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

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

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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 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

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Financial Regulation applicable to the general budget of the European Communities[(4)], 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,

HAVE ADOPTED THIS REGULATION:

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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[(5)].

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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.

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.