Basic information

1997/0146(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Decision	Procedure completed
Public health: Community action programme 1999-2003 concerning rare diseases **Subject** 4.20.01 Medicine, diseases	

Key players

European Parliament

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health and Consumer Protection	VICECONTE Guido (UPE)	19/06/1997
ENVI Environment, Public Health and Consumer Protection	VICECONTE Guido (UPE)	19/06/1997

Former committee for opinion	Former rapporteur for opinion	Appointed
BUDG Budgets	HAUG Jutta (PSE)	01/07/1997

Council of the European Union

Council configuration	Meetings	Date
Fisheries	2152	1998-12-17
Health	2013	1997-06-05
Health	2056	1997-12-04
Health	2086	1998-04-30
Social Affairs	2102	1998-06-04
Telecommunications	2172	1999-04-22

Key events

Date	Event	Reference	Summary
26/05/1997	Legislative proposal published	COM(1997)0225	Summary
05/06/1997	Debate in Council		
09/06/1997	Committee referral announced in Parliament, 1st reading		
04/12/1997	Debate in Council		

25/02/1998	Vote in committee, 1st reading		Summary
25/02/1998	Committee report tabled for plenary, 1st reading	A4-0074/1998	
10/03/1998	Debate in Parliament		Summary
15/04/1998	Modified legislative proposal published	COM(1998)0232 	Summary
30/04/1998	Council position published	06492/1/1998	Summary
18/06/1998	Committee referral announced in Parliament, 2nd reading		
23/09/1998	Vote in committee, 2nd reading		Summary
23/09/1998	Committee recommendation tabled for plenary, 2nd reading	A4-0336/1998	
07/10/1998	Debate in Parliament		
17/12/1998	Parliament's amendments rejected by Council		
04/02/1999	Formal meeting of Conciliation Committee		
04/02/1999	Final decision by Conciliation Committee		Summary
10/03/1999	Joint text approved by Conciliation Committee co-chairs	3602/1999	
25/03/1999	Report tabled for plenary, 3rd reading	A4-0166/1999	
13/04/1999	Debate in Parliament		
22/04/1999	Decision by Council, 3rd reading		
29/04/1999	Final act signed		
29/04/1999	End of procedure in Parliament		
22/06/1999	Final act published in Official Journal		

Technical information

Procedure reference	1997/0146(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Decision
Legal basis	EC Treaty (before Amsterdam) E 129
Stage reached in procedure	Procedure completed
Committee dossier	CODE/4/10660

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A4-0074/1998 OJ C 104 06.04.1998, p. 0005	25/02/1998	
		T4-0136/1998		

Text adopted by Parliament, 1st reading/single reading		OJ C 104 06.04.1998, p. 0099-0133	11/03/1998	Summary
Committee recommendation tabled for plenary, 2nd reading		A4-0336/1998 OJ C 328 26.10.1998, p. 0006	23/09/1998	
Text adopted by Parliament, 2nd reading		T4-0566/1998 OJ C 328 26.10.1998, p. 0135-0148	08/10/1998	Summary
Report tabled for plenary by Parliament delegation to Conciliation Committee, 3rd reading		A4-0166/1999 OJ C 219 30.07.1999, p. 0009	25/03/1999	
Text adopted by Parliament, 3rd reading		T4-0299/1999 OJ C 219 30.07.1999, p. 0173-0215	14/04/1999	Summary

Council of the EU

Document type	Reference	Date	Summary
Council position	06492/1/1998 OJ C 227 20.07.1998, p. 0001	30/04/1998	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(1997)0225 OJ C 203 03.07.1997, p. 0006	26/05/1997	Summary
Modified legislative proposal	COM(1998)0232  OJ C 160 27.05.1998, p. 0008	15/04/1998	Summary
Commission communication on Council's position	SEC(1998)0979 	11/06/1998	Summary
Commission opinion on Parliament's position at 2nd reading	COM(1998)0643 	05/11/1998	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1171/1997	29/10/1997	Summary
CofR	Committee of the Regions: opinion	CDR0246/1997 OJ C 064 27.02.1998, p. 0096	19/11/1997	
CSL/EP	Joint text approved by Conciliation Committee co-chairs	3602/1999	10/03/1999	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Decision 1999/1295
OJ L 155 22.06.1999, p. 0001

Summary

Public health: Community action programme 1999-2003 concerning rare diseases

1997/0146(COD) - 11/06/1998 - Commission communication on Council's position

In its opinion on the common position of the Council concerning the programme of action on rare diseases, the Commission indicates that it reserves its position on the text approved by the Council. Its reservations concern: -commitology: the Council opts for a mixed committee, which the Commission considers excessive and inappropriate in the context of the programme and its limited budget; -the amendments adopted by Parliament but not accepted by the Council. A Commission statement is annexed to the text of the common position of the Council concerning these two points.

Public health: Community action programme 1999-2003 concerning rare diseases

1997/0146(COD) - 08/10/1998 - Text adopted by Parliament, 2nd reading

In adopting the recommendation for second reading by Mr Guido VICECONTE (UPE, I), the European Parliament approved the common position of the Council with numerous amendments: - it again proposed a total allocation of ECU 14 million over five years (whereas the Council had proposed an allocation of only ECU 6.5 million); - Parliament reaffirmed that a Community approach, rather than a national approach, was the only effective means of tackling a problem whose scale in individual countries was too small to allow the proper action; - it stressed that diseases which were currently rare might in future spread to the community as a whole, which made it necessary to adopt a range of measures, such as the establishment of a rapid detection and control system; pooling of knowledge acquired in Europe; extension of the programme to genetic disorders and diseases caused by aetiological agents; the setting-up of rapid response teams; the setting-up of databases accessible to all (wide dissemination of information, particularly over the Internet, telephone helplines and free information pamphlets, etc.); training of professionals; promotion of research, etc. The European Parliament also wished agreement to be reached with the Council that, in managing projects, the Commission would be assisted by an advisory committee comprising - and this would be a first - representatives of patient support groups and voluntary organisations.

Public health: Community action programme 1999-2003 concerning rare diseases

1997/0146(COD) - 11/03/1998 - Text adopted by Parliament, 1st reading/single reading

In adopting the report by Mr Guido VICECONTE (UPE, I) on rare diseases, the European Parliament amended the programme proposed by the Commission, calling in particular for a commitment on the part of the Community to combat such diseases effectively. Although, all in all, the number of people affected by each individual rare disease was relatively small, Parliament considered that, taken together, they were quite prevalent and affected a significant percentage of the population. Accordingly it called for the programme to provide information about rare diseases (including genetic diseases and those caused by aetiological agents) to patients via self-help groups, to health professionals and to researchers. The programme should also foster a surveillance and monitoring system which would make it possible to respond rapidly and effectively when the diseases concerned appeared. Parliament also: -with regard to surveillance of rare diseases, called for action to be taken to ensure their rapid identification, assessment and treatment (it proposed, in particular, that rapid response teams be set up which could be mobilized readily in the event of an emergency); -called for the database provided for under the programme to be made widely accessible over the Internet and by means of telephone hotlines and free information pamphlets, -called for refresher courses for persons involved in dealing with rare diseases (it particularly suggested the setting-up of schools to deal with rare diseases). Lastly, Parliament: -in the field of commitology, called for the Commission to be assisted by representatives of patients or of voluntary organizations with relevant experience, -called for the appropriation for the programme for the period 1999-2003 to be increased to ECU 14 million.

Public health: Community action programme 1999-2003 concerning rare diseases

1997/0146(COD) - 14/04/1999 - Text adopted by Parliament, 3rd reading

At third reading under codecision procedure, the European Parliament approved the joint text, approved by the Conciliation Committee, and the relevant joint declaration, for a European Parliament and Council decision adopting a programme of Community action on rare diseases in the context of the framework for action in the field of public health. The Parliament's rapporteur was Guido Viceconte (UPE,IT).

Public health: Community action programme 1999-2003 concerning rare diseases

1997/0146(COD) - 05/11/1998 - Commission opinion on Parliament's position at 2nd reading

Following on from the European Parliament's second reading, the Commission accepts, in part or in full, eleven of the Parliament's twenty amendments relating to the following areas: - directing Community action towards prevention of diseases and underlining its added value; - the need to understand rare diseases as public health warning signs; - the motivation and mobilization, in particular, of patients and health professionals; - the involvement of people with disabilities; - the use of technology to enhance the achievement of the programme's objectives and actions; - the improvement of knowledge about rare diseases and the setting up of a system of surveillance for rare diseases to ensure a rapid and effective response; - the format of the advisory committee; - the use of sources other than existing databases to develop a European information network; - a more general classification of collaboration and networking, not limited to cross-border cooperation. The Commission rejects the other 9 amendments for legal or budgetary reasons, reasons of internal consistency, because they are covered elsewhere or they are unacceptably limiting.

Public health: Community action programme 1999-2003 concerning rare diseases

1997/0146(COD) - 26/05/1997 - Legislative proposal

OBJECTIVE: this proposal seeks to establish a programme on rare diseases for the period from 1 January 1999 to 31 December 2003, with the objective of: - improving information on rare diseases, - supporting patient support groups, - encouraging the creation of response and risk management teams in the event of rare diseases clusters. SUBSTANCE: Definition: rare diseases must be understood as life-threatening or chronically debilitating diseases which are of such low prevalence that specially combined efforts are needed (the generally accepted prevalence of rare diseases is less than 5 per 10 000 of the population - to date there are about 5 000 such diseases in this category). Actions eligible under this programme: 1) information actions on rare diseases to provide information to patients, health professionals and researchers: . creation of a data base on rare diseases, . creation of local, regional, national and Community information networks in order to improve access to information and coordination of existing information systems, . organization of meetings between health professionals in order to improve the identification and prevention of these diseases; 2) actions in support of patient and family support groups in order to establish and strengthen voluntary organizations involved in supporting people affected by these diseases: . aid for the establishment of groups of persons with the same rare conditions or those professionally involved, . establishment of networks of groups and the creation of umbrella bodies encouraging transnational cooperation; 3) actions on handling rare diseases clusters (temporal and physical concentrations or prevalence of rare diseases): . support for the monitoring (sentinel) of rare diseases in order to respond to the demands of detection and treatment of these diseases and the demands of statistical monitoring, . creation of rare diseases response teams and specialised training courses for those investigating clusters, . support for surveillance and early warning systems for clusters, . exchange of expertise in the evaluation and management of clusters of rare diseases that are associated with exogenic causes. Implementation: the Commission will ensure implementation of the programme in close cooperation with the Member States. It will cooperate with the institutions active in this field. In the management of this programme it will be assisted by an advisory committee consisting of representatives of the Member States; Consistency and complementarity: the programme must be implemented in consistency and complementarity with the other relevant Community actions; International cooperation: the programme is open to participation by the associated countries of central Europe and Cyprus and Malta; Monitoring and evaluation: the Commission will ensure the monitoring and continuous evaluation of the programme. It will present an evaluation report to the European Parliament and the Council during the third year of the programme. A final report will also be submitted to Parliament and the Council on completion of this programme; Budget: ECU 1.3 million for the first year (the financial framework for the following four years will be fixed after the establishment of the next financial perspective).

Public health: Community action programme 1999-2003 concerning rare diseases

1997/0146(COD) - 29/10/1997 - Economic and Social Committee: opinion, report

The Committee welcomes the action programme as a step towards a more systematic approach to the problem of rare diseases in the Community. It has however serious doubts about whether the objectives of the programme can be achieved with the envisaged budgetary resources. In addition, the Committee wishes to draw attention to the need of ensuring the programme's continuity beyond the year 2003 in an effort to optimizing the effectiveness of many of the proposed actions (e.g. the monitoring of long-term trends). Whilst the Committee agrees with the Commission that Community initiatives on rare diseases can bring important benefits, it would also stress the need for additional action and coordination at Member State level. The Committee broadly agrees with the three specific objectives of the program and the concrete actions proposed under each of them.

Public health: Community action programme 1999-2003 concerning rare diseases

1997/0146(COD) - 15/04/1998 - Modified legislative proposal

In its amended proposal on the action programme on rare diseases, the Commission incorporated 16 of the 28 amendments adopted by the European Parliament at first reading. The amendments which it accepted concerned: -prevention of diseases at Community level, their treatment being too limited at Member State level, -the fact that the number of people affected by these diseases is not negligible, and that they pose serious difficulties for sufferers, -the importance of improving understanding of diseases, -the adoption of an overall policy on the subject including provision for orphan medicinal products and research, the compilation of a Community databank and the setting-up of detection and control systems, -the implementation of the programme by organizations representing sufferers and health professionals, -the extension of the programme to patients and health professionals, -clearer provisions concerning actions relating to rare-disease clusters: the actions concerned are to identify, handle and respond rapidly to such clusters, -as part of information measures, the provision of information about rare diseases to patients' families and maximum dissemination of the information gathered concerning these diseases, -as part of measures to treat clusters, having in place an effective system to monitor rare diseases, promote Community monitoring of rare diseases and make permanent organizational arrangements for providing appropriate responses for rare diseases (networking and training for their treatment). The amendments not incorporated related in particular to the budgetary provisions proposed by Parliament (increasing the allocation) and extending the scope of the programme (aetiological diseases).

Public health: Community action programme 1999-2003 concerning rare diseases

1997/0146(COD) - 30/04/1998 - Council position

In its common position on the programme of Community action on rare diseases, the Council extensively restructured the Commission proposal and condensed the presentation of the actions. More specifically, the Council rendered more succinct the description of the actions in the annex to the programme, concentrating on cross-border activities and those offering most Community added value. The Council particularly stressed the establishment of a European information network using existing databases rather than setting up a new one. It deleted support for the setting up and strengthening of information networks at local, regional and national level. The organisation of meetings of those working in the field ('consensus meetings') has been replaced with 'recommendations' to improve early detection, identification and prevention of the diseases concerned. The actions relating to patients' groups and their families are rationalised and concentrated on cross-border aspects. The actions concerning clusters of rare diseases are more general and stress Community monitoring of these diseases and early warning systems. Besides general rationalisation of the actions to be undertaken under the programme, the Council also modified other specific aspects of the programme: -commitology: the Council favours the mixed committee procedure over the advisory committee procedure, -budgetary aspects: the Council allocates ECU 6.5 m for the duration of the programme (5 years), -monitoring and evaluation of the programme: the Council considers that the interim report to be submitted by the Commission should also take account of developments which may occur in connection with Community action in the field of public health. The Council incorporated only 6 of the 28 amendments adopted by Parliament at first reading (the Commission had accepted 16 of them). The only amendments accepted by the Council concerned: -the considerable prevalence of these diseases and the fact that they affect a significant percentage of the population, -the serious difficulties they cause to sufferers, -the fact that the treatment of these diseases should be integrated into an overall policy which also relates to orphan drugs and research, -improving, by means of the programme, the knowledge of health professionals, researchers and people directly or indirectly affected by the diseases, -the widest possible public dissemination of information about the diseases. Among the most important of Parliament's amendments which were not accepted by the Council were those concerning the budget (Parliament had called for ECU 14 m), commitology and the establishment of a monitoring and surveillance system making it possible to respond rapidly and effectively to outbreaks of the diseases (establishment of networks and courses relating to their treatment).

Public health: Community action programme 1999-2003 concerning rare diseases

1997/0146(COD) - 29/04/1999 - Final act

PURPOSE: to establish a programme of Community action on rare diseases within the framework for action in the field of public health (1999-2003). COMMUNITY MEASURE: decision 1295/1999/EC of the European Parliament and the Council. CONTENT: the programme, which has a financial framework of EURO 6.5 million for the period 1999-2003 aims, in coordination with other Community measures, to ensure a high level of protection against rare diseases by: 1) promoting the development of, and access to, a coherent and complementary European information network on rare diseases, using the existing databases; 2) contributing to training and refresher courses for professionals in order to improve early detection, recognition, intervention and prevention in the field of rare diseases; 3) promoting transnational collaboration and networking between groups of persons directly or indirectly affected by the same rare conditions or volunteers and professionals involved; 3) providing support at Community level for the monitoring of rare diseases in the Member States and rapid response to clusters. Rare diseases are defined as diseases, including those of genetic origin, which are life-threatening or chronically debilitating of such low prevalence that special combined efforts are needed to address them so as to prevent significant morbidity or perinatal or early mortality or a considerable reduction in an individual's quality of life. Generally, the prevalance of such diseases is recognised as less than 5 per 10,000 in the Community. Nonetheless, these diseases, taken together, are quite prevalent, affect a significant percentage of the general population and pose seious difficulties for sufferers and their families. The Commission will ensure the implementation of the programme in close cooperation with the Member States and will also cooperate with institutions and organisations active in the field. The Commission will also be assisted by a committee consisting of two representatives of each Member State and chaired by a representative of the Commission. The programme will be carried out in consistency and complementarity with other Community actions in the field of public health as well as initiatives in the sphere of orphan drugs (see COD98240) and medical research. The programme will be open to participation by the associated countries of Central Europe in accordance with the conditions laid down in the Association Agreements or Additional Protocols relating thereto concerning participation in Community programmes. The programme will also be open to Cyprus and Malta, in accordance with procedures to be agreed. Subject to Article 228 of the Treaty (conclusion of international agreements), the programme will also be implemented in close cooperation with the WHO and other international organisations competent in the sphere of public health. The Commission will ensure continuous monitoring and

assessment of the programme. It will submit an interim report to the European Parliament and to the Council during the programme's third year, which should take account of developments occurring within the framework for Community action in the field of publichealth. This will be followed by a final report at the end of the programme. Both of these reports will contain information on Community financing in the various fields of action and on consistency and complementarity with other actions in the field of public health. On the basis of the interim report the Commission may, if necessary, make appropriate proposals for modifications or adjustments to the programme. ENTRY INTO FORCE: 29/04/1999. It should be noted that the decision is accompanied by two declarations: 1) the first (interinstitutional) declares that the European Parliament, the Council and the Commission will pay particular attention, among the priority issues to be addressed within the framework of the future programme on public health, to rare diseases and pollution-related diseases and will duly take account of the budgetary implications; 2) the second provides and undertaking from the Commission to inform the European Parliament annually on the decisions taken to implement the programme.