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(Acts whose publication is obligatory)

REGULATION (EC) No 851/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 April 2004 establishing a European centre for disease prevention and control

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

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 of European citizens. Effective response to disease outbreaks requires a coherent approach among Member States and input from experienced public health experts, 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 ranging from preparedness and control measures to prevention of human diseases, the scope of actions should be kept broad. The danger of deliberate release of agents also requires a coherent Community response.

(3) Member States must provide information on communicable diseases through the appropriate designated structures and/or authorities, in accordance with Article 4 of Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community [3], which requires timely scientific analysis in order for effective Community action to be undertaken.

(4) Decision No 2119/98/EC expressly calls for the improvement of the coverage and effectiveness of existing dedicated 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 competent in the field of public health, and in particular to pursue closer collaboration with the World Health Organisation (WHO). The Centre for Disease Prevention and Control should therefore establish clear procedures for cooperation with the WHO.

(5) An independent agency, 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 recognised competent bodies acting on behalf of Member States' authorities responsible for human health.

(6) This Regulation does not confer any regulatory powers on the Centre.

(7) The Centre's mission should be to identify, assess and communicate current and emerging threats to human health from communicable diseases. In the case of outbreaks of illness of unknown origin which may spread within or to the Community, the Centre should be empowered to act on its own initiative until the source of the outbreak is known and then in cooperation with the relevant competent authorities at national or Community level as appropriate.

(8) In this way, the Centre will enhance the capacity of the scientific expertise in the European Community and support

[1] OJ C 32, 5.2.2004, p. 57.

[2] Opinion of the European Parliament of 10 February 2004 (not yet published in the Official Journal) and decision of the Council of 30 March 2004.

[3] OJ L 268, 3.10.1998, p. 1. Decision as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

Community preparedness planning. It should support existing activities, such as relevant Community action programmes in the public health sector, with regard to the prevention and control of communicable diseases, epidemiological surveillance, training programmes and early warning and response mechanisms, and should foster the exchange of best practices and experience with regard to vaccination programmes.

(9) As emerging health threats may have mental as well as physical health consequences, the Centre should in the fields within its mission gather and analyse data and information on emerging public health threats and developments for the purpose of protecting public health in the European Community by preparedness. It should 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 should foster, develop and steer applied scientific studies. In this way, it will enhance the visibility and credibility of scientific expertise in the Community. Moreover, it will support Community preparedness planning, strengthening links with and between the clinical and public health sectors, reinforcing the public health laboratory capacity for rapid diagnosis and supporting and coordinating training programmes.

(11) The Management Board should be selected in such a way as to secure the highest standards of competence and a broad range of relevant experience available amongst the representatives of the Member States, the European Parliament and the Commission.

(12) The Management Board should have the necessary powers to establish the budget, check its implementation, draw up internal rules, ensure coherence with Community policies, adopt the Centre's financial regulation in accordance with the provisions of the Financial Regulation applicable to the general budget of the European Communities [1], hereinafter referred to as the 'Financial Regulation', and appoint the director following a parliamentary hearing of the selected candidate.

(13) An advisory forum should advise the director in the performance of his/her duties. It should be composed of representatives of competent bodies in the Member States which undertake tasks similar to those of the Centre and representatives of interested parties at European level, such as non-governmental organisations, professional bodies or academia. The Advisory Forum constitutes a mechanism for an exchange of information on potential risks and the pooling of knowledge and for monitoring the 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 on its own initiative in the fields within its mission, 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, without prejudice to the priorities agreed by the budgetary authority within the financial perspective. The Community budgetary procedure remains applicable as regards any subsidies chargeable to the general budget of the European Union and their annual evaluation. Moreover, the Court of Auditors should undertake the auditing of accounts.

(17) It is necessary to allow for the participation of 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) An independent external evaluation should be undertaken to assess the impact of the Centre on the prevention and control of human disease and the possible need to extend the scope of the Centre's mission to other relevant Community-level activities in public health, in particular to health monitoring.

(19) 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. This should be done in an open and transparent fashion and the Centre should take into account Community expertise, structures and agencies already in place,

[1] Council Regulation (EC, Euratom) No 1605/2002 (OJ L 248, 16.9.2002, p. 1).

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation establishes an independent European agency for disease prevention and control, its mission, tasks and 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 and technical advice or capacity for action in the field of the 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 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) "communicable diseases" shall mean the categories of disease listed in the Annex to Decision No 2119/98/EC;

(e) "health threat" shall mean a condition, agent or incident which may cause, directly or indirectly, ill health;

(f) "epidemiological surveillance" shall have the meaning ascribed to it in Decision No 2119/98/EC.

(g) "Community network" shall have the meaning ascribed to it in Decision No 2119/98/EC;

(h) "early warning and response system" shall mean the network in accordance with Decision No 2119/98/EC for the prevention and control of communicable diseases, formed by bringing the Commission and the competent public health authorities in each Member State into permanent communication with one another through appropriate means specified in Commission Decision 2000/57/EC of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council [1].

Article 3

Mission and tasks of the Centre

1. In order to enhance the capacity of the Community and the Member States to protect human health through the prevention and control of human disease, the mission of the Centre shall be to identify, assess and communicate current and emerging threats to human health from communicable diseases. In the case of other outbreaks of illness of unknown origin which may spread within or to the Community, the Centre shall act on its own initiative until the source of the outbreak is known. In the case of an outbreak which clearly is not caused by a communicable disease, the Centre shall act only in cooperation with the competent authority upon request from that authority. In pursuing its mission the Centre shall take full account of the responsibilities of the Member States, the Commission and other Community agencies, and of the responsibilities of international organisations active within the field of public health, in order to ensure comprehensiveness, coherence and complementarity of action.

2. Within the field of its mission, the Centre shall:

(a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data;

(b) provide scientific opinions and scientific and technical assistance including training;

(c) provide timely information to the Commission, the Member States, Community agencies and international organisations active within the field of public health;

(d) coordinate the European networking of bodies operating in the fields within the Centre's mission, including networks arising from public health activities supported by the Commission and operating the dedicated surveillance networks;

and

(e) exchange information, expertise and best practices, and facilitate the development and implementation of joint actions.

[1] OJ L 21, 26.1.2000, p. 32.

3. The Centre, the Commission and the Member States shall cooperate to promote effective coherence between their respective activities.

Article 4

Obligations of the Member States

Member States shall:

(a) provide to the Centre in a timely manner available scientific and technical data relevant to its mission;

(b) communicate to the Centre any messages forwarded to the Community network via the early warning and response system;

and

(c) identify, within the field of operation of the mission of the Centre, recognised competent bodies and public health experts who could be made available to assist in Community responses to health threats, such as field investigations in the event of disease clusters or outbreaks.

CHAPTER 2

OPERATIONAL PROCEDURES

Article 5

Operation of dedicated surveillance networks and networking activities

1. The Centre, through the operation of the dedicated surveillance networks and the provision of technical and scientific expertise to the Commission and Member States, shall support the networking activities of the competent bodies recognised by the Member States.

2. The Centre shall ensure the integrated operation of dedicated surveillance networks of authorities and structures designated under Decision No 2119/98/EC, where necessary with the assistance of one or more of the surveillance networks. It shall in particular:

(a) provide quality assurance by monitoring and evaluating surveillance activities of such dedicated surveillance networks to ensure optimal operation;

(b) maintain the database(s) for such epidemiological surveillance;

(c) communicate the results of the analysis of data to the Community network; and

(d) harmonise and rationalise the operating methodologies.

3. By encouraging cooperation between expert and reference laboratories, the Centre shall foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health. The Centre shall maintain and extend such cooperation and support the implementation of quality assurance schemes.

4. The Centre shall cooperate with the competent bodies recognised by the Member States, particularly on preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging health threats.

Article 6

Scientific opinions and studies

1. The Centre shall provide independent scientific opinions, expert advice, data and information.

2. The Centre shall seek to maintain scientific excellence at all times through the best expertise available. Where 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 promote and initiate scientific studies necessary for the performance of its mission and applied scientific studies and projects on the feasibility, development and preparation of its activities. The Centre shall avoid duplication with Member States' or Community research programmes.

4. The Centre shall consult the Commission with regard to the planning and priority setting of research and public health studies.

Article 7

Procedure for scientific opinions

1. The Centre shall issue a scientific opinion:

(a) 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;

(b) at the request of the European Parliament or a Member State, on matters falling within its mission;

and

(c) on its own initiative, 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 a mutually agreed time frame.

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 and it concludes that there are no scientific elements justifying the re-examination, information supporting that conclusion shall be given to the institution or Member State(s) that made the request.

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

Article 8

Operation of the early warning and response system

1. The Centre shall support and assist the Commission by operating the early warning and response system and by ensuring with the Member States the capacity to respond in a coordinated manner.

2. The Centre shall analyse the content of messages received by it via the early warning and response system. The Centre shall provide information, expertise, advice and risk assessment. The Centre shall also take action to ensure that the early warning and response system is efficiently and effectively linked with other Community alert systems (e.g. animal health, food and feed and civil protection).

Article 9

Scientific and technical assistance and training

1. The Centre shall provide scientific and technical expertise to the Member States, the Commission and other Community agencies in the development, regular review and updating of preparedness plans, and also in the development of intervention strategies in the fields within its mission.

2. The Centre may be requested by the Commission, the Member States, third countries and international organisations (in particular the WHO) to provide scientific or technical assistance in any field within its mission. Scientific and technical assistance provided by the Centre shall be based on evidence-based science and technology. Such assistance may include aiding the Commission and Member States to develop technical guidelines on good practice and on protective measures to be taken in response to human health threats, providing expert assistance and mobilising and coordinating investigation teams. The Centre shall respond within its financial capacity and mandate.

3. Requests for scientific or technical assistance to the Centre shall be accompanied by a set deadline which must be agreed with the Centre.

4. In the event of such a request for assistance from the Commission, a Member State, a third country or an international organisation, where the financial capacity of the Centre is not adequate to deal with that request, the Centre shall assess the request and explore 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 No 2119/98/EC, of any such request and of its intentions.

6. The Centre shall, as appropriate, support and coordinate training programmes in order to assist Member States and the Commission to have sufficient numbers of trained specialists, in particular in epidemiological surveillance and field investigations, and to have a capability to define health measures to control disease outbreaks.

Article 10

Identification of emerging health threats

1. The Centre shall in the fields within its mission establish, in cooperation with the Member States, procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging health threats which may have mental as well as physical health consequences and which could affect the Community.

2. The Centre shall forward to the European Parliament, the Council and the Commission an annual evaluation of the current and emerging threats to health in the Community.

3. The Centre shall also inform the Commission and Member States as soon as possible about findings which require their immediate attention.

Article 11

Collection and analysis of data

1. The Centre shall coordinate data collection, validation, analysis and dissemination of data at Community level, including on vaccination strategies. 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:

— develop with the competent bodies of the Member States and the Commission appropriate procedures to facilitate consultation and data transmission and access;

— carry out technical and scientific evaluation of prevention and control measures at Community level;

and

— work in close cooperation with the competent bodies of the organisations operating in the field of data collection from the Community, third countries, the WHO, and other international organisations.

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

Article 12

Communications on the activities of the Centre

1. The Centre shall communicate on its own initiative in the fields within its mission, after having given prior information to the Member States and to the Commission. It shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information with regard to the results of its work. In order to achieve these objectives, the Centre shall make available information for the general public, including through a dedicated website. It shall also publish its opinions produced in accordance with Article 6.

2. The Centre shall act in close collaboration with the Member States and the Commission to promote the necessary coherence in the risk communication process on health threats.

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

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 one member designated by each Member State, two members designated by the European Parliament and three members representing and appointed by the Commission.

2. The members of the Board shall be appointed in such a way as to secure the highest standards of competence and a broad range of relevant expertise.

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

Members' term of office shall be four years and can be extended.

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 adopt its Rules of Procedure.

5. The Management Board shall:

(a) exercise disciplinary authority over the director and appoint or dismiss him/her pursuant to Article 17;

(b) ensure that the Centre carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation including on the basis of regular independent and external evaluations to be carried out every five years;

(c) compile a list of competent bodies referred to in Article 5 and make it public;

(d) adopt, before 31 January each year, the Centre's programme of work for the coming year. It shall also adopt a revisable multiannual 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;

(e) adopt the financial rules applicable to the Centre after the Commission has been consulted. They may not depart from Commission Regulation (EC, Euratom) No 2343/2002 of

23 December 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities [1], unless specifically required for the Centre's operation and with the Commission's prior consent;

(f) determine by unanimity of its members the rules governing the languages of the Centre, including the possibility of a distinction between the internal workings of the Centre and the external communication, taking into account the need to ensure access to, and participation in, the work of the Centre by all interested parties in both cases.

6. 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. A two-thirds majority of all members shall be required for the adoption of its Rules of Procedure, the Centre's internal rules of operation, the budget, the annual work programme and the appointment and removal of the director.

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 draft work programmes;

(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) preparing the statement of revenue and expenditure and executing 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 work programmes;

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

(d) the draft budget for the coming 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. Before appointment, the candidate nominated by the Management Board shall be invited without delay to make a statement before the European Parliament and to answer questions put by members of that institution.

[1] OJ L 357, 31.12.2002, p. 72.

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, as well as three members without the right to vote nominated by the Commission and representing interested parties at European level, such as non-governmental organisations representing patients, professional bodies or academia. Representatives may be replaced by alternates, appointed at the same time.

2. Members of the Advisory Forum shall 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 health threats 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 cooperate;

(c) the promoting, starting up and supervising of the European networks within the fields of the Centre's mission;

(d) where the Centre or a Member State identifies an emerging public health threat;

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

(f) scientific and public health priorities to be addressed in the work programme.

5. The Advisory Forum shall be chaired by the director or, in his/her absence, by a deputy from within the Centre. It shall meet regularly at the invitation of the director, 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. Representatives of the Commission's departments may participate in the work of the Advisory Forum.

7. The Centre shall provide the technical and logistic support necessary for the Advisory Forum and provide a secretariat for its meetings.

8. The director may invite experts or representatives of professional or scientific bodies, or non-governmental organisations with recognised experience in disciplines related to the work of the Centre to cooperate in specific tasks and to take part in the relevant activities of the Advisory Forum.

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 members of the Management Board, 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) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [1] shall apply to documents held by the Centre.

2. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001 within six months of entry into force of this Regulation.

3. Decisions taken by the Centre pursuant to Article 8 of Regulation (EC) No 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. Personal data shall not be processed or communicated except in cases where this is strictly necessary for the fulfilment of the mission of the Centre. In such cases, Regulation (EC) No 45/2001 of the European Parliament and of the Council of

[1] OJ L 145, 31.5.2001, p. 43.

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 [1] shall apply.

Article 21

Confidentiality

1. Without prejudice to 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. Without prejudice to Decision No 2119/98/EC, if the confidential information has been submitted by a Member State, this information cannot be disclosed without the prior consent of that Member State.

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.

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 from 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 competent bodies 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 Financial Regulation.

[1] OJ L 8, 12.1.2001, p. 1.

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 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 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 Financial Regulation shall apply to 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) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-fraud Office (OLAF) [1] shall apply without restriction to the Centre.

2. The Centre shall accede to the Inter-institutional Agreement of 25 May 1999 concerning internal investigations by the European Anti-fraud Office (OLAF) [2] and shall issue, without delay, the appropriate provisions applicable to all of its staff.

3. The decisions concerning funding and the implementing agreements and instruments resulting therefrom shall explicitly stipulate that the Court of Auditors and OLAF may carry out, if necessary, on-the-spot checks of the recipients of the Centre's funding and the agents responsible for 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 judgment 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 Management 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.

[1] OJ L 136, 31.5.1999, p. 1.

[2] OJ L 136, 31.5.1999, p. 15.

2. Referral shall be made to the Commission within 15 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.

4. An action for annulment of the Commission's explicit or implicit decision referred to in paragraph 3 to reject the administrative appeal may be brought before the Court of Justice in accordance with Article 230 of the Treaty.

Article 29

Staff

1. The staff of the Centre shall be subject to the rules and the regulations applicable to officials and other staff of the European Communities.

2. In respect of its staff, the Centre shall exercise the powers which have been devolved to the appointing authority.

3. Secondment to the Centre of public health experts, including epidemiologists, for a defined period of time, for the achievement of certain specified tasks of the Centre will be encouraged within the framework of existing regulations.

Article 30

Participation of third countries

1. The Centre shall be open to the participation of countries, which have concluded agreements with the 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 are to 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. By 20 May 2007, 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 shall assess:

(a) the possible need to extend the scope of the Centre's mission to other relevant Community-level activities in the field of public health, in particular to health monitoring;

and

(b) the timing of further such reviews.

This assessment shall take into account the tasks of the Centre, the working practices and the impact of the Centre on the prevention and control of human disease, and shall include an analysis of the synergy effects and the financial implications of such an extension. The evaluation shall 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, its working practices and the scope of its mission. The Commission shall forward the evaluation report and the recommendations to the European Parliament and the Council and make them public. After assessment of the evaluation report and the recommendations, the Commission may submit any proposals for amendments to this Regulation which it deems necessary.

Article 32

Commencement of the Centre's operation

The Centre shall be operational by 20 May 2005.

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*.

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

Done at Strasbourg, 21 April 2004.

For the EuropeanParliament
P.COX
The President

For the Council
D. ROCHE
The President