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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Establishing a European Centre [for Disease Prevention and Control]

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. OVERVIEW

Communicable disease outbreaks can pose a significant threat to the health and well being of the European Union's citizens, as shown during the recent spread of the SARS virus (Severe Acute Respiratory Syndrome) and in the anthrax alerts of late 2001, which were thought to be due to bio-terrorism. In a European Union where millions of people cross internal and external borders each day, tackling health threats requires a much closer co-operation between Member States, the European Commission, the World Health Organisation and affected countries around the world. The European Union citizens place a very high value on the protection of their health. Communicable disease outbreaks, or other threats such as the deliberate release of chemical or biological agents from terrorist attacks, can cause considerable anxiety to citizens and huge costs to society, even when the number of cases remains relatively small. A major outbreak such an influenza pandemic could have catastrophic consequences. The draft European Convention of the future of the European Union has identified common safety concerns in public health matters as an area where Community competencies should be consolidated.

Since 1999, the Commission has managed a Communicable Diseases Network. This is currently based on ad hoc cooperation between Member States within the legal framework of Council and Parliament Decision 2119/98/EC. However, there is a need for a substantial reinforcement of this system if the European Union is to be in a position to control communicable diseases effectively. In 2000 and 2001, two external evaluations of the Network highlighted weaknesses in the functioning of existing structures and reviewed options for a more effective response capacity at the EU level. In 2002, the State Epidemiologists from the Member States gave their view on the future of the surveillance of communicable diseases at the European Union level and favoured the creation of an EU-level centre. In addition, in 2002, the Network Committee also adopted conclusions favouring the creation of an EU coordinating centre.

In June 2001, the European Council meeting in Gothenburg asked that the possibility of creating a European surveillance and early warning system on health issues be examined. At the Council meeting of 15 November 2001, following agreement by the Health Ministers, the Belgian Presidency issued conclusions which requested the Commission to develop an action programme of cooperation on preparedness and response to biological and chemical agent threats from their deliberate release. The European Union's Employment, Social policy, Health and Consumer Affairs Council, at an extraordinary meeting held on 6 May 2003 to discuss SARS, and at its 2 June 2003 meeting recognised the need to strengthen the EU preparedness to deal with disease outbreaks within its borders. The Commission's intention to propose legislation creating a European Centre for disease prevention and control was widely supported.

The present proposal aims at creating a European Centre, able to provide a structured and systematic approach to the control of communicable diseases and other serious health threats, which affect European Union citizens. The creation of a European Centre for Disease Prevention and Control, an independent European agency, would mobilise and significantly reinforce the synergies between the existing national centres for disease control.

In future, the Centre will take over the existing operational instruments provided by Decision 2119/98/EC (networks), whilst the Commission will continue to be responsible for its residual legislative provisions (setting technical and procedural requirements).

The Centre will operate the Community network of national competent authorities or institutes mentioned in Decision 2119/98/EC as well as its dedicated surveillance networks dealing with specific diseases (AIDS, TB, influenza, etc…). The Centre will also steer the technical work to be conducted between national institutes, which requires shared ownership of objectives, tasks and operations and pooling of resources at EU-level. The European Centre will encourage this shared ownership and facilitate the joint use of skills and resources to discharge common responsibilities in fighting serious health threats.

The Commission will maintain its' overall supervision and existing legislative powers under Decision 2119/98/EC in order to set technical requirements and procedural obligations, which will have to be implemented and used by all the components of the Community Network. The Commission will work in close consultation with the Member States through the Regulatory Committee (the so-called 'Network Committee'). The Centre will provide EU policy makers and citizens with authoritative and independent scientific advice on serious health threats and recommend control measures to the Commission and national authorities. They in turn will then decide on the appropriate risk management response, thus enabling a rapid and effective EU-wide response.

The Centre, either on request of the Commission or on its own initiative, will issue scientific opinions and risk assessments on a wide spectrum of issues related to communicable diseases, such as clinical medicine, epidemiology, microbiology, and preventive measures. It will do so by setting up scientific panels to address specific issues that are not covered by the existing scientific excellence and expertise from the dedicated surveillance networks.

2. INTERNATIONAL HEALTH THREATS IN THE 21ST CENTURY

Communicable disease has always been one of the major threats to human health. What has changed in the past few years is the growing realisation that natural outbreaks of communicable disease can still threaten both technologically advanced regions of the world such as the European Union as much as developing regions of the world with little health infrastructures. The possibility exists that a communicable disease outbreak could be started deliberately ("bio-terrorism"). In our increasingly interconnected and global world, a disease outbreak in one country can be spread internationally in a matter of hours or days. This "new threat" and the need for a comprehensive EU approach to it, was also identified in the security strategy paper that was presented by the High Representative for the CFSP, Javier Solana, to the Thessaloniki European Council ("A secure Europe in a better world").

In controlling a disease outbreak, time is of the essence. Every day lost in identifying the threat, deciding on control measures and implementing them can result in the outbreak spreading further. These lost days can mean the difference between a small outbreak and a serious epidemic. If the disease or pathogen involved is particularly lethal, then delay may cost lives.

Speed of reaction is of particular importance within the European Union. Products and people flow freely between EU Member States and controls have been abolished at internal borders. A small communicable disease outbreak in one country can become an international public health threat if national control measures are ineffective: for example, if a disease outbreak is

not detected and contained in a timely way, if national authorities give out inconsistent or incomplete information, or even fail to notify other countries of the outbreak. Through migration or tourism, the SARS virus was able to spread in just in a few weeks from China to Europe, the Americas, and Asia. SARS was spread internationally by the movement of infected people. Since the deliberate release of anthrax in the US in late 2001 security services and authorities responsible for civil defence are taking the threat of "bio-terrorism" attacks very seriously.

Lack of appropriate co-ordination structures regionally and internationally can contribute to this problem. A rapid, effective and co-ordinated response to health threats is therefore critical. In the SARS outbreak the shortcomings of present model of disease control were well demonstrated. Delayed detection of an ongoing outbreak allowed the virus to be spread by air travel from China to Canada, where an infected traveller was able to spread the virus among health care personnel in a Toronto hospital. Only after the WHO issued global health alert on March 12th, 2003, when the public as well as health professionals were informed about SARS, could measures to contain its spread be properly implemented. In the case of SARS, however, without international collaboration between health experts it would not have been possible to identify the virus and gather knowledge about its epidemiology in such a short time.

Major communicable disease outbreaks impact the whole of a society, not just its health sector. For instance, the SARS outbreak had an immediate, negative impact on economic growth in the Asian countries it affected. SARS may also, more indirectly, have had a negative impact on the EU economy. Taking rapid and effective action against a disease outbreak, and thus being able to reassure citizens that the outbreak has been contained, will protect Member States' economies, as well as their public health.

3. LIMITATIONS OF THE CURRENT COMMUNITY NETWORK'S ACTIVITIES

Under Article 152 of the Treaty, the European Community recognised the need to work more effectively on public health threats. The Community Institutions gave this practical effect with the adoption of the Council and the European Parliament Decision 2119/98/EC setting up a network for the epidemiological surveillance and control of communicable diseases in the European Community. This Decision envisaged the creation of Europe-wide surveillance and early warning and response mechanisms.

As far as early warning and response is concerned, the Network has partially fulfilled its coordinating role, but has not been able to fully follow up on the required technical actions and interventions. For epidemiological surveillance, specialists from the national institutes concerned, who already survey each disease group, were asked to create the so-called dedicated surveillance networks (DSN). Together these form the 'network of networks', which constitute the basis on which the Community network functions.

The Commission's role in coordinating activities has been limited to operating the system of EU subsidies that co-finances the dedicated surveillance networks, and designing and operating the telematic pilot system on the Early Warning and Response System (HSSCD/EUPHIN). The Commission has barely the financial and technical resources necessary to fulfil these functions. The Network Committee has been utilised for scientific advice and coordination purposes in ways that go far beyond the limited regulatory role foreseen for it in the 1998 Decision. The growing demands being placed on the Committee demonstrate the pressing need for a substantial reinforcement of resources if the expectations for health protection at EU level are to be met.

The basic formula for cooperation amongst Member States and the Commission in the framework of Decision 2119/98/EC is not being questioned. What is required is a much-extended capacity to provide independent scientific advice and effective operational coordination. Both the disease surveillance and the early warning and response activities needs more trained specialists to assess, investigate, and analyse outbreaks across Europe and abroad, particularly when there is a significant potential threat to the health of EU citizens. In some outbreaks, there have been several investigation teams from different Member States investigating the same phenomena with slightly different methodologies, sending samples to different laboratories, and finally each of them reporting separately.

It has become evident that the Community Network cannot develop much further without new structures and arrangements to support Member States and the Commission in fulfilling their tasks. The more diseases the Network covers with the 'dedicated surveillance networks', the more the risk of fragmenting its structure has become apparent. These dedicated surveillance networks have been financed using annual subsidies from the Public Health Action Programme, in competition with many other projects. With ten new Member States in 2004 it will be impossible to continue with the existing structures and resources if surveillance activities in the Member States (and other partner states in the dedicated surveillance networks) are to be continued efficiently.

The ability to respond to an international health threat is profoundly influenced by the extent to which relevant issues have been studied in advance, and whether preparedness plans are in place for co-ordinated action. To address the threat of influenza, the World Health Organisation (WHO) has been working on a global pandemic plan, to facilitate the development of national plans. A complementary EU level preparedness plan is needed to facilitate the exchange of information between the European Community's laboratory and surveillance networks and to ensure that appropriate vaccines, antiviral agents and other materials can be made available rapidly. A European Centre could harness all these measures in a coherent and cost-effective way.

4. THE EUROPEAN UNION NEEDS A CENTRE FOR DISEASE PREVENTION AND CONTROL

The public health responsibilities of the European Union have increased substantially, with the implementation of the Amsterdam Treaty and with rising expectations on the part of its citizens. This is reflected in many ways in the demands put on the Member States and the Commission to cooperate more closely both at EU level and internationally. Recent health threats have illustrated that one Member State alone does not generally have all the expertise available to address all possible aspects of a threat. It is only through intense and constructive international collaboration that the necessary expertise can be assembled. The added value is not only coordination but also pooling the expertise.

During the last three years, the Commission has initiated three external evaluations on the performance and improvements to be introduced in the operation of the Community network for communicable diseases (http://europa.eu.int/comm/dgs/health_consumer/index_en.htm).

The first evaluation produced in September 2000 by the Institute of Public Health, North Rhine Westphalia, with the London School of Hygiene and Tropical Medicine and Public Health Laboratory Services (UK), focused on the weak points in the functioning of the existing structures, analyzing transnational outbreaks of 5 diseases. It requested the Commission to put in place a framework for long term stability and sustainability of existing

and new disease specific networks and recommended the development of some 15 types of actions at Community level which are all supporting the principles addressed in the present proposal. These cover such issues as EU level preparedness, EU coordination of outbreak investigations, and provision of assistance by experts on behalf of the European Union.

The second evaluation was completed in December 2001 by the Belgian Scientific Institute of Public Health in consultation with epidemiological institutes from all Member States, Norway and the WHO. It demonstrated the willingness and preparedness of the national competent bodies to participate in setting up a Community response capacity. It supported a strong central coordination mechanism supported by European technical co-ordination structure outside the Commission but financed by the Community budget and starting on a pilot scale as soon as possible.

Thirdly, in June 2002, the State Epidemiologists from the Member States gave their view to the Commission on the future of the surveillance of communicable diseases in Europe. They confirmed the coordination tasks identified in the two previous studies and concluded in favor of sufficiently resourced permanent technical coordinating structure at European level. They held the same view at a public seminar held in November 2002 in Brussels under the auspices of the European Parliament.

In line with Decision 2119/98/EC the Commission conducted an internal evaluation of the operation of the Community network during 2002 and submitted it to the Network Committee. The Committee endorsed the recommendations on the tasks to be preferably transferred to a European coordinating Centre. The Committee also considered the Commission did not have enough access to well trained specialist staff and that Commission arrangements for networking, surveillance and early warning would therefore be insufficient. The running of an internal operation in the Commission services would not be less costly and would not create the sense of shared ownership, which an independent centre would provide.

These orientations, already mentioned in the conclusions of the European Council at Gothenburg in June 2001, were reiterated during the extraordinary meeting of the Council of the European Union (Employment, Social policy, Health and Consumer Affairs) on 6 May 2003 and their subsequent meeting on 2 June 2003, where the idea of creating a European Centre for disease prevention and control was widely supported.

Member States epidemiological centres must have a privileged place in this cooperation. It will probably be from their resources that most of the exchanges of cooperation will take place. For example, their officials are likely to be essential partners in running dedicated surveillance networks, training actions, and intervention teams. The existence of such resources in the Member States means that a large European Centre is not needed. Arrangements to give the Centre access to resources in national centres will be the key to keeping the Centre a relatively small, but effective, coordinating entity. The Centre will provide a structure enabling experts from different Member States to work together, for example, in WHO global outbreak investigation teams, and facilitating the subsequent sharing of results. The Centre would work with national public health institutes in equal partnership.

The Centre would allow quick mobilisation of expert staff from the Member States to be used in European Community intervention teams for epidemiological investigation, and for on site check ups and risk assessments. There would be a core technical expertise in the Centre to provide technical assistance to the Commission, and to undertake technical collaboration with Member States and the WHO. The Centre would coordinate laboratory actions with microbiological laboratory networks. The Centre would be a source of information for all

partners; the information given must be timely, accurate, easily understandable by users and adjusted to the different needs of the EU Institutions, Member States, public health institutes, the media, the public. When the Commission is preparing policy proposals or draft legislation, the Centre could provide authoritative scientific advice and technical input.

The Commission believes that an independent agency would be the best approach to enhance cooperation in an enlarged European Union. Such an agency - the European Centre for Disease Prevention and Control - would focus on communicable diseases, where there is already extensive experience of European cooperation and other emerging serious health threats. It would facilitate collaboration by the Commission and the Member States with other partners (e.g. third countries and international organisations, such as the WHO). This proposal provides for an appropriate legal base and a dedicated new budget line in the Community Budget. The role of the Centre in this Regulation is to be a visible centre of excellence to which the Commission and the Member States can go for authoritative advice and opinions.

In view of the scope and the mission of the Centre, there is also a need for coordination with other Community agencies, especially the European Food Safety Authority (EFSA) and the European Agency for the Evaluation of Medicinal Products (EMEA), both of which also deal with health assessments, early warning, and risk communication. There must be a clear commitment to avoiding duplication of work between agencies.

5. MAIN TASKS OF THE EUROPEAN CENTRE

Epidemiological surveillance and networking of laboratories

The Centre would develop epidemiological surveillance at European level. In this work, the Centre could either use its own staff, staff from the dedicated surveillance networks (DSN), or, in some instances, it could subcontract tasks to a national centre of excellence. This gradual integration of epidemiological surveillance will lead to the harmonisation of surveillance methodologies, including better comparability and compatibility of the surveillance data collected in the Member States. The Centre could also identify and maintain networks of reference laboratories, and enhance the quality assurance schemes of microbiological laboratories.

To maintain high standards in the surveillance, early warning and response network, the necessary staff and technical resources need to be in place in the Member States and at the Community level. The Centre would facilitate the training of expert staff and provide opportunities for them to gain useful 'hands on' experience. It could also serve as a place where the Member States could second officials from national institutes to work a limited period as part of their career development.

There is already considerable experience of cooperation between Member States' public health institutes on communicable diseases. Recognised procedures for cooperation, accepted by all, already exist. It therefore makes sense for the Centre to focus initially on communicable diseases, though it should also be able to deal with other emerging health threats if needed. In light of the recently adopted "Communication on a European Environment and Health Strategy" (COM(2003)338 final) in which "health monitoring" is a key element, the tasks of the Centre will be extended to cover "health monitoring" as soon as feasible.

Scientific opinions

Public health decisions have to be based on independent scientific evidence. The Centre will support the Commission and Member States by providing this. The Centre would contribute to public health policies by providing scientific assessments and technical support, based on scientific excellence, and maintained through its own expertise and that existing in the Member States. If there is insufficient scientific expertise in the Centre, or in the disease surveillance networks, the Director may, in consultation with the Advisory Forum, set up independent scientific panels for this purpose drawn from recognised scientific authorities and academia.

Scientific issues arising in the area of communicable diseases vary widely, ranging from questions of clinical medicine and epidemiology through to standardisation of laboratory procedures. Creating one permanent scientific committee to cover all these issues would not, therefore, be appropriate. The Centre would, instead, bring together scientific expertise in specific fields through its various EU-wide networks and via ad hoc scientific panels.

The Advisory Forum, consisting of scientists from public health institutes in the Member States, would support the Director in ensuring excellence and independence of the Centre's scientific work. The Centre would issue scientific opinions in accordance with procedures defined in the Regulation.

Information made available through EU funded research projects and other EU agencies, such as European Food Safety Authority (EFSA) and European Agency for Evaluation of Medicinal Products (EMEA) would have to be used by the Centre where appropriate. Its scientific panels would not be allowed to duplicate work done elsewhere. The Centre should initiate applied scientific studies to enhance policy development and also studies to develop and enhance its own operation effectiveness. To avoid duplication, the Centre will co-ordinate its actions with those of the Member States and the EU Framework Programme on Research.

Early Warning and Response

To be effective the early warning and response system (EWRS) requires 'around the clock' availability of specialists in communicable diseases. Whilst the responsibility for action will remain with Member States and the Commission, technical operation of the EWRS would be undertaken by the Centre and its networks.

The Centre would coordinate, as appropriate, with relevant EU agencies, such as the European Food Safety Authority, and with other alert systems, such as those run by the WHO. Response is a key element in preparedness and control of outbreaks. Rapid reaction can ensure a disease outbreak is limited and prevent its deteriorating into a wider crisis. The Centre will be a source of assistance and advice to the Commission and the Member States in managing these risks.

Technical Assistance

The Centre's rapid reaction capacity could cover more than the European Union itself, to similar structures in such areas as the EEA/EFTA, and candidate countries. When requested, it would send an EU-team to investigate an outbreak of an unknown human disease in a European country. The Centre should also have the ability to support, if necessary those Commission services that give humanitarian aid or other types of assistance in response to disease outbreaks in third countries. In these situations, the technical assistance should be co-ordinated with the appropriate Commission services, and relevant EU programmes. The Centre would have a particular role in defining action in those states that might import the

disease. In the case of an outbreak investigation mission, depending on the identification of the source of the outbreak (environmental, food, animal, chemical, deliberate release etc.) other appropriate EU agencies, and the WHO may have to be involved, in order to strengthen the coherence of the combined efforts avoid duplicating activities.

Emergencies and Communication

The Centre should have a major role in coordinating the response to serious health threats of EU-wide significance. The need for co-ordinated action is of pivotal importance, taking into account all the actors involved in emergencies. For example, public health authorities, civil protection, the military and civil society may all need to be involved in responding to an epidemic. A combined effort of these different instruments as part of a comprehensive EU policy, will be required in such emergencies. The creation of the Centre constitutes an important contribution to this effort. Considering the relatively small size of the Centre, however, it will only be able to take on such a coordinating role where the health threat is of direct relevance to its operational goals.

Objective, reliable and easily accessible information is essential for the general public and as well as for decision-makers in the Commission, Member States, and international organisations. The Centre will communicate about its activities and results, and disseminate information tailored to meet the needs of its different audiences. Using various media and communications tools, the Centre will ensure that its information is easily accessible, reliable, and understandable.

6. THE EUROPEAN CENTRE SHOULD BE SMALL BUT INFLUENTIAL

The Centre would remain small in terms of human resources, but possessing a far larger influence through its synergy with national institutes. The staff will include relevant specialists, such as epidemiologists, public health experts, microbiologists, logisticians and medical writers, as well as administrators.

The Centre will be funded from the Community budget, based on a proposal from the Commission and approved by the Budgetary Authority.

Within this budget, in addition to its normal running costs, the Centre should have an appropriate contingency budget to enable it to respond speedily and adequately to public health threats, when needed. The contingency budget must be sufficient to cover the breadth of operations which might be called for in such diverse settings as outbreak investigations, in the European Union or elsewhere, deliberate release of biological agents, or controlling a potential influenza pandemic. The Centre should also have a consultative role in providing scientific advice in crises, such as in an influenza pandemic, where public health is involved.

7. THE ADMINISTRATIVE STRUCTURE

As with other similar independent Community agencies, the Centre will have a three pillar administrative structure:

- A Director and his/her staff. The Director will be responsible for everyday administration, as well as the preparation and implementation of the Centre's work programme.

– A Management Board will ensure that the Centre carries out its missions and tasks, by adopting its annual work programme and financial regulation. The structure of the Management Board – representatives appointed by the Commission, representatives appointed by the Council, and representatives of stakeholders – is intended to provide supervision of the activities of the Centre and at the same time ensure coherence with action under Community policies and national initiatives.

– An Advisory Forum, which will be composed of members chosen from senior scientific personnel from the national competent bodies. The Advisory Forum will be a mechanism for exchanging information and pooling knowledge, as well as monitoring the scientific excellence of the activities of the Centre.

8. MAKING THE TRANSITION FROM THE CURRENT STRUCTURE

There is a budget in place from the Public Health Action Programme to carry out some of the preparatory work to set up the Centre. Until 2006, external expertise can be used to prepare the integration of the existing Dedicated Surveillance Networks into the Centre. Projects dealing with capacity building, dissemination of information and training might be candidates for early integration into the new structure.

It is also important for relevant laboratories to become involved in European level surveillance activities. The Commission will enhance the development of laboratory networks, including those European laboratories with the capacity to handle highly contagious micro-organisms, like smallpox virus. It will maintain and update the support databases and develop the Early Warning and Response system (EWRS) further. The procedures for effective exchange of information will also be developed.

Before the Centre becomes operational the Commission will concentrate on making the intervention teams, currently set up on a national basis in an ad hoc manner, more effective. This will be done in collaboration with the Member States taking account the Commissions existing actions in third countries in particular in liaison with the WHO. Running high quality surveillance, early warning, and response is not possible without trained specialists, with a variety of expertise at national and EU level.

The Task Force on deliberate release of chemicals and biological agents (BICHAT) was set up by the Commission in 2002 to identify the special needs in surveillance and response that might be necessary should a terrorist attack be envisaged. The Task Force comprises a number of seconded national experts from the Member States over a limited time period and it reports through the Health Security Committee of personal representatives from the Ministers of Health of the Member States. Eventually the work of the Task Force will need to be taken over by the Centre.

9. CONCLUSION

The dangers posed by communicable diseases do not diminish. Multiresistant tuberculosis, HIV/AIDS and more recently SARS remind the European Union to be on its guard. Enlargement reinforces the need to put in place adequate EU-level capacity, building on Member States' systems and the existing Communicable Disease Network, to respond to such health threats. The creation of a European Centre for Disease Prevention and Control will ensure efficient networking and pooling of Member States' scientific expertise and facilitate

more effective preparedness planning. By doing this, the Centre will strengthen the EU capacity to react to future health threats.

2003/0174 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Establishing a European Centre [for Disease Prevention and Control]

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152 paragraph 4 thereof,

Having regard to the Agreement on the European Economic Area,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[4],

Whereas:

(1) The Community is committed as a priority to protect, and to improve human health by prevention of human disease, in particular communicable diseases and to counter potential threats to health with a view to ensuring a high level of protection of health, requiring a coherent approach among Member States, coordinated at Community level.

(2) The Community should address European citizens' concerns about public health threats in a coordinated and coherent way. As the protection of health can mean various actions from preparedness and control measures to prevention of human diseases, the scope of actions should be kept broad.

(3) Member States must provide information on communicable diseases through the appropriate designated structures and/or authorities, according to Article 4 of Decision N° 2119/1998/EC[5], which requires timely scientific analysis in order for effective Community action to be undertaken.

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1 OJ C , , p. .
2 OJ C , , p. .
3 OJ C , , p. .
4 OJ C , , p. .
5 OJ L268, 3.10.1998, p.1

(4) Decision N° 2119/1998/EC expressly calls for the improvement of the coverage and effectiveness of existing designated networks between Member States for the surveillance of communicable diseases on which Community actions should be built and the need to foster cooperation with third countries and international organisations, in particular the World Health Organisation.

(5) Effective response to disease outbreaks with potential effects on the health of European citizens requires coordination of Member States' contribution and input by experienced scientists at Community level. The danger of deliberate release of agents also requires a coherent Community response to such criminal threats.

(6) An independent agency, hereinafter named the European Centre [for Disease Prevention and Control] should serve as a Community source of independent scientific advice, assistance, and expertise from trained medical, scientific, and epidemiological staff from its own resources or from those of competent bodies acting on behalf of Member States' authorities responsible for human health.

(7) The Centre should, in particular, be able to assign certain tasks to recognised competent bodies in the Member States. Cooperation with other relevant EU agencies and institutions should be encouraged to avoid duplication of activities.

(8) The Centre's mission should contribute to enhance epidemiological surveillance, rapid reaction and response to communicable diseases and other serious health threats, to promote training, to improve reliable communication, and to advise on public health policy, when requested. Therefore, the Centre should complement existing activities with regard to health monitoring, epidemiological surveillance, training programmes, and early warning and response mechanisms.

(9) The Centre should gather and analyse data and information on emerging public health threats and developments for the purpose of protection of public health in the European Community by preparedness. It shall assist and coordinate with Member States in developing and maintaining the capacity to react in a timely way. In public health emergencies the Centre should operate in close collaboration with Commission services and other agencies, Member States, and international organisations.

(10) The Centre should seek to maintain scientific excellence at all times through its own expertise and the expertise in the Member States and foster, develop and steer applied scientific studies. By this way, it will enhance the visibility and credibility of the scientific expertise in the European Community. Moreover, it will support Community preparedness planning, strengthening links with and between the clinical and public health sectors, in order to reinforce the public health laboratory capacity for rapid diagnosis, developing training programs for healthcare providers, and developing educational materials.

(11) The Management Board should be appointed in such a way as to secure the highest standard of competence in public administration and in the areas of actions of the Centre.

(12) The Management Board should have the necessary powers to establish the budget, check its implementation, draw up internal rules, to ensure coherence with Community policies, to adopt financial regulations, and appoint the Director.

(13) An Advisory Forum shall advise the Director in the performance of his/her duties. It shall be composed of representatives of competent bodies in the Member States, which undertake tasks similar to those of the Centre. The Advisory Forum constitutes a mechanism for an exchange of information on potential risks and the pooling of knowledge and for monitoring scientific excellence and independence of the Centre's work.

(14) The confidence of the Community institutions, the general public and interested parties in the Centre is essential. For this reason, it is vital to ensure its independence, high scientific quality, transparency and efficiency.

(15) The independence of the Centre and its role in informing the public mean that it should be able to communicate autonomously in the fields falling within its competence, its purpose being to provide objective, reliable and easily understandable information to improve citizens' confidence.

(16) The Centre should be financed by the general budget of the European Union. The Community budgetary procedure remains applicable as far as any subsidies chargeable to the general budget of the European Union are concerned. Moreover, the Court of Auditors should undertake the auditing of accounts.

(17) It is necessary to allow for the participation of European countries which are not members of the European Union and which have concluded agreements obliging them to transpose and implement the body of Community law in the field covered by this Regulation.

(18) The Centre should also be able to initiate scientific studies necessary for the accomplishment of its duties, while ensuring that the links established by it with the Commission and the Member States will avoid duplication of effort. It should be done in an open and transparent fashion and the Centre should take into account Community expertise, structures, and agencies already in place.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SCOPE AND RESPONSIBILITIES

Article 1

1. This regulation establishes an independent European agency for disease prevention and control, its mission and tasks, and its organisation.

2. The Agency shall be named the European Centre for Disease Prevention and Control, hereinafter referred to as the 'Centre'.

Article 2

Definitions

For the purposes of this Regulation:

(a) *'Competent body'* shall mean any structure, institute, agent or other scientific body recognised by Member States' authorities as providing independent scientific advice or capacity for action in the field of prevention and control of human disease.

(b) *'Prevention and control of human disease'* shall mean the range of measures taken by the competent public health authorities in the Member States to prevent and stop the spread of the disease.

(c) *'Dedicated surveillance network'* shall mean any specific network on diseases or special health issues selected for epidemiological surveillance between accredited structures and authorities of the Member States.

(d) *'Health threat'* shall mean a condition, agent or incident, which causes, directly or indirectly, ill health.

(e) *'Epidemiological surveillance'* shall have the meaning ascribed to it in Decision N° 2119/1998/EC.

(f) *'Community network'* shall have the meaning ascribed to it in Decision N° 2119/1998/EC.

(g) *'Early warning and response system'* shall mean the network under Decision (EC) N° 2119/1998 for the prevention and control of communicable diseases, formed by bringing into permanent communication with one another through appropriate means specified in Commission Decision N° 57/2000EC implementing Decision N° 2119/1998/EC.

Article 3

Mission of the Centre

1. The mission of the Centre is to analyse and assess risks to human health from communicable diseases and other serious health threats affecting the European Community, to provide expert advice to the Commission and the Member States, and to enhance the capacity of the European Community and its Member States to protect human health through prevention and control measures on communicable diseases and other serious health threats. The scope of the Centre will be extended (from communicable diseases and emerging health threats) to cover health monitoring as soon as feasible.

2. The primary objective of the Centre shall be to cooperate with the Member States in order to achieve coherent, timely, and effective actions by:

– Promoting the European networking of bodies operating in the fields within the Centre's mission, including the use and encouragement of networks arising from public health activities supported by the Commission;

– Facilitating the coordination of networking activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practises;

– Searching for, collecting, collating, analysing and summarising relevant scientific and technical data in the fields of its mission.

3. In pursuing its mission the Centre shall take full account of the responsibilities attributed by Community legislation to the Commission, the Member States, and to other Community agencies, and the responsibilities of international organisations, in order to ensure comprehensiveness, coherence, and complementarity of action.

4. The Centre, Commission and Member States shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions within the framework of its mission.

Article 4

Responsibilities of the Member States

To ensure the accomplishment of the Centre's mission the Member States shall co-operate by:

– Providing to the Centre all the scientific and technical data and information needed to address health threats and developments at the Community level. Member States shall take the necessary measures to ensure that information and data they collect are transmitted expeditiously to the Centre;

– Communicating to the Centre any messages forwarded to the Community network via the Early Warning and Response System;

– Identifying recognised competent bodies, within the field of operation of the mission of the Centre, which could be made available to assist in Community responses to health threats.

– Seconding to the Centre public health officers, including epidemiologists, for a defined period of time, for achievement of certain tasks of the Centre, such as field investigations in case of disease clusters or outbreaks.

CHAPTER 2

TASKS OF THE CENTRE

Article 5

Networking of organisations operating in the fields within the Centre's mission

1. The Centre, through the provision of technical and scientific expertise to the Commission and Member States, shall support the networking activities and

dedicated surveillance networks of authorities and structures designated under Decision (EC) N° 2119/1998, and to ensure their integrated operation.

2. The Centre shall

– Provide quality assurance by monitoring and evaluating surveillance activities of such dedicated surveillance networks to ensure optimal operation;

– Maintain the database(s) for such epidemiological surveillance, and

– Communicate the results of the analysis of data to the Community Network.

The Centre may delegate parts or all of these tasks to one of the dedicated surveillance networks.

3. By enhancing cooperation between expert laboratories the Centre shall foster the development of sufficient capacity at the Community level for microbiological diagnostics to detect micro-organisms in routine and exceptional circumstances. The Centre shall maintain and extend such cooperation and enhance the implementation of quality assurance schemes.

4. The Centre shall work with the assistance of competent bodies recognised by the Member States. The Centre may entrust to one or more of these competent bodies certain tasks, particularly preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks, in order to provide control of public health threats.

Article 6

Scientific support and training

1. The Centre shall provide support to the Commission and the Member States with independent scientific assessments and technical support, notably from the dedicated surveillance networks, together with information on specific issues from other authoritative scientific sources, including results from Community funded research and public health projects. In carrying out this task the Centre will consult with Commission where the planning and priority setting of research and public health activities are concerned.

2. Where such independent scientific expertise is not available from existing dedicated surveillance networks the Centre may set up independent ad hoc scientific panels.

3. The Centre may initiate scientific studies necessary for the performance of its mission. The Centre shall avoid duplication with Member States' or Community research programmes by providing advice and direction on important priority issues.

4. The Centre shall seek to maintain scientific excellence at all times through the best expertise available, and initiate applied scientific studies and projects on the feasibility, development and preparation of its activities.

5. The Centre shall support and co-ordinate training programmes in order to assist Member States and the Community to have sufficient numbers of trained specialists,

in particular on epidemiological surveillance and field investigations, and to have a capability to define public health measures to control disease outbreaks.

Article 7

Procedure for scientific opinions

1. The Centre shall issue a scientific opinion:

   – At the request of the Commission, in respect of any matter within its mission, and in all cases where Community legislation makes provision for the Centre to be consulted;

   – On its own initiative, on matters falling within its mission.

   The European Parliament or a Member State may request the Centre to issue a scientific opinion on matters falling within its mission.

2. Requests referred to in paragraph 1 shall be accompanied by background information explaining the scientific issue to be addressed and the Community interest.

3. The Centre shall issue scientific opinions within the time limit specified in the requests for opinions, except in duly justified circumstances.

4. Where different requests are made on the same issues or where the request is not in accordance with paragraph 2, or is unclear, the Centre may either refuse, or propose amendments to a request for an opinion in consultation with the institution or Member State(s) that made the request. Justifications for the refusal shall be given to the institution or Member States(s) that made the request.

5. Where the Centre has already delivered a scientific opinion on the specific topic in a request, it may refuse the request if it concludes there are no scientific elements justifying the re-examination. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

6. The Centre's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.

Article 8

Operation of early warning and response

1. The Centre shall support the Community network of designated authorities and the Commission under Decision N^{o} 2119/1998/EC by providing assistance to the Commission. The Centre shall operate the Early Warning and Response System (EWRS) provided for therein and ensure at all times capacity for co-ordinated European responses to public health threats under this framework.

2. The Centre shall analyse the content of messages forwarded to Member States and the Commission via the Early Warning and Response System as laid down in Decision N^{o} 57/2000/EC and sent to it. The Centre shall provide information,

expertise, advice and analysis on risk assessment for the purposes of risk management by the Commission and the Member States. The Centre shall ensure that such actions on this Early Warning and Response System are efficiently and effectively co-ordinated and integrated into other Community alert systems (e.g. animal health, food and feed, and civil protection).

Article 9

Procedure for technical assistance

1. The Centre may be requested by the Commission to provide scientific or technical assistance in any field within its mission. The tasks of providing scientific and technical assistance shall consist of scientific or technical work involving the application of well-established scientific or technical principles. Such tasks may include in particular assistance to the Commission for the establishment or evaluation of criteria and also assistance to the Commission in the development of technical guidelines.

2. Where the Commission refers a request for scientific or technical assistance to the Centre, it shall specify, in agreement with the Centre, the time limit within which the task must be completed

3. In the case of a disease outbreak or human health crisis for which a Member State a third country or an international organisation requests assistance, the Centre, after consulting the Commission to ensure coherence with Community policies, may respond within its financial capacity and mandate. Such assistance could include mobilising and co-ordinating investigation teams, providing expert assistance, or other actions to resolve the crisis.

4. In the case of such a request for assistance from a Member State, a third country or international organisation, where the financial capacity of the Centre is not adequate to deal with that request, the Centre shall assess the request and obtain agreement of the Commission on its possibilities for response directly or through other Community mechanisms.

5. The Centre shall inform Member States authorities and the Commission without delay within the framework of the Community Network set up by Decision N^{o} 2119/1998/EC of any such request.

Article 10

Identification of emerging public health threats and preparedness

1. The Centre shall establish surveillance procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging public health threats to the European Community.

2. Where the Centre has information leading it to suspect an emerging public health threat, it can request additional information from the Member States, other Community agencies and the Commission. The Member States, the Community agencies concerned and the Commission shall reply as a matter of urgency.

3. The Centre shall annually forward the evaluation and information collected on emerging threats and risks to the Commission, the European Parliament, and the Council.

4. The Centre shall provide scientific and technical expertise to the Commission, Community bodies, and the Member States in the development of preparedness plans for pandemic situations or outbreaks caused deliberately or otherwise, and in their regular review and updating.

5. The Centre shall support the Commission, Community bodies, and the Member States in developing intervention strategies, such as immunisation, by providing scientific opinions, expert advice, data, and information.

Article 11

Collection and analysis of data

1. The Centre shall carry out coordination of data collection, validation, analysis and dissemination of data at Community level. The statistical element of this data collection will be developed in collaboration with Member States using, as necessary, the Community Statistical Programme, to promote synergy and avoid duplication.

2. For the purposes of paragraph 1, the Centre shall work in close cooperation with the competent bodies of the Member States, organisations operating in the field of data collection, from the European Community, third countries, the World Health Organisation (WHO), and other international organisations.

3. The Centre shall make available relevant information collected as referred in paragraphs 1 and 2 to the public in an objective, reliable and easily accessible way.

Article 12

Communications from the Centre

1. The Centre shall communicate on its own initiative in the fields within its mission. It shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, the Centre shall develop and disseminate information material for the general public.

2. The Centre shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process. It shall publish its advice in accordance with Article 20.

3. The Centre shall ensure appropriate cooperation with the competent bodies in the Member States and other interested parties with regard to public information campaigns.

4. The Centre shall assist the Commission and the Member States in the preparation of guidelines on good practice, and on protective measures to be taken in response to

human health threats in particular in support of actions undertaken under the Community network.

CHAPTER 3

ORGANISATION

Article 13

Bodies of the Centre

The Centre shall comprise:

(a) A Management Board;

(b) A Director and his/her staff;

(c) An Advisory Forum.

Article 14

Management Board

1. The Management Board shall be composed of 15 members, six of them representing, and appointed by the Commission, six by the Council, representing national executives, and three members nominated by the Commission, representing interested parties at European level, such as non-governmental organisations representing patients, professional bodies, or academia.

2. The members of the Board shall be appointed in such a way as to secure the highest standards of competence, a broad range of relevant expertise and, consistent with these, the broadest possible geographic distribution within the Union.

   Alternates who will represent the member in his/her absence shall be appointed by the same procedure.

   Members' term of office shall be four years, and may be extended once. However, for the first mandate, this period shall be six years for half of the members.

3. The Management Board shall adopt the Centre's internal rules on the basis of a proposal by the Director. These rules shall be made public.

   The Management Board shall elect one of its members as its Chair for a two-year period, which shall be extendable.

   The Management Board shall meet at least twice a year at the invitation of the Chair, or at the request of at least a third of its members.

4. The Management Board shall:

– Exercise disciplinary authority over the Director and appoint or dismiss him/her pursuant to Article 17.

– Ensure that the Centre carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation.

– Draw up a list, on the proposal from the Director, to be made public of competent bodies referred to in Article 5(4).

– Adopt, before 31 January each year, the Centre's programme of work for the coming year. It shall also adopt a revisable multi-annual programme. The Management Board shall ensure that these programmes are consistent with the Community's legislative and policy priorities in the area of its mission. Before 30 March each year, the Management Board shall adopt the general report on the Centre's activities for the previous year.

– Adopt the financial rules applicable to the Centre after the Commission has been consulted. They may not depart from Commission Regulation (EC, Euratom) N° 2343/2002 of 23December 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) N° 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities unless specifically required for the Centre's operation and with the Commission's prior consent.

5. The Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat.

Article 15

Voting

1. The Management Board shall take its decisions by a simple majority of all members, without prejudice to Article 17.

2. Each of these members shall have one vote. The Director of the Centre shall not vote.

3. In the absence of a member, his/her alternate shall be entitled to exercise his/her right to vote.

4. The rules of procedure shall establish the more detailed voting arrangements, in particular, the conditions for a member to act on behalf of another member.

Article 16

Director

1. The Centre shall be managed by its Director, who shall be completely independent in the performance in his/her duties, without prejudice to the respective competencies of the Commission and the Management Board.

2. The Director shall be the legal representative of the Centre and shall be responsible for:

   (a) The day-to-day administration of the Centre;

   (b) Drawing up a draft work programmes in consultation with the Commission;

   (c) Preparation of discussions within the Management Board;

   (d) Implementing the work programmes and the decisions adopted by the Management Board;

   (e) Ensuring the provision of appropriate scientific, technical and administrative support for the Advisory Forum;

   (f) Ensuring that the Centre carries out its tasks in accordance with the requirements of its users, in particular with regard to the scientific excellence and independence of activities and opinions, the adequacy of the services provided and the time taken;

   (g) The preparation of the statement of revenue and expenditure and the execution of the budget of the Centre;

   (h) All staff matters, and in particular the exercise of powers laid down in Article 29(2).

3. Each year, the Director shall submit to the Management Board for approval:

   (a) A draft general report covering all the activities of the Centre in the previous year;

   (b) Draft programmes of work;

   (c) The draft annual accounts for the previous year;

   (d) The draft budget for the becoming year.

4. The Director shall, following adoption by the Management Board, by 15 June at the latest forward the annual report on the Centre's activities to the European Parliament, the Council, the Commission, the Court of Auditors, the European Economic and Social Committee and the Committee of the Regions. The Centre shall forward annually to the budgetary authority any information relevant to the outcome of the evaluation procedures.

5. The Director shall report on the Centre's activities to the Management Board.

Article 17

Appointment of the Director

1. The Director shall be appointed by the Management Board on the basis of a list of candidates proposed by the Commission after an open competition, following publication in *the Official Journal of the European Union* and elsewhere of a call for expressions of interest, for a period of five years, which may be extended once for a further period of up to five years.

2. The Management Board shall take its decision by a two-thirds majority of all members. Power to dismiss the Director shall lie with the Management Board, according to the similar procedure.

3. Before appointment the candidate nominated by the Management Board shall be invited without delay to make a statement before the European Parliament and answer questions put by members of this institution.

Article 18

Advisory Forum

1. The Advisory Forum shall be composed of members from technically competent bodies in the Member States which undertake tasks similar to those of the Centre, on the basis of one representative designated by each Member State recognised for his/her scientific competence. Representatives may be replaced by alternates, appointed at the same time.

2. Members of the Advisory Forum may not be members of the Management Board.

3. The Advisory Forum shall support the Director in ensuring the scientific excellence and independence of activities and opinions of the Centre.

4. The Advisory Forum shall constitute a mechanism for an exchange of information on potential risks and the pooling of knowledge. It shall ensure close cooperation between the Centre and the competent bodies in the Member States in particular on the following items:

   (a) Coherence of the Centre’s scientific studies with Member States;

   (b) In those circumstances where the Centre and a national body are obliged to co-operate;

   (c) In the promoting, starting up, and supervising of the European networking of organisations operating within the fields of the Centre’s mission;

   (d) Where the Centre or a Member State identifies an emerging public health risk;

   (e) The setting up of scientific panels by the Centre;

(f) Identifying possible scientific and public health priorities for the work programme.

5. The Director shall chair the Advisory Forum. It shall meet regularly at the invitation of the Chair, or at the request of at least a third of its members, and not less than four times per year. Its operational procedures shall be specified in the Centre's internal rules and shall be made public.

6. The Centre shall provide the technical and logistic support necessary for the Advisory Forum and provide the Secretariat for its meetings.

7. Representatives of the Commission's departments may participate in the work of the Advisory Forum. The Director may invite experts or representatives from other relevant bodies to take part.

CHAPTER 4

TRANSPARENCY AND CONFIDENTIALITY

Article 19

Declaration of Interest

1. The members of the Management Board, the members of the Advisory Forum, scientific panels, and the Director shall undertake to act in the public interest.

2. The Director, the members of the Advisory Forum, as well as external experts participating in scientific panels shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

3. The Director, the members of the Advisory Forum, as well as external experts participating in scientific panels shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda. In such cases these persons have to disqualify themselves from relevant discussions and decisions.

Article 20

Transparency and protection of information

1. Regulation (EC) N° 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [6], shall apply to documents held by the Centre.

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6 OJ L 145, 31.5.2001, p. 43.

2. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) N° 1049/2001 within six months of entry into force of the present Regulation.

3. Decisions taken by the Centre pursuant to Article 8 of Regulation (EC) N° 1049/2001 may give rise to the lodging of a complaint to the Ombudsman or form the subject of an action before the Court of Justice of the European Communities, under the conditions laid down in Articles 195 and 230 of the Treaty respectively.

4. The information collected in accordance with this Regulation by the Commission and the Centre, shall be subject to Regulation (EC) N° 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data[7].

Article 21

Confidentiality

1. By way of derogation from Article 20, the Centre shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information, which must be made public if circumstances so require, in order to protect public health.

2. Members of the Management Board, the Director, as well as external experts participating in the scientific panels, members of the Advisory Forum, and members of the staff of the Centre, even after their duties have ceased, shall be subject to the requirements of confidentiality pursuant to Article 287 of the Treaty.

3. The conclusions of the scientific opinions delivered by the Centre relating to foreseeable health effects shall on no account be kept confidential.

4. The Centre shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.

CHAPTER 5

FINANCIAL PROVISIONS

Article 22

Drawing up of the budget

1. Estimates of all the revenue and expenditure of the Centre shall be prepared for each financial year, corresponding to the calendar year, and shall be shown in the budget of the Centre.

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7 OJ L 8, 12.1.2001, p. 1.

2. The revenue and expenditure shown in the budget of the Centre shall be in balance.

3. The revenue of the Centre shall, without prejudice to other resources, comprise:

   (a) A subsidy form the Community entered in the general budget of the European Union (Commission section);

   (b) Payments received for services rendered;

   (c) Any financial contributions from the organisations referred to in Article 5;

   (d) Any voluntary contribution from the Member States

4. The expenditure of the Centre shall include staff remuneration, administrative and infrastructure costs, operating expenses and expenses resulting from contracts entered into with the institutions or with third parties.

5. Each year the Management Board, on the basis of a draft drawn up by the Director, shall produce an estimate of revenue and expenditure for the Centre for the following financial year. This estimate, which shall include a draft establishment plan, shall be forwarded by the Management Board to the Commission by 31 March at the latest.

6. The estimate shall be forwarded by the Commission to the European Parliament and the Council (hereinafter referred to as the "budgetary authority") together with the preliminary draft budget of European Union.

7. On the basis of the estimate, the Commission shall enter in the preliminary draft general budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.

8. The budgetary authority shall authorise the appropriations for the subsidy to the Centre. The budgetary authority shall adopt the establishment plan for the Centre.

9. The budget of the Centre shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Union. Where appropriate, it shall be adjusted accordingly.

10. The Management Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of its budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.

    Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Management Board within a period of six weeks from the date of notification of the project.

Article 23

Implementation of the Centre's budget

1. The Director shall implement the Centre's budget.

2. By 1 March at the latest following each financial year, the Centre's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of the general Financial Regulation.

3. By 31 March at the latest following each financial year, the Commission's accounting officer shall forward the Centre's provisional accounts to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report on the budgetary and financial management for that financial year shall also be forwarded to the European Parliament and the Council.

4. On receipt of the Court of Auditors' observations on the Centre's provisional accounts, pursuant to Article 129 of the general Financial Regulation, the Director shall draw up the Centre's final accounts under his/her own responsibility and forward them to the Management Board for an opinion.

5. The Management Board shall deliver an opinion on the Centre's final accounts.

6. The Director shall, by 1 July at the latest following each financial year, forward the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.

7. The final accounts shall be published.

8. The Director shall send the Court of Auditors a reply to its observations by 30 September at the latest. He/she shall also send this reply to the Management Board.

9. The Director shall submit to the European Parliament, at the latter's request, any information required for the smooth application of the discharge procedure for the financial year in question, as laid down in Article 146(3) of the general Financial Regulation.

10. The European Parliament, on a recommendation from the Council acting by a qualified majority, shall, before 30 April of year N + 2, give a discharge to the Director in respect of the implementation of the budget for year N.

Article 24

Application of the Financial Regulation

Article 185 of the general Financial Regulation of 25 June 2002 applicable to the general budget of the European Communities applies for the discharge of the Centre's budget, its audits, and accounting rules.

Article 25

Combating fraud

1. In order to combat fraud, corruption and other unlawful activities, the Provisions of Regulation (EC) N^{o} 1073/1999 shall apply without restriction to the Centre.

2. The Centre shall accede to the Inter-institutional Agreement of May 1999 concerning internal investigations by the European Anti-Fraud Office (OLAF) and shall issue, without delay, the appropriate provisions applicable to all of it's staff.

3. The decisions concerning funding and the implementing agreements and instruments resulting from them shall explicitly stipulate that the Court of Auditors and OLAF may carry out, if necessary, on-the-sport checks of the recipients of the Centre's funding and the agents responsible allocating it.

CHAPTER 6

GENERAL PROVISIONS

Article 26

Legal personality and privileges

1. The Centre shall have legal personality. In all Member States it shall enjoy the widest powers granted by law to legal persons. In particular, it may acquire and dispose of movable and immovable property and institute legal proceedings.

2. The Protocol on the privileges and immunities of the European Communities shall apply to the Centre.

Article 27

Liability

1. The contractual liability of the Centre shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction to give judgement pursuant to any arbitration clause contained in a contract concluded by the Centre.

2. In the case of non-contractual liability, the Centre shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage.

3. The personal liability of its servants towards the Centre shall be governed by the relevant provisions applying to the staff of the Centre.

Article 28

Examination of legality

1. Member States, members of the Administrative Board and third parties directly and personally involved may refer to the Commission any act of the Centre, whether express or implied, for the Commission to examine the legality of that act.

2. Referral shall be made to the Commission within fifteen days of the day on which the party concerned first became aware of the act in question.

3. The Commission shall take a decision within one month. If no decision has been taken within this period, the case shall be deemed to have been dismissed.

Article 29

Staff

1. The Staff Regulations of officials of the European Communities, the Conditions of employment of other servants of the European Communities and the rules adopted jointly by the institutions of the European Communities for purposes of the application of those Staff Regulations and Conditions of employment shall apply to the staff of the Centre.

2. The powers conferred on the appointing authority by the Staff Regulations, and by the Conditions of employment of other servants, shall be exercised by the Centre in respect of its own staff.

3. The Centre's staff shall consist of a strictly limited number of officials assigned or seconded by the Commission or Member States to carry out management duties. The remaining staff shall consist of other employees recruited by the Centre as necessary to carry out its tasks.

Article 30

Participation of third countries

1. The Centre shall be open to the participation of countries, which have concluded agreements with the European Community by virtue of which they have adopted and apply legislation of equivalent effect to Community legislation in the field covered by this Regulation.

2. Arrangements shall be made under the relevant provisions of those agreements, specifying in particular the nature, extent and manner in which these countries will participate in the Centre's work, including provisions relating to participation in the networks operated by the Centre, inclusion in the list of competent organisations to which certain tasks may be entrusted by the Centre, financial contributions and staff.

CHAPTER 7

FINAL PROVISIONS

Article 31

Review clause

1. No later than three years after the entry into force of this regulation the Centre shall commission an independent external evaluation of its achievements on the basis of terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the tasks of the Centre, in particular its role in health monitoring, the working practices and the impact of the Centre on prevention and control of human disease. The future financing needs of the Centre for the period after N+2 will be decided in the light of this evaluation. The evaluation will take into account the views of the stakeholders, at both Community and national level.

2. The Management Board shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Centre and its working practices. The evaluation report and the recommendations shall be forwarded to the Council and the European Parliament and made public.

Article 32

Commencement of the centre's operation

The Centre shall be operational within twelve months of the entry into force of this Regulation.

The Centre is situated in […].

Article 33

Entry into force

This Regulation shall enter into force on the […20th] day following that of its publication in the *Official Journal of the European Union*.

Article 34

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): Health and Consumer Protection (SANCO, Title 17)

Activity/Activities: Public Health (Chapter 17.03)

TITLE OF ACTION: PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ESTABLISHING A CENTRE FOR IMPROVING DISEASE PREVENTION AND CONTROL IN THE EUROPEAN COMMUNITY AT MEMBER STATE LEVEL. (ECDPC: EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL)

1. BUDGET LINE(S) + HEADING(S)

For the purposes of creating the Centre, two new operational budget lines are needed in the Community budget to cover subsidy of administrative (Titles I and II) and operating (Title III) expenditure. The appropriations will be allocated on an annual basis in accordance with the current procedures of the general budget of the European Communities.

As subdivisions of chapter 17 03, these new budget lines could be designated items 17 03 03 01 (ECDPC – Subsidy of administrative expenditure – Titles I and II) and 17 03 03 02 (ECDPC – Subsidy of operating expenditure – Title III).

2. OVERALL FIGURES

2.1 Total allocation for action (from n to n+2): € 47.835 million for commitment (CA)

The present financial statement provides detailed information for the start-up period until the year n+2. The adequacy of current and future funding in n+3 and beyond will be evaluated through a review, which will take place during year n+2 at the latest.

2.2 Period of application:

Start 2005.

Indefinite.

2.3 Overall multiannual estimate of expenditure:

a) Subsidy of operational expenditure (Title III) (budget line 17 03 03 02)

(cf. breakdown in point 6.2.).

€ million (to 3 decimal places)

	Year n [2005]	[n+1] (2006)	[n+2] (2007)[8]	Total Years n to n+2
Commit-ments (CA)	1.462	8.524	20.672	30.658
Payments (PA)	1.462	8.524	20.672	30.658

b) Subsidy of administrative expenditure (Titles I and II) (budget line 17 03 03 01)

(cf. . *breakdown in* point 6.4.3).

	(2005)	(2006)	(2007)	TOTAL Years n to n+2
CA	3.291	5.779	8.107	17.177
PA	3.291	5.779	8.107	17.177

TOTAL	(2005)	(2006)	(2007)	TOTAL Years n to n+2
CA	4.753	14.303	28.779	47.835
PA	4.753	14.303	28.779	47.835

c) Complementarity with the Public Health Programme (budget line 17 03 01 01)

The Centre will be funded from the Community budget, based on a proposal from the Commission and approved by the Budgetary Authority. Total annual costs at the beginning of its operation would be around € 9.6 million in 2005 and € 20.3 million in 2006. Given the budget constraints under the financial perspectives for Heading 3, DG SANCO agrees exceptionally to fund from its own resources, i.e. Public Health Programme € 4.9 million in 2005 and € 6 million in 2006, thus reducing the net amounts of new additional funds to € 4.7 million in 2005 and € 14.3 million in 2006.

[8] For information. These appropriations will not affect the amounts adopted for the next financial perspective.

The Annual Policy Strategy for 2003 (SEC(2002)217/9 of 27/02/02) proposed earmarking €10.6 million (see table below) within the new Public Health Programme for financing the additional expenditure involved in setting up the Centre and the administrative cost of paying for external consultants. The funds are principally to be used for the prior development of networks and feasibility studies of recognised value for the Centre's future activities, prior to its creation and for the first 18 months of its operation. In addition to this € 10.6 million, the Public Health Programme will finance part of the Centre's activities to the tune of € 1.5 million per year for the first two years of its operation (2005 and 2006). These amounts will be provided from the Programme's additional funds for enlargement.

Financial resources from the Public Health Programme	2003	2004	2005	2006	Total
Annual Policy Strategy 2003	€ 1.3 million	€ 1.4 million	€ 3.4 million	€ 4.5 million	€ 10.6 million
Enlargement			€ 1.5 million	€ 1.5 million	€ 3 million
TOTAL	€ 1.3 million	€ 1.4 million	€ 4.9 million	€ 6 million	€ 13.6 million

The Centre will be operational from n+2 (2007). The communicable disease networks formally established on the basis of Annex I of Decision 2000/96/EC and in application of Decision 2119/98/EC will enter an operational phase and will be fully functional. It will therefore be possible to fund all expenditure relating to these networks from the Centre's budget from 2007.

2.4 Compatibility with financial programming and financial perspective

[X] Proposal will entail reprogramming of the relevant heading in the financial perspective.

2.5 Financial impact on revenue

[X] Proposal has no financial implications (involves technical aspects regarding implementation of a measure).

The existence of possible revenues will be part of the evaluation foreseen at the end of n+2. If revenues are identified, it is expected that they will contribute to the financing of the Centre.

3. BUDGET CHARACTERISTICS

Type of expenditure		New	EFTA contribution	Contributions from applicant countries	FP heading
Comp / Non-comp	Diff	YES	YES	YES	**No** [3]

4. LEGAL BASIS

Article 152 (4) of the Treaty establishing the European Community

5. DESCRIPTION AND JUSTIFICATION

5.1 Need for Community intervention

5.1.1 Objectives pursued

This proposal establishes an entirely independent European Agency, "The European Centre for Disease Prevention and Control (ECDPC)" with its own legal personality. The Centre will contribute to increasing Member States' disease prevention and control capacity by coordinating surveillance of health threats within the Community. It will develop and manage the capacity to react quickly, effectively and coherently to health threats and will set up a coordination system enabling the Community to respond to situations potentially affecting the health of European citizens, in particular management of health crises and epidemics.

5.1.2 Measures taken in connection with ex ante *evaluation*

There are three external evaluations done on the Community Network. The first evaluation focuses on the existing structures and weak points in its functioning and the second looks to the future - what would be the best option to create an EU level response capacity. In 2002 the State Epidemiologists from the Member States gave their view on the future of the surveillance of communicable diseases at the EU level.

In addition an evaluation in 2002 of the operation of the Community network carried out by SANCO, but for which Member States within the Committee of the Network ('comitology'), endorsed the recommendations. This evaluation also concluded in favour of a coordinating Centre.

These evaluations are in line with the conclusions of the European Council at Gothenburg in June 2001, the extraordinary meeting of the Council of the European Union (Employment, Social policy, Health and Consumer Affairs) on 6 May 2003 and the meeting of the European Council on 2 June 2003, where the need for a more structured approach at the Community level was recognised. At the last two meetings of Health Ministers the Commission's intention to submit a proposal to create a European Centre for disease prevention and control was also widely supported.

Recently the SARS outbreak showed clearly the lack of capacity to deal with serious health threats at the Community level and the existing need to enhance capacity. With the SARS outbreak the Community was lucky, with only a limited number of imported cases, which did

not arrive by surprise as in Toronto. There were no deaths or local transmission of SARS in the European Union. The next time could well be a pandemic (unknown disease, influenza, bio-terrorism) with severe consequences.

One alternative would require a larger dedicated Commission structure which would *inter alia* lack the flexibility of access to specialised staff and appropriate scientific advice.

5.1.3 Measures taken in connection with ex post *evaluation*

Not applicable.

5.2 Actions envisaged

The mission of the Centre is to enhance the capacity of the European Union and its Member States to promote health by the prevention and control of disease.

The Centre would be able to coordinate and link activities in the Member States, in other EU structures and with international organisations, such as the WHO, to achieve one focused and effective response at the Community level.

Surveillance

The Centre would develop epidemiological surveillance at Community level. The Centre would gradually take over the technical aspects of activities of existing dedicated surveillance networks formally structured under the Community Network (Decision 2119/98/CE**),** either with its own staff or subcontracting national institutes, and could better define the scope of action of new ones. This gradual integration of epidemiological surveillance will lead to a harmonised surveillance methodology, including better comparability and compatibility of the surveillance data collected in the Member States. The Centre could also set up and maintain the network of reference laboratories, and enhance the quality assurance schemes of microbiological laboratories.

Alert and response

With an operational Centre the responsibility for running the early warning system set up under Decision 2000/57/EC and assisting, on request, in the risk assessment, decision-making, and appropriate deployment of assistance would be in one place. The Centre would act in coordination with various Community agencies (e.g. EFSA, EMEA, EEA) and with other alert systems such as GOARN/WHO, when appropriate. It would also advise the Commission in its risk management tasks. The Centre could guarantee around the clock availability of expertise to maintain its co-ordinating role.

Preparedness and control of outbreaks

Response is a key element in preparedness and control of outbreaks. Resolving the problems in a limited outbreak prevents its deterioration into a wider crisis.

The Centre should have a role in the coordination of specific responses and activities to limit the epidemic and contain its effects. In practice this means mobilising experts from the Member States into the Community investigation teams, giving expert advice and technical help in defining measures to contain the epidemic at national and at the Community level. To

enable it to fulfil its tasks in these situations there should be financial mechanisms which allow mobilisation of personnel and equipment.

5.3 Methods of implementation

During 2003 and 2004, external experts will be used to prepare the integration of surveillance networks into the Centre. Projects dealing with capacity building and dissemination of information could be the ones to be integrated from the beginning. At the same time the evaluation of disease surveillance networks will start to assess their surveillance methods and whether the objectives have been reached. It is important to get the laboratories involved in surveillance also at the Community level. To this end, the Commission will enhance the development of laboratory networks, including those European laboratories with the capacity to handle highly contagious micro-organisms, like smallpox virus. The Commission will maintain and update the support databases and develop the Early Warning and Response system (EWRS) further. The procedures for effective exchange of information will also be developed. Once in place, the Centre will set up an intervention team in collaboration with the Member States and the WHO. High quality surveillance, early warning, and response are not possible without trained specialists with a variety of expertise at national and Community level. To build up European capacity, continuous training will be supported and its financing will be sustained.

The work of the Task Force against deliberate release of chemicals and biological agents (BICHAT) will be evaluated and, according to the results, transferred to the Centre.

In this way the Commission expects that, as and when Parliament and Council agree to the principles, mandate and form of the Centre, these preliminary tools and processes might be integrated rapidly so that it could become fully operational in a very short time.

The evaluation envisaged in Article 31 will assess the tasks of the Centre, in particular its role in health monitoring, the working practices and the impact of the Centre on prevention and control of human disease. The future financing needs of the Centre for the period after n+2 will be decided in the light of this evaluation.

6. TOTAL FINANCIAL IMPACT (SUBSIDY OF ADMINISTRATIVE (TITLES I ET II) AND OPERATING (TITLE III) EXPENDITURE)

6.1 Basis for calculation of administrative costs

The Centre's administrative costs have been calculated on the basis of an independent entity, i.e. one which does not depend on the Commission's infrastructure.

The personnel costs (salaries + contributions) are based on the annual average used within the Commission of € 0.108 million per year per official/temporary agent, and are estimated at 72% of this average, i.e. € 0.08 million per year per official/temporary agent.

Start-up funding will be needed for period n, which will commence on the date of adoption of this Regulation as, during the first few years of its operation, the Centre will incur additional costs to cover, *inter alia*:

- advertising of posts and recruitment

- office equipment

- software acquisition and development

- the fact that the Agencies have a higher average percentage of A-grade staff than the Commission average.

The remaining administrative expenditure (furniture, computer equipment, etc.) is based on the actual rates used at the Commission's centres of activity.

Concerning expenditure on buildings, the estimated average area needed per person is 35 m² (offices, meeting rooms, archives, computer room, common areas such as corridors). On this basis, a surface area of around 1 750 m² would be required for the 50 staff envisaged for the first two years of the Centre's operation and for the organisation of scientific meetings and network coordination activities. At an estimated rent of € 172 per m² per year, the annual building rental cost would be € 0.301 million for years n (2005) and n+1 (2006), depending on where the headquarters are to be located, to be confirmed by the European Council.

6.1.1 First year of operation (2005)

A subsidy of **€ 4.753 million** will be required for the first year of operation**.**

a) Personnel costs (salaries + contributions) (see point 6.4.3)	€ 1.215 million
b) Administrative expenditure (IT, buildings, etc.) (see point 6.4.3)	€ 2.076 million
c) Operating costs (see point 6.2)	€ 0.462 million
d) Expenditure on concerted actions	€ 1.000 million
Total	**€ 4.753 million**

a) Personnel expenditure (€ 1.215 million)

For the start-up phase, the staff will number 35. They are expected to be in place by the **end of 2005** and will be responsible for the set-up and initial operational phase of the new Centre.

Estimated expenditure on staff for the first year of operation is based on an average of 15 man/year posts for calculating the wage cost.

b) Administrative expenditure (€ 2.076 million)

Part of the administrative expenditure is accounted for by start-up investment in computer and telematic equipment (hardware, software, information systems), estimated at € 0.8 million for 2005. Estimated expenditure on information technology/office equipment required for start-up of the Centre's activities is € 1.5 million for the first year of operation.

The buildings and infrastructure costs included in the start-up estimate represent the total rented space needed for the 50 staff envisaged. The corresponding investment schedule will depend largely on the decision regarding the Centre's headquarters (see point 6.1).

Cost of meetings (€ 0.176 million)

Basis for calculation:

1) Journey to/from meeting: € 800 per person and

2) € 150 for daily allowances, if necessary adding logistical, interpreting, translation costs, etc.

– Management Board (15 MS reps., 10 experts): 3 x 2-day meetings

3 meetings x 25 persons x € 1 100 ➔ € 82 500

– Advisory Forum (25 MS reps., 1 COM rep., 1 EP rep.): 4 x 3-day meetings

3 meetings x 25 persons x € 1 250 ➔ € 93 750

Cost of staff assignments (€ 0.05 million) (see table 6.4.3)

This estimate is based on the actual expenditure of comparable agencies and specific job descriptions in the various fields of activity. The estimated cost per assignment is € 800 per day for Europe and € 1 200 per day for the rest of the world.

Translation/interpreting costs (€ 0.05 million)

The cost of translations is calculated on an average standard rate of € 76 per translated page

c) Operating expenditure (€ 0.462 million)

This covers the 15 2-day meetings of experts for the first year.

Basis for calculation:

1) Journey to/from meeting: € 800 per person and

2) € 150 for daily allowances

- Scientific meetings (disease surveillance, scientific panels) of 28 persons (25 MS reps., 3 EFTA reps. 1 COM rep.): 15 meetings x 28 persons x € 1100 = € 0.462 million

d) Operating expenditure – concerted actions (€ 1 million)

In the course of its disease surveillance and control activities, the Centre may be called upon to deal with individual public health emergency situations. The research and response request time must be rapid, and the Agency must therefore have access to operating funds.

An initial amount of € 1 million could be allocated for this purpose from the Community budget for the first year of the Centre's operation (initial phase). This would be reviewed annually under the budget procedure. The evaluation provided for under Article 31 will also cover this aspect.

The Agency would make use of these funds only in the event of crisis. If part or all of the funds are unused, the unused amount will automatically lapse and will not be added to the amount requested under the budgetary procedure for the following year. This means that new appropriations will have to be applied for under the budgetary procedure for the following year.

Particular attention should also be paid to this funding when evaluating the Centre's overall resources at n+3 (cf. Article 31 of the Regulation).

6.1.2. Second year of operation (2006)

A subsidy of € 14.303 million will be required for the second year of operation**.**

a) Personnel costs (salaries + contributions) (see point 6.4.3)	€ 3.816 million
b) Administrative expenditure (IT, buildings, etc.) (see point 6.4.3)	€ 1.963 million
c) Operating costs (see point 6.2)	€ 6.524 million
d) Operating costs – concerted actions	€ 2.000 million
Total	**€ 14.303 million**

The increase in the subsidy is due principally to the increase in the Centre's activities. The additional staff (rising to 50) and integration of the networks into the Centre will necessarily entail a rise in administrative costs (missions, translation/interpreting) and operating costs (training, surveillance, scientific studies, meetings of experts (based on 4 meetings per year per network)).

6.1.3 Third year of operation (2007)[9]

a) Personnel costs (salaries + contributions) (see point 6.4.3)	€ 5.436 million
b) Administrative expenditure (IT, buildings, etc.) (see point 6.4.3)	€ 2.671 million
c) Operating costs (see point 6.2)	€ 17.672 million
d) Operating costs – concerted actions	€ 3.000 million
Total	**€ 28.779 million**

This year is marked by the continued development of the Centre's activities, and in particular an estimated increase in staff to 70 by the end of 2007.

Depending on the results of the evaluation during year n+2, the resources needed for the Centre will be reviewed. The competent department is currently basing its estimates on an ultimate staffing level of 98 persons.

Operating expenditure for n+2 can be broken down as follows:

- Dedicated Surveillance Networks € 7 million

- Training/placement programme € 4 million

- Scientific studies € 2 million

- Material and equipment € 1.5 million

- Scientific meetings € 2.772 million (based on 4 meetings per year per network)

- Information/publication/other € 0.400 million.

[9] For information. These appropriations will not affect the amounts adopted for the next financial perspective.

Ultimately, the "other" operating expenditure will comprise the cost of collecting and disseminating information, publication of reports, organisation of seminars, evaluations/audits and the technical library (books).

6.2 (Subsidy of operating expenditure – Title III*)*

The subsidy of operating expenditure will be covered by an operational heading in the Community budget (17 03 03 02).

Commitments (in € million to three decimal places)

Breakdown	[Year n] 2005	[n+1] 2006	[n+2][10] 2007	Total Years n to n+2
Dedicated Surveillance Networks	0.00	2.500	7.000	9.500
Training/placement programme	0.00	1.500	4.000	5.500
-Scientific studies	0.00	0.600	2.000	2.600
Materials and equipment	0.00	0.500	1.500	2.000
Expenditure on concerted actions	1.000	2.000	3.000[11]	6.000
Meeting of experts	0.462	1.124	2.772	4.358
Information and publications	0.000	0.300	0.400	0.700

[10] For information. These appropriations will not affect the amounts adopted for the next financial perspective.

[11] For information. These appropriations will not affect the amounts adopted for the next financial perspective.

TOTAL	**1.462**	**8.524**	**20.672**	**30.658**

6.3 Details of activities envisaged for the Centre (without prejudice to the outcome of the evaluation at n+2)

The mission of the Centre is to analyse and assess risks to human health from communicable diseases and other serious health threats, to provide expert advice to the Commission and the Member States and to enhance the capacity of the European Union and its Member States to protect human health through prevention and control measures on communicable diseases and other serious health threats. The capacity of the Centre comprises its own resources and those of agents, institutes, and other bodies acting on behalf of Member States' authorities competent for health. The primary objective of the Centre shall be to co-operate with the Member States in order to achieve coherent, timely, and effective actions.

Task 1 Scientific support and training

The Centre shall provide the Community Institutions and the Member States with the best possible scientific opinions based on information from dedicated surveillance networks and other authoritative scientific sources. Where the best possible scientific expertise is not available within the Centre or in the dedicated surveillance networks the Centre may set up ad hoc scientific panels for this purpose. Member States shall supply the necessary scientific assistance available to them.

Task 2 Networking of organisations operating in the fields within the Centre's competence, collection and analysis of data, identification of emerging risks, and preparedness for crises

The Centre shall, with the support of the Member States, maintain and extend the networking activities and dedicated surveillance networks of authorities and structures designated under Community legislation and integrate them into its operation by strengthening their technical and scientific support, and by monitoring and evaluating their surveillance activities.

The Centre shall establish surveillance procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks within its competence.

The Centre shall search for, collect, collate, analyse and summarise relevant scientific and technical data in its fields of competence. This shall involve in particular the collection of data relating to operation of Decision 2119/98/EC, and information concerning existing and proposed mechanisms and procedures for control of health threats.

For the purposes of paragraph 1, the Centre shall work in close co-operation with the organisations operating in the field of data collection, including those from applicant countries, third countries, and international organisations.

Task 3 Early warning and response

Member States shall in a timely way communicate to the Centre any messages forwarded via the Early Warning and Response System (EWRS) under the provisions of Decision 2000/57/EC.

The Centre shall, under the overall control of the Commission, mobilise and co-ordinate investigation teams and concerted actions in situations where health may be affected within or outside the Community in co-operation with the Commission, the Member States, Candidate Countries, third countries, and international organisations.

Task 4 Communications from the Centre

The Centre shall communicate on its own initiative in the fields within its competence, without prejudice to the Commission's competence to communicate its own decisions. It shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, the Centre shall develop and disseminate information material for the general public.

Task 5 Administration and support

Depending on the outcome of the evaluation at n+2, the administrative and support functions may be changed.

To safeguard the quality objectives and ensure effective operation, the Centre will operate an internal and external evaluation system (peer reviews, benchmarking and audits).

The following meetings and costs are envisaged:

	Meetings	Days	Participants
Management Board	3	2	25
Advisory Forum and working parties	4	3	28

6.4 Breakdown of subsidy of administrative expenditure (Titles I and II) (line 17 03 03 01)

6.4.1 The Centre's human resources

Staffing in 2005 (year n)

Type of post		Staff to be assigned to management of the measure using new resources		Total	Description of the tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A		16A, 7B, 6C	29	
	B				*If necessary, a more detailed description of the tasks may be*

	C				*annexed*
Other human resources			6 "C" AUX	6	
Total			35	35	

Staffing in 2007[12]

Type of post		Staff to be assigned to management of the measure using existing or additional resources		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A B C	5A, 4B, 3C	34A, 7B, 11C	64	*The personnel of the Centre will be highly specialised (such as epidemiologists, public health specialists, microbiologists, virologists, logisticians, IT experts) or for administrative functions of the Centre.*
Other human resources			6 "C" AUX	6	
Total		12	58	70	

Development of staffing levels 2005➔2007

Type of human resources	(Year n) 2005	(n+1) 2006	(n+2)[13] 2007
Officials Temporary staff	29	+ 15 (9 "A", 2 "B", 4 "C")	+20 (14 "A", 2 "B", 4 "C")
Other human resources	6		
Total	35	50	70

Without prejudice to the outcome of the evaluation envisaged in n+2 (2007), and depending on the opinion of the competent departments, the Centre could ultimately employ a staff of 98.

12 For information. These appropriations will not affect the amounts adopted for the next financial perspective.

13 For information. These appropriations will not affect the amounts adopted for the next financial perspective.

6.4.2 Overall financial impact of Centre's human resources

Year 2005:

Type of human resources	Amount in euro	Method of calculation *
Agents	1 215 000	€ 81 000 x 15
Total	1 215 000	

The amounts represent total expenditure over 12 months for an average of 15/35 permanent posts because of the difficulty of recruiting in the first year.

Year 2007:

Type of human resources	Amount in euro	Method of calculation *
Agents	5 184 000	€ 81 000 x 64
Other human resources, 'C' auxiliaries	252 000	€ 42 000 x 6
Total	5 436 000	

The Centre will take over the technical activities of the 1 'A' grade, 2 'B' grades, 1 'C' grade together with the 8 ENDs (seconded national experts) (financed *hors quota*) from the Bichat team (bio-terrorism task force). The economy of 1 'A' official could be made from some technical activities in support of the Community network.

However, there will be a need for a liaison function in the Commission of approximately the same number of staff.

Therefore, the net effect of resources in the Commission (SANCO) will be zero with the exception of the 8 ENDs of the Bichat team.

6.4.3 Total subsidy of the Centre's administrative expenditure (line 17 03 03 01) for the first 3 years

The subsidy of administrative expenditure will be covered by an operational heading of the Community budget (17 03 03 01).

Million EUR	(Year n) 2005	(n+1) 2006	(n+2)[14] 2007	TOTAL Years n to n+2
Human resources	35	50	70	70
Calculation basis	15 agents	44 agents, 6 externals	64 agents, 6 externals	64 agents, 6 externals
Annual cost of human resources	1.215	3.816	5.436	10.467
Other administrative expenditure				
Missions	0.050	0.200	0.200	0.500
Management Board meetings	0.082	0.082	0.082	0.246
Advisory Forum meetings	0.093	0.093	0.093	0.279
Interpreting/translation	0.050	0.287	0.294	0.631
IT & office equipment	1.500	1.000	1.400	3.900
Buildings expenditure	0.301	0.301	0.602	1.204
Total Other administrative expenditure	2.076	1.963	2.671	6.710
Total	3.291	5.779	8.107	17.177

[14] For information. These appropriations will not affect the amounts adopted for the next financial perspective.

7. FOLLOW-UP AND EVALUATION

7.1 Follow-up arrangements

The European Commission will be in daily contact with the Centre, which may give an opinion on questions submitted to it by the Commission. The extent to which the Centre meets its agreed deadlines and objectives will be an objective indicator of its performance.

The proposed regulation provides (31) that, within three years of the Centre taking up its activities, the Commission shall draft a report on its implementation and effectiveness, where appropriate making proposals for changes to or extension of its activities. The report will also include an assessment of the adequacy of the financial and human resources and recommendations to ensure the Centre's proper functioning over subsequent years.

7.2 Arrangements and schedule for the planned evaluation

■ The overall evaluation of the Centre's activities proposed in Article 31 of the Regulation will help to ensure that the Centre is responding to the Commission's needs. If necessary, a mechanism will be put in place to adapt those activities. The conclusions of the evaluations will be made public.

■ No later than three years after the entry into force of this Regulation the Centre shall commission an independent external evaluation of its achievements on the basis of terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the tasks of the Centre on prevention and control of human disease. In addition, the future financing needs of the Centre for the period after n+2 will be decided in the light of this evaluation. The evaluation will take into account the views of the stakeholders, at both Community and national level.

■ The Management Board of the Centre shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Centre and its working practices. The evaluation and the recommendations shall be made public.

8. ANTI-FRAUD MEASURES

The Management Board is responsible for ensuring that its fraud prevention systems conform to those of the Commission as set down in Article 25 of the Centre's Regulation.

The staff assigned under the Commission's Staff Regulations shall cooperate with OLAF in combating fraud.

Article 23 provides that the European Court of Auditors shall examine the accounts in accordance with Article 248 of the Treaty.