative programming					
	Identification, review, and critical analysis of existing data and indicators and assessment of future needs	0.7	0.3	0.1	0.1	0.1	1.3
	Creation of a set of Community health indicators	0.2	0.3	0.2	0.1	0.1	0.9
	Development of routine collection of comparable, progressively harmonised data in Member States (including data dictionaries, conversions and harmonisation of definition and collection methods	0.2	0.3	0.4	0.5	0.5	1.9
	Elaboration of specific surveys and modules or agreed questions in existing surveys	0.1	0.2	0.4	0.6	0.7	2.0
	Cooperation with international organizations	0.1	0.1	0.1	0.1	0.1	0.5
	Support for the development of standardised health resource statistics	0	0.1	0.1	0.1	0.1	0.4

network development	Development of data specifications and procedures to be used in networking, focusing on Community-wide electronic interchange of data	0.7	0.7	0.8	0.8	0.8	3.8
Analysis and reporting	Development of a capacity for analyses, including methodologies and tools	0.2	0.2	0.2	0.2	0.2	1.0
	Support to the analysis and evaluation of the impact of Community actions and programmes in public health	0	0.1	0.2	0.3	0.4	1.0
	Support to the production and dissemination of reports and other information material on health status and trends, health determinants, and the impact of other policies	0.1	0.2	0.2	0.2	0.3	1.0
	TOTAL	2.3	2.5	2.7	3.0	3.3	13.8

7.3 Indicative schedule of appropriations (in ECU million)

	1997	1998	1999	2000	2001	TOTAL
Commitment appropriations	2.3	2.5	2.7	3.0	3.3	13.8
Payment appropriations						
1997	1.15					1.15
1998	0.81	1.25				2.06
1999	0.34	0.88	1.35			2.57
2000		0.37	0.95	1.5		2.82
2001			0.4	1.05	1.65	3.10
Subsequent years				0.45	1.65	2.10
TOTAL	**2.3**	**2.5**	**2.7**	**3.0**	**3.3**	**13.8**

8 FRAUD PREVENTION MEASURES; RESULTS OF MEASURES TAKEN

The grant application forms will require information on the identity and nature of potential beneficiaries so that their reliability can be assessed in advance.

Fraud prevention measures (checks, intermediate reports, final report) are included in the agreements or contracts between the Commission and beneficiaries. The Commission will check reports and ensure that work has been properly carried out before intermediate and final payments are made.

In addition, spot checks are carried out by the Commission to verify how funds have been used. Checks have already been carried out in other public health budget lines in relation to the financial years 1991, 1992, 1993, and 1994 and have shown their effectiveness.

9 ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

9.1 Specific and quantifiable objectives;

The Community measures aim at establishing a Community health monitoring system by the accomplishment of the following specific objectives:

- the establishment of a set of Community (core and background) health indicators which can be used to monitor health in the Community, which can facilitate planning, monitoring and evaluation of Community programmes and actions, and which can provide added value to Member States' own health information systems and thus support the development of national health policies;
- the establishment of content specifications for a network for the purpose of collection and dissemination of the health data and indicators, mainly using telematics;
- the establishment of a capacity to undertake analyses, and support to the preparation and dissemination of reports on health status, trends and determinants and the impact of policies.

Target Population

1. Competent health authorities of the Member States, at national, regional and local level and competent international organisations;
2. Health professionals, health epidemiological and statistical services, health and medical associations, academic institutions, especially schools of public health (especially for the first and third objectives);
3. NGO's and other bodies interested in health matters, and the public in general (third objective).

9.2 Grounds for the operation

Health information is specifically mentioned in Article 129 as an area to which Community action should be directed. The Council (Resolution of the Council and the Ministers for Health meeting within the Council of 27 May 1993 on future action in the field of public health, OJ No C 174, 25.6.1993 p.1; Council Resolution of 2 June 1994 on the framework for action in the field of public health OJ No C165, 17.6.1994, p.1), the European Parliament (Report and Resolution of the European Parliament on public health after Maastricht OJ No C 329, 6.12.93, p.375), and the Commission (Communication on the framework for action in the field of public health, COM (93) 559final of 23.11.93), have identified health data and indicators as a fundamental instrument in the Community policy-making process and an invaluable tool in supporting Member States' policies, and as an essential part of a health monitoring system which will serve to monitor health and health determinants, and permit comparisons to be made and facilitate the planning, monitoring and implementation of actions.

The proposed 5-year programme is to develop such a health monitoring system to support the Community and the Member States in health policy-making and evaluation, to permit Member States to carry out meaningful comparisons and to assist them in allocating

resources to the various problem areas more effectively. In accordance with the principle of subsidiarity, such a system would have to be developed at Community level since it only can serve the needs of the Member States both with regard to information in support of their national policies and with regard to their role in Community policy-making. In view of the scale of the operation involved, i.e. comparable health data and common indicators, and network creation and development linking competent authorities in all Member States, the pertinent activities can only take place at Community level.

As regards the intervention methods and the allocation of funds, the following will apply:

- specific application of the principle of subsidiarity when identifying measures to be undertaken and co-financed;
- identification and selection of projects for co-financing in the fields of health monitoring. These projects will be selected and implemented, where necessary, with the assistance of national coordinating committees that may be established in the Member States, with participation of persons and bodies involved in the production and use of health data and indicators;
- the concept of added Community value, which will continue to be realised in particular through the coordination of national measures, the dissemination of information and experiences, the establishment of priorities, the development of networking as appropriate, selection of European projects and the motivation and mobilisation of all involved.

  Two methods will be employed to implement the programme. One is to support projects carried out in Member States and at the Community level. The selection of priority projects is based largely on general and intermediate objectives, and implementation of the measures themselves depends on the quality and effectiveness of projects submitted to the competent department during the course of the year. The other is to undertake specific activities necessary to achieve the objectives of the programme, which will be fully financed by the programme.

The selection criteria for projects are as follows:

- Compatibility with the objectives and conformity with at least one of the established objectives;
- Examination of the "added Community value" of the projects (transnational participation, development of a model applicable in other Member States, information usable in other Member States, etc.);
- Presumed effectiveness and profitability;
- Clarity and justification of requirements;
- Relevance of selected methodology;
- Organizational competence and experience;
- Suitability of budget for objectives;
- Support for projects from national partners;
- Objective assessment;
- Opinion of the advisory committee involved;

9.3 Monitoring and evaluation of the operation

9.3.1 Monitoring of the operation

Monitoring at the Community level is to be carried out by the Commission, which will submit a report half-way through the implementation of the programme, and a final report after its completion to the Council, the European Parliament, the Economic and Social Committee, and the Committee of the Regions, drawing from national reports as well as evaluations of the actions under the programme and of individuals projects.

9.3.2 Evaluation

Evaluation will be by means of:

- An evaluation of the main measures and of subsidised projects involving, where necessary, the participation of independant experts;
- An overall report on the quality and effectiveness of projects implemented under the action plan, to be submitted by the Commission to the other Community institutions after completion of the programme.

Performance indicators selected for this evaluation:

- Evaluation of projects by Commission officials and/or those cooperating with them;
- Analysis of intermediate reports on measures scheduled and financed, allowing a shifting of emphasis where possible;
- Impact studies by external bodies
- Relevance of the methodology used by organizers;
- Suitability of the budget for the objectives;
- Skills and experience of bodies;
- Dissemination of results;

Evaluation procedures and intervals:

- Drawing up of intermediate and final reports on the various measures undertaken in the field;
- Development of a "standard" evaluation form for the measure, to be forwarded by the beneficiaries with their final reports, and checking of these documents by officials either at the Commission or in the field.

10 ADMINISTRATIVE EXPENDITURE (PART A OF THE BUDGET)

Actual mobilisation of the necessary administrative resources will be conditioned by the Commission's annual decision on the allocation of resources, having regard in particular to additional staff and funds provided by the budgetary authority.

10.1 Impact on the number of employees

Types of employees		staff carrying out action		source of employee		duration
		permanent employees	temporary employees	from within DG or service	supplementary staff	
Officials or temporary agents	A B C	1 1 1	0	1 1 1	0 0 0	
Other resources						
Total		3	0	3	0	

10.2 Financial impact of supplementary staff

10.3 Increase in other running costs arising from the action

Budget line	Amounts	Method of calculation
Meetings A2510	231,000	*2 meetings of advisory committee, 2 reps./Member State 2 x 30 x 770 ecu x 5 years

The resources necessary to cover the expenditure below for the 5-year period will be obtained by re-deployment of existing financial resources and the use of supplementary resources will not be required.

a) Personnel Expenses (Title A1, A2 and A5)
3 x 100,000 ecus x 5 years = 1,500,000 ecus

b) Operational Expenses

- Expenses for meetings (A-250)
  2 meetings x 15 experts x 879 ecus x 5 years = 131,850 ecus
- Expenses for travel (A-130)
  24 missions Brussels-Luxembourg x 5 years = 240,000 ecus
  60 missions to Member States x 5 years = 300,000 ecus

c) Total: 2,171,850 ecus

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