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**COMMUNICATION FROM THE COMMISSION TO THE COUNCIL,  
THE EUROPEAN PARLIAMENT, THE ECONOMIC AND SOCIAL COMMITTEE  
AND THE COMMITTEE OF THE REGIONS**

**on the health strategy of the European Community**

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**Proposal for a**

**DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**adopting a programme of Community action in the field of public health (2001-2006)**

**(Presented by the Commission)**

## EXECUTIVE SUMMARY

People attach great priority to their health. They expect to be protected against illness and disease. They demand that their food is safe and wholesome, and that the products and services on the market meet high safety standards. They want to bring up their children in a healthy environment and they expect their workplace to be safe and hygienic. When travelling within the European Community, they need access to reliable and high-quality health advice and assistance. In all these areas public authorities in Member States have a responsibility to ensure that these concerns are reflected in their policies. The Community, also, has a vital role to play through the obligations placed on it by the Treaties.

This Communication sets out the Community's broad health strategy - how it is working to achieve a coherent and effective approach to health issues across all the different policy areas. A key element of this is a new public health framework which includes the attached proposal for a decision of the European Parliament and of the Council for a programme of Community action in the field of public health.

The framework will enable the Community to respond more effectively to its obligations by setting out clear objectives and policy instruments. This is particularly important in the light of a number of factors:

- The expectation of the public that the Community should act to ensure that their health is protected;
- The strengthening of the EC's obligations in relation to public health in recent years, especially through successive changes to the Treaty;
- The emergence of new health challenges and priorities, especially related to enlargement of the EU, increased demands on health services and demographic change;
- The experience of implementing the current public health actions within the framework put in place in 1993;
- The views of the other Community Institutions, especially the European Parliament and the Council, that a new approach is necessary to address future challenges.

The Communication takes full account of the extensive consultations on the Commission's Communication of April 1998 on the development of public health policy in the European Community which confirmed the need for a more ambitious Community health strategy. The Treaty objectives on public health set out in Articles 3(p) and 152 are central to this strategy.

The public health programme focuses on three priorities:

(1) Improving health information and knowledge

A comprehensive health information system will be put in place which will provide policy makers, health professionals and the general public the key health data and information that they need.

(2) Responding rapidly to health threats

An effective rapid response capability will be put in place to deal with threats to public health, for example, arising from communicable diseases. The integration of the EU based on the principle of free movement increases the need for vigilance.

(3) Addressing health determinants

The programme will help to improve the health status of the population and reduce premature deaths in the EU by tackling the underlying causes of ill health, through effective health promotion and disease prevention measures.

The public health programme is a key initiative which will provide significant added value while reflecting the Treaty provision that Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

In addition to the public health programme, the new framework also encompasses other legislative measures. These include the possibility of harmonising measures in the veterinary and phytosanitary fields, in the area of standards of quality and safety of organs and substances of human origin and in relation to blood and blood derivatives.

Moreover, it is intended to set up a new mechanism, the European Health Forum, to give the public health community at large an opportunity to play a role in the development of health policy.

The EU's competence in health is not confined to specific public health actions. There is a specific requirement that "a high level of human health protection shall be ensured in the definition and implementation of *all* Community policies and activities". This means that proposals in other key areas of Community activity (internal market, social affairs, research and development, agriculture, trade and development policy, environment, etc.) should actively promote health protection. The new health strategy therefore includes a number of specific measures to give effect to this requirement, for example by improving coordination arrangements and by demonstrating how activities are taking account of the potential impact on health.

The Community's health strategy presented in this document, is an important and timely initiative. It will enable the Community to play fully its part in health and to add value to Member States' actions. By so doing it represents an effective and realistic response to the legitimate expectations and concerns of the public.

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## 1. INTRODUCTION

Health is a priority for the general public.

How long people live, how healthy they are and which illnesses they get are determined by a host of factors. In addition to every person's genetic make up, their social and economic conditions, their personal behaviour – smoking, drinking, diet - and their working and living conditions all play a major role.

Public health takes up these issues. Its concern is with the state of health of the population as a whole which it aims to protect and improve. There are a number of means which public health can use to achieve this far-reaching goal. The main ones include taking preventive measures, such as vaccination and screening and more generally taking precautions to protect people from risks and dangers. Another method is education and information campaigns. Then, more broadly, there is health promotion which involves empowering people and communities to make healthy choices to improve their health. Public health also has to look at how health systems function and ensuring that they work as well as possible. Public health is therefore all about tackling the underlying causes of ill health. Since there are many factors involved, other policies outside the health domain have a role to play in supporting public health objectives.

Maintaining and improving public health therefore requires a comprehensive approach. The Community's situation is not the same as that of Member States. It does not itself manage health services or medical care, which under the Treaty is the clear responsibility of the Member States. The Community' role in public health is to complement their efforts, to add value to their actions and in particular to deal with issues that Member States cannot handle on their own. Infectious diseases, for example, do not respect national borders; neither does air and water pollution. This is why the Treaty has given the Community an important responsibility to tackle health concerns in the widest sense.

This is in line with what the European public expects. People rightly want to be protected against illness and disease. They demand that their food is safe and wholesome, and that the products and services on the market meet high safety standards. They want to bring up their children in a healthy environment and they expect their workplace to be safe and hygienic. When travelling within the European Community, they need access to reliable and high-quality health advice and assistance.

In all these areas the Community has a vital role to play.

The proposals being announced in this document are very ambitious. The new public health programme, both in its scope and in the way it marshals resources, is itself a major new initiative. But it is only one part, albeit a key part, of the broad Community health strategy through which all Community policies and actions must contribute to achieving a high level of health protection.

This communication shows that the Community is already making a real contribution to the health of the population. But beyond this, it demonstrates its commitment to make an even more powerful contribution in future in order to improve the quality of life of everyone in the Community.

## 2. THE CONTEXT OF HEALTH STRATEGY

The rapid changes that Europe is undergoing have a profound impact on people's lives and on their health. This means that there is now a need to develop a Community health strategy able to respond both to present conditions and to emerging trends. This strategy must not only reflect the new public health powers in the Treaty, but also be able meet key challenges to the health of the public.

### 2.1 The Legal Context

There are a number of Articles in the Treaty which relate to health. These are set out in **Table 1**. The key objectives in relation to public health are in Articles 3 and 152. These include:

- Contributing towards ensuring the attainment of a high level of health protection;
- Improving public health;
- Preventing human illness and disease; and
- Obviating sources of danger to human health.

These objectives are taken up in a wide range of Community policies, including the Internal Market, Environment, Consumer Protection, Social Affairs, including health and safety at work, Agriculture, Research, Trade and Development etc. Community policies in these and other areas have to ensure a high level of human health protection in their definition and implementation.

Article 152 includes specific provisions which allow the Community to take actions with a direct bearing on health protection, while respecting the responsibilities of the Member States for the organisation and delivery of health services and medical care.

These include:

*Measures in the field of veterinary and phytosanitary legislation which have as their direct objective the protection of public health.* These are already the basis of a substantial body of Community legislation with major health implications. The difference now is that such proposals fall within the public health context.

*Measures in relation to the quality and safety of organs and substances of human origin and blood and blood derivatives.* The scope and potential of this new provision has not yet been fully explored. However, given the importance for health protection of ensuring a safe blood supply, and the rapidly growing need for human organs and substances of human origin, the potential, taking into account national provisions on the donation or medical use of organs and blood, is considerable.

*Incentive measures designed to protect and improve public health.* These non-harmonising provisions have served as a basis for the current set of eight public health programmes and for the decision on a network on the epidemiological surveillance and control of communicable diseases, and they also form the basis of the new programme.

The Treaty also provides for *Council recommendations* for the purposes of public health protection. While non-binding, these have been used to take initiatives in areas such as electro-magnetic radiation<sup>1</sup>.

## 2.2 Health Trends and Challenges

### *Health Trends*

In general terms the health of the Community population has never been better. Infant mortality has fallen sharply in recent years. People are living longer: life expectancy at birth has increased to between 75 and 79 years in all Member States. Indeed the rise in life expectancy in recent decades is very striking. For example, from 1970 to 1996 it increased in France by six years (from 72.9 to 78.9) and in the UK by five years (71.8 to 77.1).

Nevertheless, serious public health problems remain which cannot be ignored:

- high levels of premature death (one fifth of all deaths are premature i.e. before the age of 65) from diseases related to lifestyle, notably cardio-vascular diseases and cancer, and from accidents.<sup>2</sup> Smoking is a key factor. It is the cause of over half a million deaths a year in the European Union, of which nearly half are in the 35 to 69 year age group,<sup>3</sup>
- a substantial level of morbidity and disability from mental illness, musculo-skeletal diseases and diabetes,
- new risks to health, for example from the emergence of new diseases, such as new variant Creutzfeldt-Jakob Disease and from food-borne illnesses,
- a resurgence of major infectious diseases, for example tuberculosis, made worse by the growing problem of resistance to anti-microbial drugs,
- an increase in the incidence of diseases related to old age, such as cancers, cardio-vascular diseases, stroke, and the impairment of functional capacity through physical disabilities and mental disorders, which results from the lengthening life expectancy. About one quarter of people aged 85 or older for example are estimated to have a form of dementia<sup>4</sup>; and

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<sup>1</sup> The full list of programmes and other actions is in Table 2.

<sup>2</sup> Taking the population as a whole, the commonest causes of death are, in order, ischaemic heart disease and cerebrovascular disease followed by cancer, chronic liver disease, transport accidents and suicides, Eurostat Mortality Statistics.

<sup>3</sup> Peto R, Lopez AD, Boreham J, Thun M, Heath C, Mortality From Tobacco in Developed Countries, 1950-2000, Oxford, OUP, 1998. Ischaemic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease and lung cancer, all linked with smoking, are four of the top ten causes of death world-wide, according to The Global Burden of Disease Study of Murray and Lopez (cited in a Lancet editorial, Vol. 349, No 9061).

<sup>4</sup> "The Prevalence of Dementia in Europe: A Collaborative Study of 1980 - 1990 Findings", International Journal of Epidemiology, 20, 1991, A. Hoffman *et al.*

- wide variations and inequalities in health status (both morbidity and mortality) with substantial evidence that poorer people, the disadvantaged, and socially excluded groups have significantly higher health risks and mortality.

### *Challenges For Health Systems*

The *costs of health systems* are a major charge on national budgets and one that is continuing to grow as resources chase rising demand. In the last three decades, health care spending in the Community as a proportion of GDP has substantially increased in all Member States. In Italy in 1977 it represented 5.7 % of GDP; in 1997 the figure was 7.4%. In the same period Spain saw an increase from 5.6% to 7.3%. In response to this development, Member States have been undertaking a wide range of structural reforms and cost containment measures in order to improve the efficiency and effectiveness of their health systems. Several factors, affecting both the supply of and the demand for health services, have contributed to the rise in health expenditure.

*Demographic trends* are a key factor. The Community population is ageing because of the falling birth rate and lengthening life expectancy. By 2020, there will be 40% more people aged 75 and above than in 1990. This is likely to increase demand for health services and to require changes to their organisation and structure. With more people living into their 80s and 90s, more people will need long-term health care services and specialised social services. Moreover, these trends may lead to significant cost increases. Per capita expenditure on health care for the very old is greater than for those of working age. The question of how to pay for the increasing costs is made more difficult because the total dependency ratio (the ratio of dependants to workers) will rise from its current levels.

The *development of medical technologies* in the coming decades will make an ever greater impact on health services. Important innovations include the use of computers and robotics, the application of communications and information technology, new diagnostic techniques, genetic engineering, cloning, the production of new classes of pharmaceuticals, and the work now beginning on growing replacement tissues and organs. These developments can contribute significantly to improved health status. Leaving aside the significant ethical issues raised, they will have an impact on costs by, for example, reducing length of stay in hospitals or avoiding the need for complicated surgery. However, they may add to overall costs because more conditions can be treated. The issue of the affordability and justification of new techniques and products thus inevitably arises. Despite the importance of this question for resource allocation, the cost-effectiveness of relatively few technologies or interventions has so far been rigorously examined.

Health services must respond to people's *expectations and concerns*. An encouraging trend in Member States is the growing attention being paid to the views of the public in the planning and provision of services and priority setting. This welcome development, however, also puts pressure on services and budgets, since people are reluctant to accept any rationing of services or cuts in their levels. A Eurobarometer<sup>5</sup> survey showed that only 5% of the Community population would accept lower public spending on health care, whereas 50% wanted higher spending.

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<sup>5</sup> Eurobarometer 44.3 carried out early in 1996.

The situation has become more complex with the increasing availability of information, especially through the Internet, about risks to health, diseases and therapies. In turn, however, this is also fuelling increasing expectations and demands on health services.

Experience from the Commission's 'Dialogue with Citizens' Initiative shows that issues related to social security and cross border health care issues are major concerns. These include problems relating to social security rules and the recognition of diplomas or access to jobs in the health sector. These issues need to be addressed for the internal market to function properly.

### **3. THE ELEMENTS OF THE COMMUNITY STRATEGY**

The Community's *broad strategy on health* responds to the legal obligations and takes full account of key health developments, as set out above. The strategy includes:

First, a *public health framework* which consists of an *action programme* and related policy and legislation in the public health field. This framework is described below.

Second, the contribution that other Community policies and activities make towards attaining a high level of health protection, and the mechanisms to ensure an integrated approach. This is discussed in Part 4 of this document<sup>6</sup>.

#### **3.1 The Public Health Framework: The Action Programme**

In 1998 the Commission adopted a Communication on the development of public health policy in the European Community<sup>7</sup>. While this Communication stressed that within the current framework much valuable and important work was being undertaken, it also identified several weaknesses. The Commission proposed that a new public health programme should be drawn up to give effect to the new Treaty provisions, to support the development of legal instruments and policy, to face up to the new challenges and to take account of experience so far. Three main strands of action were identified: improving health information; establishing a rapid response mechanism; and tackling health determinants. This broad strategy was endorsed by the other Community Institutions.

##### *Rationale and Objectives of the programme*

The attached proposal for a new public health programme builds upon that consensus and takes it forward by strengthening visibility and responsiveness to popular concerns; working closely with the Member States to support their efforts to improve the health of the population and the effectiveness of their health systems; and creating sustainable mechanisms which will enable them to coordinate their health-related activities. Moreover, the programme will enable the Community to meet its key

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<sup>6</sup> The various Commission reports on the integration of health protection requirements in Community policies contain details of the relevant activities. Cf. COM(95) 196 final of 29.5.1995, COM(96) 407 final of 4.9.1996, COM(1998) 34 final of 27.1.1998 and COM(1999) 587 final of 16.11.1999.

<sup>7</sup> COM(98) 230 final of 15 April 1998

responsibility to contribute towards a high level of health protection as set out in the Treaty.

Member States spend a large amount of their GDP on health (the Community average is now around 8%). Health spending has been rising and will continue to rise in the future owing to factors such as ageing populations; development of technology, rising popular demand. In view of this, Member States are trying to improve the cost-effectiveness of their health systems in order to accommodate new priorities while also respecting budgetary constraints. To meet this challenge, they require better and comparable data and information, e.g. on health status and the effectiveness of particular health interventions. The Community has the potential to provide much of this.

A further issue is that Member States are faced with cross-border health threats which they cannot properly address on their own, because they do not all have the necessary resources, infrastructures and expertise. Examples include nvCJD, HIV and conditions related to pollution. The Community can help Member States to coordinate their actions in response to these threats.

There is an increasing recognition that to reduce morbidity and mortality, underlying health determinants must be effectively addressed. For example, tackling smoking, the leading cause of death in the Community, requires an integrated strategy on tobacco control which involves measures taken both at the level of the Member States and the Community. More generally the Community can also identify best practice and carry out benchmarking in order to raise quality and standards across the European Union.

By focussing on these areas where the Community can make a difference and can act in a way that individual Member States cannot, the programme with its limited budget can make a positive impact on the health of Community citizens and on making health systems in Member States more effective. It thus provides real Community added value.

The general objectives of the programme are:

- To improve information and knowledge for the development of public health and the strengthening and maintenance of effective health interventions and efficient health systems;
- To enhance the capability of responding rapidly and in a coordinated fashion to threats to health by the development, strengthening and assistance to the capacity, operation and inter-linking of surveillance, early warning and rapid reaction mechanisms;
- To address health determinants through health promotion and disease prevention measures, through support to and the development of broad health promotion activities and disease prevention actions and specific risk reduction and elimination instruments.

### *Outputs*

The actions to be undertaken are set out in the annex of the programme proposal. But it is worth highlighting some of the programme's main outputs to show how they will produce value for the Community.

**First, a comprehensive health information system will be developed**, targeted at the general public, health professionals and other stakeholders, and health authorities. This will provide Community-wide access to reliable and up to date information on key health-related topics. To establish this system full use will be made of the Internet, including links to national websites, and of the impetus that the e-Europe initiative gives to the introduction of information technologies in the health sector. The statistical part of the health information system will be developed as part of the Community Statistical Programme.

The system will be based on the establishment of agreed Community-wide indicators for health status, diseases and determinants covering demographic and social factors, lifestyle factors, living and working conditions, as well as health promotion and disease prevention interventions including, where feasible, their costs. Information will be compiled concerning trends and effectiveness of health systems, health technologies, quality standards and criteria for best practice. Common databases and systems for transferring and sharing information will also be developed.

The outputs of the system will be packages of information of varying kinds which respond to the needs of the different target groups. These are:

- *the general public* - information will be provided to empower people to make key choices about life styles and health risks, and advise them on sources of support and expert help, such as disease support groups. A special focus will be on giving people the health information they need as they move about the EU, such as health and social insurance coverage and how to access specific health services;
- *health professionals and other stakeholders* – information will help them to enhance their skills and knowledge. It will include inventories and directories, results of studies, and evaluations of health interventions and technology, analyses of good practice, and guidelines, advice and recommendations;
- *national, regional and local health authorities* – information will assist them in developing policy and in decision-making by providing up to date and comparative data on health trends and developments, and by establishing benchmarks to measure progress and effectiveness of health interventions and strategies.

In this way, the system will furnish the data and information necessary for developing health policy and initiatives at Community level and within Member States. Moreover, the system will also provide easily accessible information targeted at health professionals and the general public.

**Secondly, there will be mechanisms to respond to major health threats, including a rapid reaction capability.** Such mechanisms are necessary to ensure that the Community is able to respond effectively and in a coordinated way to potentially serious threats to public health both from major diseases and emerging risks which cannot be effectively tackled by Member States on their own. Creating these mechanisms will involve not only harnessing the resources of health and surveillance authorities and centres of expertise, but also building up the necessary capacity in Member States and applicant countries. Actions will entail improving communications between the national authorities involved, linking with the various Community alert systems, putting in place the necessary arrangements for surveillance and transfer of

information, and creating the means to mobilise the necessary resources and expertise to respond quickly and effectively to health threats as they arise.

At the same time, actions will underpin the development and implementation of policy in other key areas of the public health framework, such as securing the safety and quality of blood, organs and substances of human origin and strengthening the surveillance and control of communicable diseases. Actions will also cover developing responses to tackle health threats from non-communicable diseases, illicit drugs and physical agents that may be linked to specific health conditions, and the prevention of injuries and accidents. In these areas links to existing surveillance, notification and alert mechanisms will be set up.

With each new health threat, public concern about the way their health is being protected inevitably rises. This rapid response capability will help to alleviate these concerns by enabling decisive action to be taken in those cases where Member States cannot act effectively on their own.

**Finally, the programme will address health determinants**, in other words the underlying factors which affect people's health. Main priorities will include seeking to address the high levels of premature deaths and illness in the EU from major diseases, cancer and cardio-vascular diseases, as well as mental illness. This will be achieved by focussing on key lifestyle factors, such as smoking, alcohol, nutrition, physical activity, stress and drug abuse (including doping in sport), as well as major socio-economic and environmental factors. Actions will be especially targeted at young people since key decisions on lifestyle and health-related behaviour are taken in youth and adolescence. In all these areas the programme will set up mechanisms to help improve the effectiveness of health interventions by providing to health authorities, health professionals and the general public accurate information covering the whole Community on major trends, supporting innovative projects, evaluating new technologies, taking steps to improve quality, and drawing up guidelines of good practice. It will also develop the means to compare and analyse policies so that policy makers and the wider community can see what approaches are being taken in Member States and to decide what works best and why.

These actions will help Member States and the Community in the development of policies which have a positive influence on health determinants. Health professionals and the general public will benefit from the results of the various actions, such as the identification and dissemination of best practice. In this way, the Community will contribute to effective health promotion and disease prevention actions which will improve the quality of life and help relieve the pressure on health services.

Moreover, the programme will be of particular importance for applicant countries which have specific, and often more serious, health problems. In addition they have limited resources to devote to health and in certain areas lack the necessary infrastructure. The programme will provide a valuable source of support in tackling their problems.

The new programme will also build upon those elements of the existing public health programmes and activities that have proved effective and which are relevant to the

concerns and challenges that the Community will be confronting over the next years.<sup>8</sup> These include the development of health indicators and the creation of a telematic Community network for health data exchange between Member States, and networks in a number of areas in relation to disease prevention and health promotion, including mental health promotion.

### *Evaluation*

The Commission attaches importance to ensuring that the public health programme is efficiently and effectively implemented. It has established the general objectives and targets to be achieved by the new programme based on the experience gained from the previous public health programmes. More specific objectives and detailed outputs will be an important part of the annual work programmes.

The Commission will also assure independent, external mid-term and *ex-post* evaluations of the public health programme on the basis of indicators and outputs in the annual work programmes. The evaluations will assess the impact and efficiency of the resources used, they will help fine-tune the management of the programme and they will help to indicate any changes required. The evaluation reports and results of the actions undertaken will be made publicly available.

### *Structure of the new programme*

The structure of the new programme is presented in the attached proposal for a decision of the European Parliament and the Council.

The programme will run for six years in order to ensure that there is sufficient time to develop and implement sustainable actions (Article 1). The overall aim of the programme is to make a contribution towards a high level of health protection and it has the following general objectives: to improve information and knowledge for the development of public health; to enhance the capability of responding rapidly to threats to health; and to address health determinants through health promotion and disease prevention measures (Article 2). The actions to be taken under the programme and the kinds of the measures implementing them are set out in Article 3. The measures of the programme may be implemented as joint actions with related Community programmes and activities (Article 4). Article 5 describes how the measures to implement the programme actions will be undertaken, including by means of an annual workplan and through the establishment of appropriate mechanisms at Community and national levels. The means to ensure consistency and complementarity with other Community policies and activities are set out in Article 6. The overall funding for the programme is EUR 300 million (Article 7). A committee will be established to assist the Commission in implementing the programme (Article 8). The programme will be open for the participation of the EFTA/EEA countries, the associated countries of Central and Eastern Europe, Cyprus, Malta and Turkey (Article 9), and there will stress on cooperation with third countries and relevant international organisations (Article 10). In order to ensure the effectiveness and

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<sup>8</sup> This will draw upon the evaluations of the existing programmes; c.f. Final report on the implementation of the 2nd Cancer Action Plan, COM(99) 408 final of 8.9.1999, and Interim report on mid-term evaluation of the cancer, AIDS and drug programmes, COM(99) 463 final of 14.10.1999.

efficiency of the actions undertaken, there will be thorough evaluation and monitoring arrangements (Article 11). The decision to set up the programme repeals the existing public health programmes (Article 12). This decision will enter into force on the date of its publication in the Official Journal (Article 13). The programme's specific objectives and actions are detailed in an annex.

#### *Extension of existing public health programmes*

Four of the existing programmes come to an end this year and two at the end of next year. It is of importance that there is no interruption or delay in key actions in these programmes that will be sustained under the new programme. It may therefore be necessary to extend these programmes for a limited time until the new programme comes into effect in order to guarantee the continuity of actions.

The Commission intends to put forward a proposal for that purpose.

### **3.2 The Public Health Framework: Other Key Elements**

As part of the public health framework, work on the development of policy and legislation is underway in a number of key areas. The public health programme will provide support for developmental work in connection with this work.

A network for the epidemiological surveillance and control of *communicable diseases* in the Community was set up in 1999<sup>9</sup>. It has two main components: early warning and response, and epidemiological surveillance. Both are closely interrelated and will form the basis for prevention and control strategies on communicable diseases within the Community. This work also has an international dimension and includes, for example, cooperation with WHO and the United States. A working paper on the future strategy for this network will be published shortly.

In relation to *drug prevention*, the programme will underpin the efforts in the EU's Action Plan to Combat Drugs covering the period 2000 to 2004. This action plan includes several initiatives aimed at reducing demand and drugs-related health damage. The programme will also continue actions with the European Monitoring Centre for the Drugs and Drug Addiction, particularly in relation to data and information on drug-related issues, and will support work on exchanging information on policies at national level.

A number of important initiatives have been taken on *smoking and tobacco control*. A proposal for a new Directive to strengthen and up-date the measures on tobacco control was adopted by the Commission in November 1999<sup>10</sup>. It contains revised provisions on the content of cigarettes and product labelling, introduces a limit on nicotine and carbon monoxide content of cigarettes and proposes restrictions on product description as well as requiring a declaration of tobacco additives. The public health programme will address smoking as a major determinant of health and will provide support for preventive measures in this area.

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<sup>9</sup> Decision 2119/98/EC of the European Parliament and of the Council, OJ L 268, 3.10.1998, p. 1.

<sup>10</sup> COM(99) 594 final of 16.11.1999.

Preliminary work has been done on the quality and safety of *organs and substances of human origin*. An overall strategy is being developed which will set the parameters for the preparation of legislation, as foreseen by Article 152, as well as on the use of substances of human origin in medical devices.

Work has progressed on *blood and blood derivatives*. A proposal for a Directive setting a framework for standards of quality and safety is in preparation. Work is also underway on the possible creation of a Community haemovigilance network and the promotion of optimal use of blood and blood derivatives.

Article 152 also provides for *Veterinary and phytosanitary* measures. The White Paper on Food Safety adopted by the Commission in January 2000<sup>11</sup>, includes an extensive programme of legislative actions aimed at putting in place high standards of food safety from “farm to table”. It also includes a proposal for a Food Safety Authority which will embrace independent scientific advice, the operation of rapid alert systems, communication with consumers and networking with national agencies and scientific bodies. There is scope for considerable synergies with these activities under all three strands of action in the public health programme, and particularly with the actions in the area of nutrition.

### **3.3 Key Characteristics of the Public Health Framework**

#### *Visibility and responsiveness*

A central theme of the Community approach is openness and transparency. Only in this way can public concerns and expectations be fully met. The Commission intends therefore to set up a European Health Forum as a consultative mechanism to ensure that the aims of the Community’s health strategy and how they are being pursued are made clear to the public and respond to their concerns. Representative organisations of patients, health professionals and other stakeholders will have an opportunity to make inputs into health policy and the setting of priorities for action. The Forum would provide an opportunity to organise consultations and present views on a wide range of topics. The Commission intends to launch a consultation later this year on the detailed functioning, organisation and composition of the Forum.

The Commission will also build upon the informal networks which have already been supported under the existing public health programmes, for example, those dealing with cancer registration and screening and health promotion. These networks will be complemented by new ones in the priority areas identified, such as data collection, health technology assessment, smoking and drug abuse prevention, as well as the numerous networks supported by the Community’s research programmes. It will also strengthen European umbrella organisations active in public health.

The considerable body of health and health-related research carried out by the Community’s RTD programmes will be a key input in this process.

#### *Involvement of Member States*

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<sup>11</sup> COM(99) 719 final of 12 January 2000.

In accordance with the principles of subsidiarity and proportionality, Community actions in the public health field should be undertaken only if their objective can be better achieved by the Community. This is reinforced in Article 152 which states that Community public health action shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

In light of this actions must aim at providing added value and complement the work of Member States. They should address issues that have a transnational dimension, where common approaches are required, or where there is a need for effective cooperation and coordination. Achieving the programme's objectives will require the active cooperation and full commitment of all the Member States. Indeed, to ensure that actions have tangible and measurable outputs relevant to the Member States, their full and active participation is essential.

### *The International Dimension*

The draft decision on the new programme enables the associated Central and Eastern European countries, Cyprus, Malta and Turkey, as well as the EFTA/EEA countries to participate. It is very important that the applicant countries join the programme as soon as possible so that they are fully involved in the development of the actions which will support them in tackling the major health problems they face.<sup>12</sup> Moreover, in the period before the programme comes into effect, there will be continuing contact with the applicant countries to ensure that as far as possible the Community's broad health strategy reflects their needs and concerns.

There will also be emphasis on fostering cooperation with other countries. Full use will be made of such mechanisms as the European-Mediterranean Partnership, the Transatlantic Agenda, the Northern Dimension for the policies of the Union and Partnership and cooperation with Russia.

Article 152 of the Treaty calls for cooperation with the competent international organisations in the sphere of public health. The WHO, which has a central role in addressing threats to health world-wide, is a key partner. Co-operation covers a range of Community policies. A political agreement has been reached to strengthen relations with WHO on the basis of a new exchange of letters. Work on this is at an advanced stage of preparation.

The Community's relationships with the Council of Europe under Article 303 of the Treaty and OECD, under Article 304, as well as with relevant United Nations Agencies will also be further developed.

## **4. ACHIEVING AN INTEGRATED HEALTH STRATEGY**

In order to ensure that the Community's broad health strategy is coherent, the actions under the public health framework must be properly linked with health-related initiatives in other policy areas.

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<sup>12</sup> The Commission's Staff Working Paper on Health and Enlargement, SEC(99) 713 of 18 May 1999, sets these out in detail.

To begin with, the *single market* has important consequences for health and health systems. When the Commission adopted its new Strategy for Europe's Internal market of (COM(99)624, 24 November 1999), emphasis was placed on the need to improve the quality of life in the Community and to respond to increasing public expectations, a high level of consumer protection and a proper enforcement of the rules are considered essential if the internal market is to work properly. A number of the target actions within the Strategy will help both to achieve the high levels of protection expected and at the same time to harmonise legislation across the European Union. The free movement of health professionals is governed by legislation regulating the mutual recognition of professional qualifications. Community legislation also deals with the provision of medical care in the event of stays in other Member States. Legislation relating to the free movement of goods and services covers health-related products, such as pharmaceuticals, medical devices, health insurance, and also food, alcohol and tobacco.

To complement Community policies related to the authorisation, marketing and free movement of *pharmaceuticals*, the public health programme will cover issues related to their costs, use and cost-effectiveness. The aim is to assist Member States in identifying and disseminating good practice. Relevant action areas are the creation of information systems on patterns of prescriptions and consumption, and promoting the evaluation of the therapeutic value of pharmaceutical products. Ways will also be explored to strengthen cooperation between Member States on such matters as cost containment, guidelines for health professionals and the control of advertising and promotion of products. A further focus will be on improving information on medicines available to the general public. The Internet offers great potential to provide authoritative and understandable information about safeguarding and promoting health and about pharmaceuticals.

The 'Dialogue with Citizens' initiative has shown that in cases where pharmaceuticals are only available in other Member States, consumers are willing to make cross border purchases. This may suggest gaps in Community legislation.

In the context of *consumer protection* work will be developed on health claims, as well as on the so-called nutraceuticals<sup>13</sup> and medicines available without prescription. In addition to initiatives announced in the White Paper on Food Safety, complementary actions on *food and nutrition* will be taken. The Community can provide information about diet, nutritional values of foods, ingredients and additives, to encourage people to make healthy choices. It can also work with manufacturers to improve the nutritional value of processed food. There would also be benefit in exploring linkages between the rapid alert systems.

In its Communication on *Modernising and Improving Social Protection*,<sup>14</sup> the Commission proposed a strategy on cooperation between and coordination of social security systems, which will also include work on certain features of health systems, such as the reimbursement of health expenses between systems, and questions relating to costs and financing. This will complement the actions in the public health

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<sup>13</sup> Products, such as functional foods, which have been designed to address specific health problems, such as high levels of cholesterol.

<sup>14</sup> COM(1997) 102 final of 12.3.1997.

programme on issues in relation to health systems, such as the cost-effectiveness and appropriateness of health interventions, quality and standards, the links between promotion, prevention, treatment and care services, and identifying and disseminating best practice.

The Community policy on *health and safety at work* is of particular relevance to public health and to ensuring the attainment of a high level of health protection. It is based on a preventive approach towards protection against work place risks, work accidents and occupational diseases.

*Technological developments* in the health field will be a focus for action in the new programme. The Commission intends to strengthen health technology assessment structures and mechanisms by supporting collaboration between the agencies involved in order to refine methodologies, promote joint working and help disseminate the results of studies effectively. New technologies will also be used to collect and disseminate validated information.

The Community's *policy on the environment* has as a direct objective the protection of human health, and is based on the precautionary principle. It stresses preventive action, rectifying environmental damage at source and that the polluter should pay. It has resulted in a stream of effective policies and measures on emissions, practices and concentrations of substances and agents. Through the integration of environmental protection requirements in all Community policies, as required by Article 6 of the Treaty, a major contribution towards ensuring the attainment of a high level of health protection should be made. The links between health and environment are further strengthened through the proposed programme and activities involving international cooperation, such as the WHO Ministerial Conference on Health and the Environment.

The Community's *Fifth Framework Programme for Research, Technological Development and Demonstration Activities*<sup>15</sup> contains the Quality of life and management of living resources<sup>16</sup> programme which has a strong link with health policy. Five of the six key actions, 'Food', 'Nutrition and Health', 'Control of Infectious Diseases', 'The Cell Factory', 'Environment and Health' and 'The Ageing Population and Disabilities' are targeted towards crucial health-related issues. In addition, most of the Generic Activities address areas of strategic importance for health, e.g. chronic and degenerative diseases, genomes and diseases of genetic origin, neurosciences, public health and health services, people with disabilities as well as bioethics. Another specific programme which contributes to the support of health-related activities is that on 'Environment and sustainable development'.

Moreover, the INCO programme fosters international cooperation on research with a large number of countries, including Central and Eastern European Countries and Newly Independent States (INCO-Copernicus), Mediterranean Partner Countries (INCO-Med) and, most importantly, developing countries (INCO-Dev). Finally, the

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<sup>15</sup> Decision 1999/182/EC of the European Parliament and of the Council, OJ L 26, 1.2.1999, p. 1.

<sup>16</sup> Council Decision 1999/167/EC, OJ 64, 12.3.1999, p. 1.

User-friendly information society programme<sup>17</sup> includes work relevant to health systems and public health, notably on health telematics.

All these research programmes place an emphasis on ensuring that the findings of projects are widely disseminated and that they are taken into consideration in policy development and decision-making and that they contribute to a high level of health protection.

Within the framework of *the Community Statistical Programme 1998-2002*, the European Statistical System (ESS) has launched major projects in the field of health and social statistics, in particular on health status, health care services and resources, and health determinants. Building on these initiatives, the statistics needed for health information will be further developed.

Finally, the Community has a wider commitment to health as a basic component in its *enlargement and its development, external relations and trade policies*. Agreements between the Community and third countries provide the framework for assistance to tackle diseases in these countries, help to create social and economic conditions conducive to better health, and establish health systems to provide the care needed by their populations. In doing so, they serve also to provide protection for the peoples of the Community. Under Article 177 of the Treaty, the Community shall address poverty in developing countries. The health field is particularly important in poverty reduction strategies, and is a key element of the Community's overall development policy.

#### *Mechanisms to ensure that policies and activities contribute to health protection*

Developing links between the public health framework and other policies is important, but it is not sufficient to ensure that Community health strategy is fully coherent with the primary objectives of other policies. It is also essential that all the Community's activities which can affect health contribute to the overall strategy. In this respect there are two major limitations in the way that health issues have so far been tackled at Community level:

- First, the potential impact on health of individual policy initiatives other than those directly related to health is not always fully considered.
- Secondly, the various health-related activities are not always properly linked and taken forward in a fully coherent manner.

These two shortcomings need to be dealt with. That is why various instruments are being introduced to ensure that health is given due weight in the development and implementation of Community policies and actions.

First, from 2001, proposals with a particular relevance to health will include an explanation of how health requirements have been addressed, normally by including a statement in the proposal's explanatory memorandum. The aim would be to show

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<sup>17</sup> Council Decision 1999/168/EC, OJ L 64 of 12.3.1999, p. 20

clearly how and why health considerations were taken into account and the expected health impact.

Second, within the public health programme, a priority task will be to develop criteria and methodologies, such as appraisal guidelines and checklists, for evaluating policy proposals and their implementation. In addition, certain Community actions or policies could be singled out for a thorough impact assessment. The intention is to launch pilot projects in this area, which could also address issues related to the implementation of Community policies in Member States. Third, the public health programme includes provision for taking joint actions in cooperation with other Community programmes and agencies, which will help develop inter-sectoral approaches to tackling major factors influencing health.

Finally, within the Commission, the mechanisms to ensure that health-related activities are properly coordinated will be strengthened.

These new steps will enable the Community to ensure that its health strategy is consistent and coherent. But since Member States are equally bound by the Treaty obligation, its implementation requires a joint effort if it is to succeed.

## **5. CONCLUSIONS**

People in Europe have high expectations that public policy will promote and protect health. This expectation relates to the full range of policies and not only measures with a direct health dimension. This communication shows how Community policies actively respond to the objective of ensuring a high level of health protection. This in turn will ensure that people can be confident that a key concern – their health – is afforded top priority in the ongoing process of European integration.

The new public health framework, with an ambitious action programme at its centre, represents a major commitment and demonstrates that the Commission is giving public health a high place on the Community's policy agenda.

The Commission will take the necessary steps to develop its broad health strategy over the coming years in a forward-looking and innovative manner. The Commission hopes that the other Institutions and the Member States will join it in undertaking the vital task of protecting and improving the population's health. The credibility of the European project will be undermined if we do not work together towards its accomplishment.

**TABLE 1**

**The Most Important Treaty Articles Relating To Health Protection**

<p>Articles 43 - 48 (Right of establishment, which covers inter alia doctors and other health sector professionals);</p> <p>Articles 49 and 50 (Services, including medical and other health services);</p> <p>Article 71 (Transport safety);</p> <p>Article 95 (Approximation of laws, which includes food safety, tobacco, pharmaceuticals, medical devices, chemicals and other dangerous substances, applications of biotechnology);</p> <p>Articles 131-133 (Common Commercial Policy, e.g. on food and on pharmaceuticals);</p> <p>Article 137 (Social security and social protection of workers);</p> <p>Article 149 (Education and vocational training, including exchanges in the health field);</p> <p>Articles 158 and 161 (Economic and Social Cohesion, i.e. the structural funds and the cohesion fund which support inter alia health-related projects);</p> <p>Articles 163-173 (Research and Technological Development, which includes the area of health);</p> <p>Article 177 (Development Co-operation, including in the health field); and</p> <p>Articles 300 and 302 (Conclusions of agreements with third countries and international organisations, including on health and health-related matters.</p>
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**TABLE 2****Actions under the 1993 Public Health Framework**

The programme of Community action on health promotion, information, education and training<sup>1</sup>,  
The action plan to combat cancer<sup>2</sup>,  
The programme of Community action on the prevention of AIDS and certain other communicable diseases<sup>3</sup>,  
The programme of Community action on the prevention of drug dependence<sup>4</sup>,  
The programme of Community action on health monitoring<sup>5</sup>,  
The programme of Community action on injury prevention<sup>6</sup>,  
The programme of Community action on rare diseases<sup>7</sup>, and  
The programme on pollution-related diseases<sup>8</sup>.

**Other Activities**

A strategy on tobacco consumption<sup>9</sup>, a Directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products<sup>10</sup>; a report on smoking prevention<sup>11</sup>, and a proposal for a directive on tobacco products<sup>12</sup>

A strategy on blood safety and self-sufficiency<sup>13</sup> and the Council Recommendation on the suitability of blood and plasma donors and the screening of donated blood<sup>14</sup>;

Commission reports on health status in the Community<sup>15</sup> and on the integration of health protection requirements in Community policies<sup>16</sup>;

Commission staff working papers on the epidemiology and surveillance of Creutzfeldt-Jakob disease and other transmissible spongiform encephalopathies;

A Community network for the epidemiological surveillance and control of communicable diseases in the Community<sup>17</sup>, and

A Council Recommendation on the limitation of exposure of the general public to electromagnetic fields 0 Hz to 300 GHz<sup>18</sup>.

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<sup>1</sup> Decision No 645/96/EC of the European Parliament and of the Council, OJ L 95, 16.4.1996, p. 1.  
<sup>2</sup> Decision No 646/96/EC of the European Parliament and of the Council, OJ L 95, 16.4.1996, p. 9.  
<sup>3</sup> Decision No 647/96/EC of the European Parliament and of the Council, OJ L 95, 16.4.1996, p. 16.  
<sup>4</sup> Decision No 102/97/EC of the European Parliament and of the Council, OJ L 19, 22.1.1997, p. 25.  
<sup>5</sup> Decision No 1400/97/EC of the European Parliament and of the Council, OJ L 193, 22.7.1997, p. 1.  
<sup>6</sup> Decision No 372/1999/EC of the European Parliament and of the Council, OJ L 46, 20.2.1999, p. 1.  
<sup>7</sup> Decision No 1295/1999/EC of the European Parliament and of the Council, OJ L 155, 22.6.1999, p. 1.  
<sup>8</sup> Decision No 1296/1999/EC of the European Parliament and of the Council, OJ L 155, 22.6.1999, p. 7.  
<sup>9</sup> Commission Communication on the present and proposed Community role in combating tobacco consumption, COM(96) 609 final of 18.12.1996.  
<sup>10</sup> Directive 98/43/EC of the European Parliament and of the Council, OJ L 213, 20.7.1998, p. 8.  
<sup>11</sup> COM(99) 407 final of 8.9.1999.  
<sup>12</sup> COM(99) 594 final of 16.11.1999.  
<sup>13</sup> COM(94) 652 final of 21.12.1994.  
<sup>14</sup> OJ L 203, 21.7.1998, p. 14.  
<sup>15</sup> COM(95) 357 final of 19.7.1995 and COM(97) 224 final of 22.5.1997  
<sup>16</sup> COM(95) 196 final of 29.5.1995, COM(96) 407 final of 4.9.1996, COM(1998) 34 final of 27.1.1998 and COM(1999) 587 final of 16.11.1999.  
<sup>17</sup> Decision No 2119/98/EC of the European Parliament and of the Council OJ L 268, 3.10.1998, p. 1.  
<sup>18</sup> Council Recommendation of 12 July 1999, OJ L 199, 30.7.1999, p. 59.

**Proposal for a**  
**DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**adopting a programme of Community action in the field of public health (2001-2006)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152 thereof,

Having regard to the proposal from the Commission<sup>1</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>2</sup>,

Having regard to the opinion of the Committee of the Regions<sup>3</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>4</sup>,

Whereas:

- (1) The Community is committed to promoting and improving health, reducing avoidable mortality and activity-impairing disability, preventing disease, and countering potential threats to health. The Community must address in a coordinated and coherent way the concerns of its people about risks to health and their expectations for a high-level of health protection and, therefore, all health-related activities of the Community must have a high degree of visibility and transparency and allow consultation and participation of all stakeholders in a balanced way, in order to promote better knowledge and communication flows and thus enable a larger involvement of individuals in decisions that concern their health.
- (2) In the context of the public health framework set out in the Commission communication of 24 November 1993 on the framework for action in the field of public health<sup>5</sup>, eight action programmes were adopted, namely:
  - Decision No 645/96/EC of the European Parliament and of the Council of 29 March 1996 adopting a programme of Community action on health promotion, information, education and training within the framework for action in the field of public health (1996 to 2000)<sup>6</sup>;

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<sup>1</sup> OJ C [...], [...], p. [...].

<sup>2</sup> OJ C

<sup>3</sup> OJ C

<sup>4</sup> OJ C

<sup>5</sup> COM(93) 559 final of 24.11.1993.

<sup>6</sup> OJ L 95, 16.4.1996, p. 1.

- Decision No 646/96/EC of the European Parliament and of the Council of 29 March 1996 adopting an action plan to combat cancer within the framework for action in the field of public health (1996 to 2000)<sup>7</sup>;
- Decision No 647/96/EC of the European Parliament and of the Council of 29 March 1996 adopting a programme of Community action on the prevention of AIDS and certain other communicable diseases within the framework for action in the field of public health (1996 to 2000)<sup>8</sup>;
- Decision No 102/97/EC of the European Parliament and of the Council of 16 December 1996 adopting a programme of Community action on the prevention of drug dependence within the framework for action in the field of public health (1996 to 2000)<sup>9</sup>;
- Decision No 1400/97/EC of the European Parliament and of the Council of 30 June 1997 adopting a programme of Community action on health monitoring within the framework for action in the field of public health (1997 to 2001)<sup>10</sup>;
- Decision No 372/1999/EC of the European Parliament and of the Council of 8 February 1999 adopting a programme of Community action on injury prevention in the framework for action in the field of public health (1999 to 2003)<sup>11</sup>;
- Decision No 1295/1999/EC of the European Parliament and of the Council of 29 April 1999 adopting a programme of Community action on rare diseases within the framework for action in the field of public health (1999 to 2003)<sup>12</sup>; and
- Decision No 1296/1999/EC of the European Parliament and of the Council of 29 April 1999 adopting a programme of Community action on pollution-related diseases in the context of the framework for action in the field of public health (1999 to 2001)<sup>13</sup>.

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<sup>7</sup> OJ L 95, 16.4.1996, p. 9.

<sup>8</sup> OJ L 95, 16.4.1996, p. 16.

<sup>9</sup> OJ L 19, 22.1.1997, p. 25.

<sup>10</sup> OJ L 193, 22.7.1997, p. 1.

<sup>11</sup> OJ L 46, 20.2.1999, p. 1.

<sup>12</sup> OJ L 155, 22.6.1999, p. 1.

<sup>13</sup> OJ L 155, 22.6.1999, p. 7.

- (3) Other activities in the context of the public health framework included the Council Recommendation 98/463/EC 29 June 1998<sup>14</sup> on the suitability of blood and plasma donors and the screening of donated blood in the European Community of Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community<sup>15</sup>, and Recommendation 1999/519/EC on 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields 0 Hz to 300 GHz<sup>16</sup>.
- (4) The public health framework was reviewed in the Commission communication of 15 April 1998 on the development of public health policy in the European Community<sup>17</sup>, which indicated that a new health strategy and programme were needed in view of the new Treaty provisions, new challenges and experience so far;
- (5) The Council in its conclusions of 26 November 1998 on the future framework for Community action in the field of public health<sup>18</sup>, and in its Resolution of 8 June 1999<sup>19</sup>, the Economic and Social Committee, in its opinion of 9 September 1998<sup>20</sup>, the Committee of the Regions, in its opinion of 19 November 1998<sup>21</sup>, and the European Parliament, in its Resolution A4-0082/99 of 12 March 1999<sup>22</sup>, welcomed the Commission communication of 15 April 1998 and supported the view that actions at Community level should be set out in one overall programme to run for a period of at least five years and comprising three general objectives, namely improving information for the development of public health, reacting rapidly to health threats and tackling health determinants through health promotion and disease prevention, underpinned by inter-sectoral action and the use of all appropriate Treaty instruments;
- (6) The overall aim of the public health programme should be to make a contribution towards the attainment of a high level of health protection by directing action towards improving public health, preventing human illness and diseases, and obviating sources of danger to health. Action should be guided by the need to prevent premature death, increase life expectancy without disability or sickness, promote quality of life and physical and mental well-being, and minimise the economic and social consequences of ill health, thus reducing health inequalities;
- (7) Achieving this aim, and the general objectives of the programme requires effective cooperation of the Member States, their full commitment in the implementation of Community actions, and the involvement of actors in the health field as well as the public at large;

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<sup>14</sup> OJ L 203, 21.7.1998, p. 14.

<sup>15</sup> OJ L 268, 3.10.1998, p. 1.

<sup>16</sup> OJ L 199, 30.7.1999, p. 59.

<sup>17</sup> COM(1998) 230 final.

<sup>18</sup> OJ C 390, 15.12.1998, p. 1.

<sup>19</sup> OJ C 200, 15.7.1999, p. 1.

<sup>20</sup> OJ C 407, 28.12.1998, p. 26.

<sup>21</sup> OJ C 51, 22.2.1999, p. 53.

<sup>22</sup> OJ C 175, 21.6.1999, p. 135.

- (8) In accordance with the principles of subsidiarity and proportionality set out in Article 5 of the Treaty, Community action on matters which do not fall within the exclusive competence of the Community, such as public health, should be undertaken only if and insofar as, by reason of its scale or effects, its objective can be better achieved by the Community. The objectives of the programme cannot be sufficiently accomplished by the Member States because of the complexity, transnational character and lack of complete control at Member State level over the factors affecting health status and health systems. The programme will enable the Community to contribute towards fulfilling its Treaty obligations in the field of public health while fully respecting the responsibilities of the Member States for the organisation and delivery of health services and health care. This Decision does not go beyond what is necessary to achieve those objectives.
- (9) The measures under the programme underpin the health strategy of the Community and will yield Community added value by responding to needs in health policy and health systems arising out of conditions and structures established through Community action in other fields, by addressing new developments, new threats and new problems for which the Community would be in a better position to act to protect its people, by bringing together activities undertaken in relative isolation and with limited impact at national level and by complementing them in order to achieve positive results for the people of the Community, and by contributing to the strengthening of solidarity and cohesion in the Community.
- (10) In order to ensure that actions can address broad health issues and threats effectively in cooperation with other Community policies and activities the programme should provide for the possibility of undertaking joint actions with related Community programmes and actions.
- (11) In the execution of the programme, full use should be made of the results generated from the Community research programmes, which support research in areas covered by the programme.
- (12) The programme should last six years in order to allow sufficient time to implement measures to achieve its objectives.
- (13) It is essential that the Commission should ensure implementation of the programme in close cooperation with the Member States. Moreover, in order to obtain scientific information and advice, the Commission should cooperate with high-level committees of scientific experts.
- (14) Consistency and complementarity should be ensured between actions to be implemented under the programme and those envisaged or implemented under other policies and activities, in particular in the light of the requirement to ensure a high level of human health protection in the definition and implementation of all Community policies and activities.

- (15) 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 33 of the interinstitutional agreement of 6 May 1999 between the European Parliament, the Council and the Commission on budgetary discipline and improvement of the budgetary procedure<sup>23</sup>, for the budgetary authority during the annual budgetary procedure.
- (16) It is essential that there should be flexibility to allow re-deployment of resources and adaptation of activities while respecting the criteria for selecting and ordering priorities according to magnitude of risk or potential of effect, public concerns, availability of interventions or potential for their development, subsidiarity, added value and impact on other sectors.
- (17) In accordance with Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>24</sup>, measures for the implementation of this decision should be adopted by use of the advisory procedure provided for in Article 3 of that Decision.
- (18) The Agreement on the European Economic Area (EEA Agreement) provides for greater cooperation in the field of public health between the European Community and its Member States, on the one hand, and the countries of the European Free Trade Association participating in the European Economic Area (EFTA/EEA countries), on the other. Provision should also be made to open the programme to participation of the associated Central and Eastern European countries in accordance with the conditions established in the Europe Agreements, in their additional protocols and in the decisions of the respective Association Councils, of Cyprus, funded by additional appropriations in accordance with the procedures to be agreed with that country, as well as of Malta and Turkey, funded by additional appropriations, in accordance with the provisions of the Treaty.
- (19) Cooperation with third countries and the competent international organisations in the sphere of health should be fostered.
- (20) In order to increase the value and impact of the programme there should be monitoring and evaluation of the measures taken. It should be possible to adjust or modify the programme in the light of these evaluations and of developments that may take place in the general context of Community action in health and health-related fields.
- (21) The programme of Community action in the field of public health builds on the activities and the programmes under the previous framework in order to ensure a smooth transition therefrom, while adapting and expanding on their actions. The decisions concerning those programmes should therefore be repealed with effect from the date of entry into force of this Decision,

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<sup>23</sup> OJ C 172, 18.6.1999, p. 1.

<sup>24</sup> OJ L 184, 17.7.1999, p. 23.

HAVE DECIDED AS FOLLOWS:

*Article 1*

**Establishment of the programme**

1. This decision establishes a programme of Community action in the field of public health, hereinafter referred to as “the programme”.
2. The programme shall be implemented in the period starting on 1 January 2001 and ending on 31 December 2006.

*Article 2*

**Overall aim and general objectives**

1. The programme shall aim to make a contribution towards the attainment of a high level of health protection by directing action towards improving public health, preventing human illness and diseases, and obviating sources of danger to health.
2. The programme shall have the following general objectives:
  - (a) To improve information and knowledge for the development of public health and the strengthening and maintenance of effective health interventions and efficient health systems, by developing and operating a well-structured and comprehensive system for collecting, analysing, evaluating and imparting health information and knowledge to competent authorities, health professionals and the public, and by undertaking assessments of and reporting on health status and health-related policies, systems and measures;
  - (b) To enhance the capability of responding rapidly and in a coordinated fashion to threats to health by the development, strengthening and assistance to the capacity, operation and inter-linking of surveillance, early warning and rapid reaction mechanisms covering health hazards;
  - (c) To address health determinants through health promotion and disease prevention measures, through support to and the development of broad health promotion activities and disease prevention actions and specific risk reduction and elimination instruments.

*Article 3*

**Community actions**

1. The general objectives of the programme as set out in Article 2 shall be pursued by means of the following groups of actions, the objectives and operational content of which are described in the Annex:

- (a) Improving health information, by:
    - developing and operating a health monitoring system;
    - developing and using mechanisms for analysis, advice, reporting, information and consultation on health issues.
  - (b) Responding rapidly to health threats, by:
    - enhancing the capacity to tackle communicable diseases;
    - strengthening the capacity to tackle other health threats.
  - (c) Addressing health determinants, by:
    - developing strategies and measures on lifestyle-related health determinants;
    - developing strategies and measures on socio-economic health determinants;
    - developing strategies and measures on health determinants related to the environment.
2. The actions set out in paragraph 1 shall be implemented through the following types of measures, which may, where appropriate, be combined and involve the countries referred to in Article 9:
- (a) Support for the preparation of Community legislative instruments and for cooperation on the position of the Community and its Member States in fora in which health-related matters are discussed.
  - (b) Support for the development of the statistical part of health information in the context of the Community Statistical Programme and for the preparation and dissemination of reports and communications on the situation on specific health topics in all Member States as well as reviews and advice on issues of interest to the Community and to all Member States.
  - (c) Development of, and support for information and consultation on health and health-related matters at Community level, involving representative organisations of patients, health professionals and other stakeholders.
  - (d) Support for the mobilisation of resources to counter health threats and react to unforeseen events, undertake investigations, and coordinate responses at Community and Member State level.
  - (e) Support for the sharing of experience and exchange of information between the Community and authorities and competent organisations in the Member States, and for building capacity to plan for, and respond to health threats and provide appropriate training.
  - (f) Promotion of the availability and, where appropriate, provision of information by the Community and authorities and competent organisations in the Member States, to health professionals and to the public.

- (g) Support for the development and implementation by the Community and the Member States of disease prevention and health promotion activities involving, as appropriate, non-governmental organisations, and to innovative or pilot projects of value to all Member States.

#### *Article 4*

### **Joint actions**

As part of the effort to ensure a high level of health protection in the definition and implementation of all Community policies and activities, the measures of the programme may be implemented as joint actions with related Community programmes and actions, notably in the areas of consumer protection, social protection, research and technological development, telematic interchange of data between administrations (IDA), statistics, education and environment, and with actions undertaken by the Joint Research Centre and Community agencies.

#### *Article 5*

### **Implementation**

1. The Commission shall ensure the implementation of the actions set out in Article 3. To this end, it shall adopt, in accordance with Article 8 (2), measures concerning the annual plan of work and for monitoring.
2. The Member States shall take appropriate action to secure, nationally, the coordination, organisation and the follow-up needed for the attainment of the objectives of the programme, involving all the parties concerned with public health in accordance with national legislation and practice. They shall endeavour to take the necessary steps to ensure the efficient running of the programme.

The Commission and Member States shall take appropriate action to develop mechanisms established at Community and national level to achieve the objectives of the programme. They shall ensure that appropriate information is provided about actions supported by the programme and that the widest possible participation is obtained in actions requiring implementation through local and regional authorities and non-governmental organisations.

3. The Commission, in cooperation with the Member States, shall ensure the transition between the actions developed within the public health programmes referred to in Article 12 and those to be implemented under the programme.

#### *Article 6*

### **Consistency and complementarity**

The Commission shall ensure that there is consistency and complementarity between the actions to be implemented under the programme and those implemented under other Community policies and activities. In particular, the Commission shall identify those proposals of relevance to the objectives and actions of the programme and shall inform the committee referred to in Article 8 (1).

#### *Article 7*

#### **Funding**

1. The financial framework for the implementation of the programme for the period referred to in Article 1 is hereby set at EUR 300 million.
2. The annual appropriations shall be authorised by the budgetary authority within the limits of the financial perspectives.

#### *Article 8*

#### **Committee**

1. The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by the representative of the Commission.
2. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

#### *Article 9*

#### **Participation of the EFTA/EEA countries, the associated Central and Eastern European countries, Cyprus, Malta and Turkey**

The programme shall be open to the participation of:

- (a). The EFTA/EEA countries in accordance with the conditions established in the EEA Agreement.
- (b). The associated countries of Central and Eastern Europe, in accordance with the conditions laid down in the Europe Agreements, in their Additional Protocols and in the Decisions of the respective Association Councils;
- (c). Cyprus, funded by additional appropriations in accordance with the procedures to be agreed with that country.
- (d). Malta and Turkey, funded by additional appropriations in accordance with the provisions of the Treaty.

#### *Article 10*

#### **International cooperation**

In the course of implementing the programme, cooperation with third countries and with international organisations competent in the sphere of public health, in particular the World Health Organisation, the Council of Europe and the Organisation for Economic Cooperation and Development, shall be fostered.

*Article 11*

**Monitoring, evaluation and dissemination of results**

1. The Commission shall identify performance indicators, monitor achievement of results, and carry out independent evaluations in the third year (mid-term evaluation) and during the last year (*ex-post* evaluation) of the programme. The evaluations shall particularly assess the impact achieved and the efficiency of the use of resources.
2. The Commission shall make the results of actions undertaken and the evaluation reports publicly available.
3. The Commission shall submit a mid-term report to the European Parliament and to the Council during the third year and a final report upon completion of the programme. It shall incorporate into these reports information on Community financing within the framework of the programme and on consistency and complementarity with other relevant programmes, actions and initiatives, as well as the relevant evaluation results. The reports shall also be submitted to the Economic and Social Committee and the Committee of the Regions.

*Article 12*

**Repeal**

The following decisions are hereby repealed:

Decision No 645/96/EC,  
Decision No 646/96/EC,  
Decision No 647/96/EC,  
Decision No 102/97/EC,  
Decision No 1400/97/EC,  
Decision No 372/1999/EC,  
Decision No 1295/1999/EC,  
Decision No 1296/1999/EC.

*Article 13*

**Entry into force**

This Decision shall enter into force on the date of its publication in the Official Journal of the European Communities.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

## ANNEX

### SPECIFIC OBJECTIVES AND ACTIONS

#### **1. IMPROVING HEALTH INFORMATION AND KNOWLEDGE**

##### **1.1. Developing and operating a health monitoring system**

1st Objective: To establish Community indicators for health status, diseases and health determinants, methods for the collection of data for monitoring and analysis, and create corresponding databases

- (1) Complete the framework for the stepwise establishment of health indicators fully covering health status, diseases, health resources and interventions, and health determinants, and collect relevant data using methods to be agreed;
- (2) Implement the framework for establishing indicators, collecting data and integrating it in databases, and develop versions of the databases for use by health professionals and the public.

The statistical element of this work will be developed as part of the Community Statistical Programme.

2nd Objective: To improve the system for the transfer and sharing of health data

- (1) Review and improve the system linking the Commission and Member State health administrations via the Internet and other means in order to transfer and share Community indicators and data;
- (2) Make the health data collected in the information system available on Commission and Member States' Web sites and regularly update it, for access by administrations, health professionals and the public.

##### **1.2. Developing and using mechanisms for analysis, advice, reporting, information and consultation on health issues**

1st Objective: Developing mechanisms for analysis and advice on health issues

- (1) Develop and operate a Community network to undertake analysis and the preparation of reports on health status and on the impact of health determinants and policies, identify risk factors and gaps in knowledge and forecast trends for use in policy formulation, priority setting and resource allocation;
- (2) Develop and operate a Community network to monitor and undertake analysis and provide advice on health technologies;
- (3) Develop and operate a benchmarking mechanism for Community strategies and national policies and activities on disease prevention, health promotion and health protection, with appropriate parameters and data sets;

- (4) Develop and operate a Community network to monitor, undertake analysis and provide advice on clinical guidelines and quality and good practice in health care interventions.

2nd Objective: Reporting on health issues

- (1) Report on Community health status and identify trends giving rise to concern; report on the impact of selected activities, policies and measures and health determinants;
- (2) Present reviews, advice and guidelines on health technologies, health interventions and quality and good practice.

3rd Objective: Consultation and information and dissemination of reports, advice and recommendations

- (1) Make available reports, reviews, advice and guidelines referred to in section 1.2 of this Annex on Commission and Member States' Web sites and through other appropriate means;
- (2) Develop and use mechanisms for informing and consulting representative organisations of patients, health professionals and other stakeholders about health-related matters at Community level;
- (3) Identify key information about health and health services, including issues related to access and entitlements, and make it available, as appropriate, notably to people moving from one Member State to another.

## **2. RESPONDING RAPIDLY TO HEALTH THREATS**

### **2.1. Enhancing the capacity to tackle communicable diseases**

1st Objective: Support the further implementation of Decision 2119/98/EC on the Community network on the epidemiological surveillance and control of communicable diseases

- (1) Develop:
  - (a) case definitions, epidemiological and surveillance methods, technical means and procedures, and define nature and type of data to be collected and transmitted concerning prioritised diseases or special issues;
  - (b) procedures for the information, consultation and coordination between Member States, for the prevention and control of communicable diseases, including provisions for a Community incident investigation team;
  - (c) guidelines on the protective measures to be taken, in particular at external frontiers and in emergency situations; links with applicant countries and other third countries;

- (2) Assemble surveillance data and network inventories held in existing databases;
- (3) Underpin the network operation in particular in relation to common investigations, training, continuous assessment and quality assurance.

2nd Objective: To enhance the safety and quality of human blood

- (1) Complete and implement the framework on high standards of quality and safety for the collection, processing, storage and distribution and use of whole blood, blood components, and blood precursors;
- (2) Develop and operate a haemovigilance network and prepare guidelines on the optimum use of blood.

3rd Objective: To enhance the safety and quality of organs and substances of human origin

- (1) Develop and implement a Community strategy on organs and substances of human origin;
- (2) Develop and operate a Community network on organs and substances of human origin.

## **2.2. Strengthening the capacity to tackle other health threats**

1<sup>st</sup> Objective: To develop strategies and mechanisms for responding to non-communicable disease threats

Review and develop strategies on responses to non-communicable disease threats, including, if appropriate, developing a Community network with links to existing surveillance, notification and alert mechanisms;

2<sup>nd</sup> Objective: To promote the formulation of guidelines and measures on electromagnetic fields and other physical agents

Review and further develop guidelines and advice on protective and preventive measures on exposure to:

- 1) electromagnetic fields;
- 2) other physical agents, such as optical and ultra-violet radiation, laser radiation, pressure, noise and vibration.

## **3. ADDRESSING HEALTH DETERMINANTS**

### **3.1. Developing strategies and measures on lifestyle-related health determinants**

Objective: To develop and implement, in close cooperation with the Member States, strategies and measures on life-style related health determinants supporting, in particular, their integration in overall health promotion and disease prevention policies

Further develop and implement Community strategies, including benchmarking and analysis of policies and measures, preparation of reports and guidelines, setting up networks, identification of scope and objectives of further Community action, and prepare Community instruments on lifestyle-related health determinants.

### **3.2. Developing strategies and measures on socio-economic health determinants**

Objective: To contribute to the formulation and implementation of strategies and measures on socio-economic determinants

- (1) Develop a methodology for benchmarking and linking strategies to identify health inequalities using data from the Community health information system, and, if appropriate, develop Community instruments relating to health services and insurance arrangements and to the impact on them of Community policies and activities. Actions will also cover questions related to consumption, cost-effectiveness and expenditure on medicinal products;
- (2) Review and identify obstacles to access to health services across internal borders in the Community and, if appropriate, develop guidelines.

### **3.3. Develop strategies and measures on health determinants related to the environment**

Objective: To contribute to the formulation and implementation of strategies and measures on health determinants related to the environment

- (1) Contribute to the further development and implementation of guidelines and recommendations issued by the European Ministerial Environmental Health Conference and to the monitoring of effectiveness of national strategies and measures;
- (2) Identify and prepare reports on good practice in monitoring, early warning systems and measures on pollutants and associated diseases, and, if appropriate, prepare guidelines.

## **4. CARRYING OUT THE ACTIONS**

- (1) The actions to be taken may be funded by service contracts following calls for tender or by subsidies for joint financing with other sources. In the latter case, the level of financial assistance by the Commission may not exceed, as a general rule, 50% of the expenditure actually incurred by the recipient.
- (2) In carrying out the programme, the Commission may require additional resources, including recourse to experts. These requirements will be decided in the context of the Commission's ongoing assessment of resource allocation.
- (3) The Commission may also undertake information, publication and dissemination actions. It may also undertake evaluation studies and organise seminars, colloquia or other meetings of experts.

- (4) The Commission will prepare annual work plans setting out the priorities and actions to be undertaken. Moreover, it will also specify the arrangements and criteria to be applied in selecting and financing actions under this programme. In so doing, it will seek the opinion of the Committee mentioned in Article 8.
- (5) Actions undertaken will fully respect the principles of data protection.

## FINANCIAL STATEMENT

### **1. TITLE OF OPERATION**

Proposal for a Decision of the European Parliament and of the Council adopting a programme of Community action in the field of public health (2001-2006)

### **2. BUDGET HEADINGS INVOLVED**

B3-4300, B3-4301, B3-4302, B3-4303, B3-4304, B3-4305, B3-4306, B3-4307

### **3. LEGAL BASIS**

Article 152 of the Treaty establishing the European Community

### **4. DESCRIPTION OF OPERATION**

#### **4.1 Objective**

The objective of the decision is to establish a programme of action comprising incentive measures, the overall aim of which is to make a contribution towards the attainment of a high level of health protection by directing action towards improving public health, preventing human illness and diseases and obviating sources of danger to health.

#### **4.2 Period covered and arrangements for renewal**

The proposed programme covers a period of six years beginning on 1 January 2001. The Commission shall carry out an evaluation of the actions undertaken and will submit relevant mid-term and final reports, and if appropriate, propose an extension.

### **5. CLASSIFICATION OF EXPENDITURE OR REVENUE**

#### **5.1 Compulsory/Non-compulsory expenditure**

NCE

#### **5.2 Differentiated/Non-differentiated appropriations**

CD

#### **5.3 Type of revenue involved**

Appropriations to cover the funding of actions carried out on the initiative of the Commission or to provide financial support for projects by third parties.

## 6. TYPE OF EXPENDITURE OR REVENUE

- Subsidy for joint financing with other sources in the public and/or private sector
- Service contracts following calls for tenders

## 7. FINANCIAL IMPACT

### 7.1 Method of calculating the total cost of operation (relation between individual and total costs)

Commitment appropriations EUR million (at current prices)

Financial year	N	n+1	n+2	n+3	n+4	n+5	Total
Total per year	46.5	50.5	50.5	50.5	51	51	300

The figures shown above are indicative. The actual amounts will be set in the annual budgetary procedures.

As a general rule, the level of financial assistance from the Commission may not exceed 50% of the expenditure actually incurred by the recipients.

### 7.2 Itemised breakdown of cost

The figures given below are indicative. They provide estimates for the level of expenditure corresponding to the different areas of the programme. The actual amounts will be determined in accordance with the outcome of the annual budgetary procedures.

EUR million (at current prices)

Year	N	n+1	n+2	n+3	n+4	n+5	Total
<u>1. Improving health information and knowledge</u>	13.5	19.5	24.5	24.5	25	25	132
1.1. Developing a health monitoring system	9	13.5	18.5	16.5	16.5	16.5	90.5
1.1.1 Indicators, methods of collection and databases	7.5	12	16	15	15	15	80.5
1.1.2 System for transfer and sharing of data	1.5	1.5	2.5	1.5	1.5	1.5	10
1.2. Developing and using mechanisms for analysis, advice, reporting, information and consultation on health issues	4.5	6	6	8	8.5	8.5	41.5
1.2.1 Mechanisms for analysis	1.5	2	2	3	3	3	14.5
1.2.2 Reporting on health issues	2	2.5	2.5	3.5	3.5	3.5	17.5
1.2.3 Consultation and information and dissemination of reports	1	1.5	1.5	1.5	2	2	9.5
<u>2. Responding rapidly to health threats</u>	18	19	14	14	14	14	93
2.1 Enhancing the capacity to tackle communicable diseases	14	14.5	11.5	11.5	11.5	11.5	74.5
2.1.1 Support to the Community network on communicable diseases	11.5	11	9	9	9	9	58.5
2.1.2 Enhance the safety and quality of human blood	1.75	1.75	0.75	1.25	1.25	1.25	8
2.1.3 Enhance the safety and quality of organs and substances of human origin	0.75	1.75	1.75	1.25	1.25	1.25	8
2.2 Strengthen the capacity to tackle other health threats	4	4.5	2.5	2.5	2.5	2.5	18.5
2.2.1 Strategies and mechanisms for non-communicable disease threats	3	3.5	1.5	1.5	1.5	1.5	12.5

Year	N	n+1	n+2	n+3	n+4	n+5	Total
2.2.2 Electromagnetic fields and other physical agents	1	1	1	1	1	1	6
<u>3. Addressing health determinants</u>	12.86	9.86	9.86	9.86	9.86	9.86	62.16
3.1 Lifestyle-related	8.86	7.36	7.36	7.36	7.36	7.36	45.66
3.1.1 Tobacco	1	1	1	1	1	1	6
3.1.2 Alcohol	1	1	1	1	1	1	6
3.1.2 Drug dependence	1.5	1.5	1.5	1.5	1.5	1.5	9
3.1.3 Nutrition	2	1	1	1	1	1	7
3.1.4 Physical activity	0.5	0.5	0.5	0.5	0.5	0.5	3
3.1.5 Sexual behaviour	0.5	0.5	0.5	0.5	0.5	0.5	3
3.1.6 Mental health	2.36	1.86	1.86	1.86	1.86	1.86	11.66
3.2 Socio-economic determinants	2	1.5	1.5	1.5	1.5	1.5	9.5
3.3. Health determinants related to the environment	2	1	1	1	1	1	7
Total	44.36	48.36	48.36	48.36	48.86	48.86	287.16

### 7.3 Operational expenditure for studies, experts etc. included in Part B of the budget

Commitment appropriations EUR million (at current prices)

Year	n	n+1	n+2	n+3	n+4	n+5	Total
– Studies	0.65	0.65	0.65	0.65	0.65	0.65	<b>3.9</b>
– Meetings of experts <sup>1</sup>	0.75	0.75	0.75	0.75	0.75	0.75	<b>4.5</b>
– Information and publications	0.74	0.74	0.74	0.74	0.74	0.74	<b>4.44</b>
<b>Total</b>	<b>2.14</b>	<b>2.14</b>	<b>2.14</b>	<b>2.14</b>	<b>2.14</b>	<b>2.14</b>	<b>12.84</b>

### 7.4 Schedule of commitment and payment appropriations

EUR million

Year	n	n+1	n+2	n+3	n+4	n+5	Total
Commitment appropriations	46.5	50.5	50.5	50.5	51	51	<b>300</b>
Payment appropriations							
year n	13.95	20.93	9.3	2.32			
n+1		15.15	22.73	10.1	2.52		
n+2			15.15	22.73	10.1	2.52	
n+3				15.15	22.73	10.1	2.52
n+4					15.3	22.95	12.75
n+5 and subs. Yrs						15.3	35.7
<b>Total</b>	<b>13.95</b>	<b>36.08</b>	<b>47.18</b>	<b>50.3</b>	<b>50.65</b>	<b>50.87</b>	<b>50.97</b>

## 8. FRAUD PREVENTION MEASURES

All proposals for subsidies will be assessed for technical content and financial criteria which include adequacy of own resources, sound finances and financial management, past record of performance or reliability as regards the capability of fulfilling the terms of subsidy, relationship between partners in a given project and potential for effective accounting and control. These also apply in cases of service contracts.

<sup>1</sup> Costs satisfying the criteria in the Commission Communication of 22 April 1992 (SEC(92) 769).

Requests for final payment must be accompanied by an evaluation of the operational and financial status of the project concerned.

- Specific control measures envisaged

Checks in situ will be carried out using appropriate selection criteria (scale of subsidy, interim report, results of on-going monitoring, information on progress with the execution of the relevant work-plan). In cases where there are reasons to believe that the performance of a project that has received a subsidy, or that of a service contract, is seriously being compromised, an urgent check will be carried out and, if there are remaining suspicions, the service concerned will refer the matter to the relevant audit services and the Anti-fraud Service.

## **9. ELEMENTS OF COST-EFFECTIVENESS ANALYSIS**

### **9.1 Objectives; target population**

- General objectives: links with the overall aim

The overall aim of the programme is to make a contribution towards the attainment of a high level of health protection by directing action towards improving public health, preventing human illness and diseases, and obviating sources of danger to health. Its general objectives are:

- To improve information and knowledge for the development of public health and the strengthening and maintenance of effective health interventions and efficient health systems, by developing and assisting in the operation of a well-structured and comprehensive system for collecting, analysing, evaluating and imparting health information and knowledge to competent authorities, health professionals and the public, and by undertaking assessments of and reporting on health status and health-related policies, systems and measures;
- To enhance the capability of responding rapidly and in a coordinated fashion to threats to health by the development, strengthening and assistance to the capacity, operation and inter-linking of surveillance, early warning and rapid reaction mechanisms covering health hazards;
- To address health determinants through health promotion and disease prevention measures, through support to and the development of broad health promotion activities and disease prevention actions and specific risk reduction and elimination instruments.

- Specific and quantifiable objectives

Objectives that are specific and quantifiable have been set for all the actions under the programme.

- Target population: distinguish for any individual objectives; indicate the end-beneficiaries of the Community's financial contribution and the intermediaries involved.

The general population and target population sub-groups are the ultimate beneficiaries of the actions being undertaken. The programme foresees actions permitting the monitoring of health status among the public at large as well as particular groups at risk, and the timely identification of adverse trends so that long-term plans can be formulated to address the factors that are implicated. Using Member States as key multiplier-effect parties, it actively promotes the implementation of strategies on health determinants that have significant effect on health, especially slow acting ones the effects of which only manifest themselves later in life. Finally, the programme aims at providing an effective shield over the peoples of the Community to protect them against rapidly acting agents of disease and accidents in leisure, travel or work.

The direct beneficiaries of the Community's financial contribution are governmental or quasi-governmental agencies and institutes competent in health matters, associations of health professionals and learned institutions, and representative NGOs active in the field of health information, prevention of diseases and health promotion. Criteria for eligibility, depending on the type of action to be undertaken (Article 3 of the proposed decision), are the involvement of partners from all Member States or the potential for the action to benefit and/or be applicable in all Member States, integration in the strategy of the Community and the Member States, and added value.

## **9.2 Grounds for the operation**

- Need for Community financial aid, with particular regard to the principle of subsidiarity

The present proposal for a decision by the European Parliament and the Council pursuant to Article 152 of the EC Treaty is adopted in an area where the Community does not have exclusive competence. The objectives of the programme cannot be sufficiently accomplished by the Member States because of the complexity, trans-national character and lack of complete control at Member State level over the factors affecting health status and health systems.

In the absence of the proposed programme of action, neither the Community nor the Member States will have an adequate basis on which to plan future health policies and measures and prepare to counter in an effective way the threats to health, whether known or unforeseen, and health professionals and the public would be deprived of key information concerning health and health services.

- Choice of ways and means

The actions to be implemented under the programme have been so designed as to have tangible aims and measurable outputs benefiting all the Member States and they will yield added value in a number of ways:

- They would lead to the setting up of sustainable procedures and structures, in particular networks, and the production of data and information necessary for the assessment of Community policies and activities;
- They will foster and underpin policy formulation at Member State and Community level and may lead to the preparation of legislative instruments;

- They would support activities that expand and consolidate efforts already undertaken by Member States;
  - They would enable the production of reports and the conduct of analysis on a unique and large scale and quality in the Community.
- advantages over possible alternatives (comparative advantages)

The programme provides enough flexibility through the drawing-up of annual work plans to allow deployment of resources and adaptation of activities to address emerging priorities, unanticipated events, and adjustments in the form of outputs, while respecting the fundamental criteria of selecting and ordering priorities according to the magnitude of risk or potential of effect, public concerns, availability of instruments and methods for effective intervention and response or potential for their development, subsidiarity and added value, and likely impact on other sectors. The action programmes undertaken in the past suffered from a lack of flexibility to handle new or re-emerging threats and could not allow the re-deployment of resources.

### **9.3 Monitoring and evaluation of the operation**

- Performance indicators selected

\*output indicators (measurement of resources employed and efficiency)

The programme provides for quantifiable deliverables, annual work plans and on-going monitoring of actions undertaken using as indicators the number and quality of networks to be established, guidelines and reports to be issued, ad hoc surveys on health status, health systems and public perceptions, effectiveness of strategies and quality of information, and up-take, emulation and multiplier effects in Member States by competent authorities and local groups and associations.

\*impact indicators (measurement of performance against objectives)

The programme is subject to evaluation, especially on performance, including effectiveness against objectives for each of the action involved, by Commission staff and by independent experts using direct, i.e. health-related indicators and indirect measurements (e.g. setting-up and proper operation of mechanisms and procedures for health improvement).

- Details and frequency of planned evaluations

The Commission submits evaluation reports mid-way and at the end of the programme in which the effectiveness and added value of the actions will be evaluated.

- Assessment of the results obtained (where the operation is to be continued or renewed)

In the light of the evaluations mentioned above, the Commission may propose an extension of the programme, if appropriate.

**10. ADMINISTRATIVE EXPENDITURE (SECTION III, PART A OF THE BUDGET)**

Actual mobilisation of the necessary administrative resources will depend on the Commission's annual decision on the allocation of resources, taking into account the number of staff and additional amounts authorised by the budgetary authority.

**10.1 Effect on the number of posts**

Type of post		Staff to be assigned to managing the operation		Source		Duration
		Permanent posts	Temporary posts	Existing resources in the DG or department concerned	Additional resources	
Officials or temporary staff	A	24	4	28		Full time over 6 years
	B	9		9		
	C	15		15		
Other resources:- Seconded national experts			5	5		Full time over 6 years
Total		48	9	57		

If additional resources are required, indicate the pace at which they will have to be made available.

## 10.2 Overall financial impact of additional human resources

No resources additional to those existing in the Directorate are envisaged.

EUR

	Amounts	Method of calculation
Officials		
Temporary staff		
Other resources (indicate budget heading)		
Total		

The amounts given must express the total cost of additional posts for the entire duration of the operation, if this duration is predetermined, or for 12 months if it is indefinite.

## 10.3 Increase in other administrative expenditure as a result of the operation

No increase in other administrative expenditure is envisaged.

EUR

Budget heading	Amounts	Method of calculation
Total		

The amounts given must correspond to total expenditure arising from the operation if its duration is predetermined or expenditure for 12 months if it is indefinite.

## **IMPACT ASSESSMENT FORM**

### **THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES (SMEs)**

#### **TITLE OF PROPOSAL**

Proposal for a Decision of the European Parliament and of the Council adopting a programme of Community action in the field of public health

#### **DOCUMENT REFERENCE NUMBER**

#### **THE PROPOSAL**

1. Taking account of the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims?

In accordance with Article 152 of the EC Treaty, the Commission is presenting this proposal for a programme of incentive measures for adoption by the European Parliament and the Council. The overall aim of the programme is to make a contribution towards the attainment of a high-level of health protection by directing action towards improving public health, preventing human illness and diseases and obviating sources of danger to health. The objectives of the programme cannot be sufficiently accomplished by the Member States because of the complexity, trans-national character and lack of complete control at Member State level over the factors affecting health status and health systems.

#### **THE IMPACT ON BUSINESS**

2. Who will be affected by the proposal?

There will be no effects on business by this proposal. The programme provides for the financing of actions encouraging cooperation between Member States, promoting coordination of their policies and programmes, promoting the exchange of information on health status and health determinants, and the sharing of experience on strategies to counter threats to health and prevent disease.

3. What will business have to do to comply with the proposal?

There are no requirements placed on business.

4. What economic effects is the proposal likely to have?

There are no economic effects on employment, investment and the creation of new business or on the competitiveness of business by this proposal.

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms (reduced or different requirements etc)?

As there are no effects on business, there is no need for such measures.

#### **CONSULTATION**

6. List the organisations that have been consulted about the proposal and outline their main views.

No organisation has been consulted about this proposal. The proposal forms part of the Commission strategy on health on which there is consensus among, and support from, all Community Institutions, following an in-depth debate launched by the Commission with its communication COM(1998) 230 of 15 April 1998, and has benefited from the advice of the High-level Committee on Health.