

Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2003/0174(COD) Procedure completed
Public health: European Centre for Disease Prevention and Control ECDC Amended by 2020/0320(COD)	
Subject 4.20.01 Medicine, diseases	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy		25/09/2003
		PPE-DE BOWIS John	
	Committee for opinion	Rapporteur for opinion	Appointed
	BUDG Budgets		07/10/2003
		PSE KUCKELKORN Wilfried	
Council of the European Union	Council configuration	Meeting	Date
	Justice and Home Affairs (JHA)	2574	30/03/2004
	Employment, Social Policy, Health and Consumer Affairs2549		01/12/2003
European Commission	Commission DG	Commissioner	
	Health and Food Safety		

Key events			
08/08/2003	Legislative proposal published	COM(2003)0441	Summary
04/09/2003	Committee referral announced in Parliament, 1st reading		
01/12/2003	Debate in Council	2549	Summary
27/01/2004	Vote in committee, 1st reading		Summary
27/01/2004	Committee report tabled for plenary, 1st reading	A5-0038/2004	
10/02/2004	Debate in Parliament		
10/02/2004	Decision by Parliament, 1st reading	T5-0078/2004	Summary
30/03/2004	Act adopted by Council after Parliament's 1st reading		

21/04/2004	Final act signed		
21/04/2004	End of procedure in Parliament		
30/04/2004	Final act published in Official Journal		

Technical information	
Procedure reference	2003/0174(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amended by 2020/0320(COD)
Legal basis	EC Treaty (after Amsterdam) EC 152-p4
Stage reached in procedure	Procedure completed

Documentation gateway					
Legislative proposal		COM(2003)0441	08/08/2003	EC	Summary
Economic and Social Committee: opinion, report		CES1394/2003 OJ C 032 05.02.2004, p. 0057-0060	29/10/2003	ESC	
Committee report tabled for plenary, 1st reading/single reading		A5-0038/2004	27/01/2004	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0078/2004 OJ C 097 22.04.2004, p. 0033-0093 E	10/02/2004	EP	Summary

Additional information	
European Commission	EUR-Lex

Final act
Regulation 2004/851 OJ L 142 30.04.2004, p. 0001-0011 Summary

Public health: European Centre for Disease Prevention and Control ECDC

PURPOSE : to establish the European Centre for Disease Prevention and Control. **CONTENT** : this Communication discusses the significant threat to the health of EU citizens through outbreaks of communicable diseases. It cites the recent spread of the SARS virus and the anthrax alerts of 2001, as well as multi-resistant tuberculosis and HIV/AIDS. Communicable disease has always been one of the major threats to human health. What has changed in the past few years is the realisation that natural outbreaks of communicable disease can threaten both technologically advanced regions of the world such as the EU as much as developing regions. 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 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 EU 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. The Centre would provide EU policy makers and citizens with authoritative and independent scientific advice on serious health threats and recommend control measures, thus enabling a rapid and effective EU-wide response. The technical work to be conducted between national disease control centres requires shared ownership of objectives, tasks and operations and pooling of resources at EU-level. The European Centre would create this shared ownership and facilitate the joint use of skills and resources to discharge common responsibilities in fighting serious health threats. The Commission would maintain its' overall supervision and existing decision making powers under Decision 2119/98/EC, in close consultation with the Member States through the Network Committee. The Commission's memberships in the Management Board would also ensure the coherence of the Centre's work with other Community policies dealing with health issues (e.g. development aid, research) and with international organisations, such as the WHO. The

main tasks of the European Centre will be as follows: - epidemiological surveillance and networking of laboratories at European level : in this work, the Centre could either use its own staff, staff from the dedicated surveillance networks (DSN), or 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; - scientific opinions : the Centre will support the Commission and Member States by providing independent scientific evidence. 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; - 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; - technical assistance : when requested, the Centre 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; - 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. Public health authorities, civil protection, the military and civil society may all need to be involved in responding to an epidemic. 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. With regard to staff and size, 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. Total annual costs in the beginning of its operation would be around EUR 12 million and after five years around EUR 48 million. Within this budget, in addition to its normal running costs, the Centre should have an appropriate contingency budget of up to EUR 5 Million to enable it to respond speedily to public health threats. 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. As with other similar independent Community agencies, the Centre will have a three pillar administrative structure: - a director and his/her staff; - 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 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. FINANCIAL STATEMENT : - Budget lines - for the purposes of creating the Centre, two new operational budget lines are needed to cover subsidy of administrative (Titles I and II) and operating (Title III) expenditure. As subdivisions of chapter 17 03, these new budget lines could be designated items 17 03 01 and 17 03 03 02 respectively. - Total allocation of action for the start up period until the year n+2: EUR 47.835 million for commitment. - Period of application: Start 2005. - Overall multiannual estimate of expenditure: Subsidy of operational expenditure (Title III budget line 17 03 03 02): Total years EUR 30 658 (CA) EUR 30 658 (PA). - Subsidy of administrative expenditure (Titles I and II): A subsidy of EUR 4.753 million will be required for the first year of operation. Of this EUR 1.215 million will be personnel costs. The number of staff will be 35. For the second year, the subsidy is EUR 14.303 million. For the third year, it is EUR 28.779 million.?

Public health: European Centre for Disease Prevention and Control ECDC

The Council held an extensive policy debate on a proposal for a Regulation establishing a European Centre for disease prevention and control (ECDC), and reached a common general approach on the main content of the proposal. The Italian Presidency took note of the general agreement of delegations regarding the need for such an ECDC and urged the Council to adopt the proposal during the first semester 2004. The Opinion of the European Parliament in first reading, pursuant to the co-decision procedure, is expected in February 2004 so that amendments could be taken into account by the Council with a view to adopt the proposal in first reading during the first semester 2004. The Regulation is expected to apply from early 2005. The Council agreed in particular that the mission and tasks of the Centre would be limited to communicable diseases and health threats whose origin are as yet unknown, and that the need for a possible extension would have to be envisaged in the context of a later review. Some changes were brought to the text with a view to ensure that the European Centre would not be entitled to regulatory powers. Other issues discussed among the delegations concerned the voting rules and the composition of the management board as well as the translation facilities and the budget of the Centre.?

Public health: European Centre for Disease Prevention and Control ECDC

The committee unanimously adopted the report by John BOWIS (EPP-ED, UK) amending the proposal under the 1st reading of the codecision procedure. It proposed inter alia that the European Parliament should be able to appoint two representatives to the Centre's Management Board and that the Board should be expanded so that every Member State can have one representative. Parliament should also play a role in the procedure for appointing the Director, by holding a parliamentary hearing of the selected candidate. MEPs amended the description of the Centre's tasks so that, as well as assessing communicable diseases and other health threats, "in the event of other outbreaks of serious illness, including when biological and non-biological agents are a possible cause, and if there is a possibility of spread within or to the Community, the Centre shall act on its own initiative until the source of the outbreak is known and then, as appropriate, in cooperation with the relevant competent authority or authorities identified as being responsible". The Centre should also, they said, identify the strategic areas and aims of applied research and "contribute to the improvement and strengthening of the prevention and monitoring of human diseases in the EU". When identifying emerging health threats, both physical and mental health threats should be covered. In addition, one of the Centre's key tasks should be to ensure that the dedicated surveillance networks operate efficiently, inter alia by harmonising and rationalising the operating methodologies. The committee pointed out that the benefits of the Centre's technical research capacity should not be restricted solely to the Commission and therefore amended the text to enable Member States, third countries and international organisations (in particular the WHO) to request scientific and technical assistance. It specified that "the Centre shall respond within its financial capacity and mandate". To improve accessibility of information to the public, MEPs said that the Centre should have its own website to communicate information about its work and should publish its opinions. Lastly, they said that, in addition to the external review scheduled to take place three years after the regulation comes into force, there should be provision for further reviews at five-yearly intervals. The evaluation should assess whether or not the scope of the Centre's mission should be extended.?

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The European Parliament adopted a resolution based on the report by John BOWIS (EPP-ED, UK) and made several amendments to the Commission's proposal. The version adopted is, in large part, the result of an agreement reached in advance with the Council and a compromise between five political groups. The creation of the Centre, whose main task will be to combat risks of epidemics, had benefited from the start from a wide consensus, which was further strengthened by the avian flu outbreak. The following principal amendments were voted by the Parliament: -the European Parliament should be able to appoint two representatives to the Centre's Management Board and that the Board should be expanded so that every Member State can have one representative. There will be three members appointed by the Commission. -the description of the Centre's purpose is amended so that the mission of the Centre is 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 must 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. -the Centre must also 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; -when identifying emerging health threats, both physical and mental health threats should be covered; -in addition, one of the Centre's key tasks should be to ensure that the dedicated surveillance networks operate efficiently, inter alia by harmonising and rationalising the operating methodologies; -Member States, third countries and international organisations (in particular the WHO) may request scientific and technical assistance. The Centre shall respond within its financial capacity and mandate; -the Centre should have its own website; -the Centre must conduct an annual evaluation of the current and emerging threats to health in the Community; -in addition, the Centre should foster the exchange of best practices and experience with regard to vaccination programmes; -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; -the Centre must provide scientific and technical expertise to the Member States, the Commission and other Community agencies in the development of preparedness plans, and also in the development of intervention strategies in the fields within its mission; -it will support and co-ordinate 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; -On the rules of the center, Parliament specified that the Management Board must 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.?

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PURPOSE : to establish the European Centre for Disease Prevention and Control. **LEGISLATIVE ACT :** Regulation 851/2004/EC of the European Parliament and of the Council establishing a European Centre for disease prevention and control. **CONTENT :** this Decision creates a European Centre, able to provide a structured and systematic approach to the control of communicable diseases and other serious health threats, which affect EU citizens. The Centre is an independent agency, which will serve as a Community source of independent scientific advice, assistance and expertise from trained medical, scientific and epidemiological staff. The mission of the Centre is to identify, assess and communicate current and emergent threats to human health from communicable diseases. In the case of other outbreaks of illness of unknown origin, the Centre will act on its own initiative until the source of the outbreak is known. In the case of an outbreak which is clearly not caused by a communicable disease, the Centre will act only in cooperation with the competent authority upon request from that authority. In pursuing its mission, the Centre will take full account of the responsibilities of Member State, 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. For their part, the Member States must: - provide the Centre with relevant scientific and technical data; - communicate to the Centre any messages forwarded to the Community network via the early warning and response system; - identify competent bodies and public health experts who could be made available to assist in Community responses to health threats. Within the field of its mission, the Centre has the following tasks: - collect, evaluate and disseminate scientific and technical data; - provide scientific opinions and technical assistance, including training; the Centre must issue a scientific opinion at the request of the Commission, the European Parliament or a Member State on matters falling within its mission; - provide timely information to the Commission, Member States, Community agencies and international organisations; - coordinate the European networking of bodies operating in the fields within the Centre's mission, including networks arising from public health activities operating the dedicated surveillance networks; and - facilitate the development and implementation of joint actions. With regard to the organisation of the Centre, the latter will comprise a management board, a director (with a term of five years, which may be extended once) and his staff, and an advisory forum. The Management Board will 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. The Advisory Forum will be composed of members from technically competent bodies in the Member States which undertake tasks similar to those of the Centre. It will constitute a mechanism for an exchange of information and the pooling of knowledge. Turning to the Centre's revenue, this will comprise a subsidy from the Community and payments received for services rendered as well as any financial contributions from the competent bodies, and voluntary contributions from the Member States. There are provisions relating to the discharge of the budget as well as provisions on combating fraud. Finally, by 20 May 2007, the Centre must commission an independent evaluation of its achievements on the basis of terms of reference issued by the Management Board in agreement with the Commission. **ENTRY INTO FORCE :** 20/05/04. The Centre will be operational from 20/05/05.