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## Legislation

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## I

(Acts whose publication is obligatory)

**DECISION No 1786/2002/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of 23 September 2002  
adopting a programme of Community action in the field of public health (2003-2008)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(2)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(3)</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(4)</sup>, in the light of the joint text approved by the Conciliation Committee on 15 May 2002,

Whereas:

(1) The Community is committed to promoting and improving health, preventing disease, and countering potential threats to health, with a view to reducing avoidable morbidity and premature mortality and activity-impairing disability. To contribute to the well-being of European citizens, the Community must address in a coordinated and coherent way the concerns of its people about risks to health and their expectations for a high level of health protection. Therefore, all health-related activities of the Community must have a high degree of visibility and transparency and allow consultation and participation of all stakeholders in a balanced way, in order to promote better knowledge and communication flows and thus enable a greater involvement of individuals in decisions that concern their health. In this framework, attention should be given to the right of the Community population to receive simple, clear and scientifically sound information about measures to protect health and prevent diseases, with a view to improving quality of life.

(2) Health is a priority and a high level of health protection should be ensured in the definition and implementation of all Community policies and activities. Under Article 152 of the Treaty, the Community is required to play an active role in this sector by taking measures which cannot be taken by individual States, in accordance with the principle of subsidiarity.

(3) In the context of the public health framework set out in the Commission communication of 24 November 1993 on the framework for action in the field of public health, eight action programmes were adopted, namely:

— Decision No 645/96/EC of the European Parliament and of the Council of 29 March 1996 adopting a programme of Community action on health promotion, information, education and training within the framework for action in the field of public health (1996 to 2000) <sup>(5)</sup>,

— Decision No 646/96/EC of the European Parliament and of the Council of 29 March 1996 adopting an action plan to combat cancer within the framework for action in the field of public health (1996 to 2000) <sup>(6)</sup>,

— Decision No 647/96/EC of the European Parliament and of the Council of 29 March 1996 adopting a programme of Community action on the prevention of AIDS and certain other communicable diseases within the framework for action in the field of public health (1996 to 2000) <sup>(7)</sup>,

— Decision No 102/97/EC of the European Parliament and of the Council of 16 December 1996 adopting a programme of Community action on the prevention of drug dependence within the framework for action in the field of public health (1996 to 2000) <sup>(8)</sup>,

<sup>(1)</sup> OJ C 337 E, 28.11.2000, p. 122 and C 240 E, 28.8.2001, p. 168.

<sup>(2)</sup> OJ C 116, 20.4.2001, p. 75.

<sup>(3)</sup> OJ C 144, 16.5.2001, p. 43.

<sup>(4)</sup> Opinion of the European Parliament of 4 April 2001 (OJ C 21, 24.1.2002, p. 161), Council Common Position of 31 July 2001 (OJ C 307, 31.10.2001, p. 27) and Decision of the European Parliament of 12 December 2001 (not yet published in the Official Journal). Decision of the European Parliament of 3 July 2002 and Decision of the Council of 26 June 2002.

<sup>(5)</sup> OJ L 95, 16.4.1996, p. 1. Decision as last amended by Decision No 521/2001/EC (OJ L 79, 17.3.2001, p. 1).

<sup>(6)</sup> OJ L 95, 16.4.1996, p. 9. Decision as last amended by Decision No 521/2001/EC.

<sup>(7)</sup> OJ L 95, 16.4.1996, p. 16. Decision as last amended by Decision No 521/2001/EC.

<sup>(8)</sup> OJ L 19, 22.1.1997, p. 25. Decision as amended by Decision No 521/2001/EC.

- Decision No 1400/97/EC of the European Parliament and of the Council of 30 June 1997 adopting a programme of Community action on health monitoring within the framework for action in the field of public health (1997 to 2001) <sup>(1)</sup>,
- Decision No 372/1999/EC of the European Parliament and of the Council of 8 February 1999 adopting a programme of Community action on injury prevention in the framework for action in the field of public health (1999 to 2003) <sup>(2)</sup>,
- Decision No 1295/1999/EC of the European Parliament and of the Council of 29 April 1999 adopting a programme of Community action on rare diseases within the framework for action in the field of public health (1999 to 2003) <sup>(3)</sup>, and
- Decision No 1296/1999/EC of the European Parliament and of the Council of 29 April 1999 adopting a programme of Community action on pollution-related diseases in the context of the framework for action in the field of public health (1999 to 2001) <sup>(4)</sup>.

Furthermore, Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 on setting up a network for the epidemiological surveillance and control of communicable diseases in the Community <sup>(5)</sup> was adopted. Pursuant to that Decision, the Commission adopted on 22 December 1999 Decision No 2000/57/EC on the early warning and response system for the prevention and control of communicable diseases <sup>(6)</sup>.

- (4) Other activities in the context of the public health framework included Council Recommendation 98/463/EC of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community <sup>(7)</sup> and Recommendation 1999/519/EC of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields 0 Hz to 300 GHz <sup>(8)</sup>.
- (5) The public health framework was reviewed in the Commission communication of 15 April 1998 on the development of public health policy in the European Community, which indicated that a new health strategy and programme were needed in view of the new Treaty provisions, new challenges and experience so far.
- (6) The Council in its Conclusions of 26 November 1998 on the future framework for Community action in the

field of public health <sup>(9)</sup>, and in its Resolution of 8 June 1999 <sup>(10)</sup>, the Economic and Social Committee, in its opinion of 9 September 1998 <sup>(11)</sup>, the Committee of the Regions, in its Opinion of 19 November 1998 <sup>(12)</sup>, and the European Parliament, in its Resolution A4-0082/99 of 12 March 1999 <sup>(13)</sup>, welcomed the Commission communication of 15 April 1998 and supported the view that actions at Community level should be set out in one overall programme to run for a period of at least five years and comprising three general objectives, namely improving information for the development of public health, reacting rapidly to health threats and tackling health determinants through health promotion and disease prevention, underpinned by inter-sectoral action and the use of all appropriate Treaty instruments.

- (7) In its Resolution of 29 June 2000 on the follow-up to the Evora conference on health determinants, the Council considered that the increasing differences in health status and health outcomes between and within Member States called for renewed and coordinated efforts at national and Community level; welcomed the Commission's commitment to submit a proposal for a new public health programme containing a specific strand of action aimed at addressing health determinants by means of health promotion and disease prevention underpinned by intersectoral policy and agreed that there was a need to develop the appropriate knowledge base for this and, therefore, that an efficacious health monitoring system should be established for this purpose; stressed the importance of the new Community public health strategy building upon the activities on specific determinants taken in the existing programmes, especially with respect to tobacco, nutrition and alcohol and that it was important not only to ensure continuity with existing actions, but also to take forward work on these issues in a fully coherent and systematic way.

- (8) The Council reaffirms its Conclusions on combating tobacco consumption of 18 November 1999, in which it underlined the necessity of developing an overall strategy, and invited the Commission, *inter alia*, to strengthen cooperation between health and other policy areas, with the aim of ensuring a high level of health protection in these areas.

- (9) The Council on 18 November 1999 agreed unanimously a Resolution on the Promotion of Mental Health.

<sup>(1)</sup> OJ L 193, 22.7.1997, p. 1. Decision as amended by Decision No 521/2001/EC.

<sup>(2)</sup> OJ L 46, 20.2.1999, p. 1.

<sup>(3)</sup> OJ L 155, 22.6.1999, p. 1.

<sup>(4)</sup> OJ L 155, 22.6.1999, p. 7. Decision as amended by Decision No 521/2001/EC.

<sup>(5)</sup> OJ L 268, 3.10.1998, p. 1.

<sup>(6)</sup> OJ L 21, 26.1.2000, p. 32.

<sup>(7)</sup> OJ L 203, 21.7.1998, p. 14.

<sup>(8)</sup> OJ L 199, 30.7.1999, p. 59.

<sup>(9)</sup> OJ C 390, 15.12.1998, p. 1.

<sup>(10)</sup> OJ C 200, 15.7.1999, p. 1.

<sup>(11)</sup> OJ C 407, 28.12.1998, p. 21.

<sup>(12)</sup> OJ C 51, 22.2.1999, p. 53.

<sup>(13)</sup> OJ C 175, 21.6.1999, p. 135.

- (10) According to the WHO World Health Report 2000 the five major burdens of disease (in disability-adjusted life years) are: 1. neuropsychiatric disorders, 2. cardiovascular diseases, 3. malignant neoplasms, 4. unintentional injuries and 5. respiratory diseases. Infectious diseases, such as HIV/AIDS, and anti-microbial resistance are also becoming a threat to the health of all people in Europe. An important task of the programme would be to identify better the main burdens of disease in the Community and, in particular, the main health determinants.
- (11) The programme should contribute to the exchange of information on quality standards identified in the field of public health.
- (12) It is essential to collect, process and analyse data at Community level for the purpose of effective public health monitoring at Community level and in order to obtain objective, reliable and compatible and comparable information which could be exchanged and would enable the Commission and the Member States to improve information to the public and formulate appropriate strategies, policies and actions to achieve a high level of human health protection. Data from the private sector should also be taken into account for the completeness of the programme. All relevant statistics should be broken down and analysed by gender.
- (13) The Community and its Member States have at their disposal certain means and mechanisms in relation to information and monitoring in the field of public health. It is therefore necessary to ensure a high level of coordination between actions and initiatives taken by the Community and the Member States to implement the programme, to promote cooperation between Member States and to enhance the effectiveness of existing and future networks in the field of public health.
- (14) It is essential that the Commission ensure the effectiveness and the cohesion of measures and actions of the programme at both micro- and macro-level as well as the promotion of cooperation between the Member States. Any structural arrangements which would be established under the auspices of the Commission to this end should collect, monitor and evaluate data, and develop surveillance methods and a basis for rapid and coordinated responses to health threats. Such structural arrangements would consist of a strengthened central resource and closely involve the relevant institutions designated by the Member States.
- (15) There is in particular a need to ensure, relying on competent and relevant expertise, appropriate sustainable coordination, in the area of health information, of activities in relation to the following: definition of information needs, development of indicators, collection of data and information, comparability issues, exchange of data and information with and between Member States, continuing development of databases, analyses, and wider dissemination of information. Such coordination should also be ensured in the area of rapid reaction to health threats, of activities in relation to epidemiological surveillance, development of surveillance methods, exchange of information on guidelines and on prevention and control actions, mechanisms and procedures.
- (16) It is essential that the Commission, through appropriate structural arrangements, ensures the effectiveness and cohesion of measures and actions contained in the programme and promotes cooperation between the Member States. To enable such structural arrangements to operate smoothly and effectively, it is essential to establish sustained cooperation with the health authorities of the Member States, while respecting Member States' responsibilities.
- (17) The Commission should make, as appropriate, further proposals on the kind of structural arrangements needed for the implementation of the public health strategy, especially regarding health monitoring and rapid reaction to health threats.
- (18) The overall aim of the public health programme is to contribute towards the attainment of a high level of physical and mental health and well-being and greater equality in health matters throughout the Community, by directing action towards improving public health, preventing human diseases and disorders, and obviating sources of danger to health with a view to combating morbidity and premature mortality, while taking gender and age into consideration. To fulfil this aim, actions should be guided by the need to increase life expectancy without disability or sickness, promote quality of life and minimise the economic and social consequences of ill health, thus reducing health inequalities, while taking into account the regional approach to health issues. Priority should be given to health-promoting actions that address the major burdens of disease. The programme should support the development of an integrated inter-sectoral health strategy to ensure that Community policies and actions contribute to protecting and promoting health.
- (19) In order to achieve this, the programme should take into account the importance of education, training and networking.

- (20) The Treaty requires that a high level of human health protection is ensured in the definition and implementation of all Community policies and activities. A strong link is to be established between all Community policies having an impact on health and the Community strategy for public health. Within the public health programme, a priority task will be to develop criteria and methodologies for evaluating policy proposals and their implementation. In developing the measures under the programme, and joint strategies and actions with other relevant Community programmes and actions, it should be ensured that these other Community policies and actions incorporate the health aspect, and that they are underpinned by intersectoral policy.
- (21) Achieving the overall aim, and the general objectives of the programme requires effective cooperation of the Member States, their full commitment in the implementation of Community actions, and the involvement of institutions, associations, organisations and bodies in the health field as well as the public at large. To ensure sustainability and efficient use of existing Community investment and capacity, established Community and national networks should be used to pull together expertise and experience from Member States on effective methods for implementation of health promotional and preventive interventions and on quality criteria. A dialogue should be ensured with all key partners committed to improving public health and their expertise should be incorporated in an efficient and transparent Community knowledge base. Cooperation should be established with bodies and non-governmental organisations active in the field of health through appropriate mechanisms, such as health fora.
- (22) In accordance with the principles of subsidiarity and proportionality set out in Article 5 of the Treaty, Community action on matters which do not fall within the exclusive competence of the Community, such as public health, should be undertaken only if and in so far as, by reason of its scale or effects, its objective can be better achieved by the Community. The objectives of the programme cannot be sufficiently achieved by the Member States because of the complexity, transnational character and lack of complete control at Member State level over the factors affecting health, and therefore the programme should support and complement the Member States' actions and measures. The programme can provide a significant added value to health promotion and to health systems in the Community through the support of structures and programmes which enhance the capabilities of individuals, institutions, associations, organisations and bodies in the health field by facilitating the exchange of experience and best practices and by providing a basis for a common analysis of the factors affecting public health. Also, the programme may have added value in the event of threats to public health of a cross-border nature, such as infectious diseases, environmental pollution or food contamination, to the extent that they prompt joint strategies and actions. The programme will enable the Community to contribute towards fulfilling its Treaty obligations in the field of public health while fully respecting the responsibilities of the Member States for the organisation and delivery of health services and health care. This decision does not go beyond what is necessary to achieve those objectives.
- (23) The measures under the programme underpin the health strategy of the Community and will yield Community added value by responding to needs arising out of conditions and structures established through Community action in other fields, by addressing new developments, new threats and new problems for which the Community would be in a better position to act to protect its people, by bringing together activities undertaken in relative isolation and with limited impact at national level and by complementing them in order to achieve positive results for the people of the Community, and by contributing to the strengthening of solidarity and cohesion in the Community. The new health strategy and public health action programme should provide the opportunity to further develop the citizens' dimension of Community health policy.
- (24) In order to ensure that actions can address broad health issues and threats effectively in cooperation with other Community policies and activities, while avoiding duplication, the programme should provide for the possibility of undertaking joint actions with related Community programmes and actions. A proactive use of other Community policies, such as structural funds and social policy could influence health determinants in a positive way.
- (25) Effective implementation of the measures and actions and achievement of the desired impact of the programme require comparability of the data collected. Compatibility and interoperability of the systems and networks for exchanging information and data for the development of public health would also make a valuable contribution and further efforts towards these objectives should be pursued. It is of prime importance that information is exchanged on the basis of comparable and compatible data.



- (26) In general, the measures and actions under the programme should take account of the development of new technologies and IT applications and, in particular, there should be close coordination with the plans drawn up and implemented in the field of public health under the integrated action programme for an electronic Europe (e-Europe), and other relevant programmes, while avoiding overlapping, and taking particular care to ensure equal accessibility to health information.
- (27) The Feira European Council in June 2000 endorsed the 'e-Europe 2002 Action Plan on an Information Society for All', which under Health Online urges Member States to develop an infrastructure of user-friendly, validated and interoperable systems for health education, disease prevention and medical care. It is essential that the new information technology is exploited to make health information as accessible as possible to citizens.
- (28) In the execution of the programme, full use should be made of the relevant results generated from the Community research programmes, which support research in areas covered by the programme.
- (29) The experience acquired from different charters in the field of public health should be taken into account.
- (30) In the implementation of the Community programme there must be compliance with all the relevant legal provisions in the field of protection of personal data, and the establishment of mechanisms to ensure the confidentiality and security of those data.
- (31) The programme should last six years in order to allow sufficient time to implement measures to achieve its objectives.
- (32) It is essential that the Commission should ensure implementation of the programme in close cooperation with the Member States. In order to obtain scientific information and advice to implement the programme, cooperation with scientists and experts of international standing is desirable.
- (33) Consistency and complementarity should be ensured between actions to be implemented under the programme and those envisaged or implemented under other policies and activities, in particular in the light of the requirement to ensure a high level of human health protection in the definition and implementation of all Community policies and activities.
- (34) Close cooperation and consultation will be expected with Community bodies responsible for risk assessment, monitoring and research in the fields of food and feed safety, environmental protection and product safety.
- (35) This decision lays down, for the entire duration of the programme, a financial framework constituting the prime reference, within the meaning of point 33 of the Interinstitutional Agreement of 6 May 1999 between the European Parliament, the Council and the Commission on budgetary discipline and improvement of the budgetary procedure<sup>(1)</sup> for the budgetary authority during the annual budgetary procedure. The financial framework should correspond to the needs and objectives of the programme.
- (36) Funding from other Community policies earmarked for joint actions under the programme is additional to the financial framework laid down for the programme.
- (37) It is essential that there should be flexibility to allow redeployment of resources and adaptation of activities while respecting the need for transparency as well as the criteria for selecting and ordering priorities according to magnitude of risk or potential of effect, the outcome of evaluation, public concerns, availability of interventions or potential for their development, subsidiarity, added value and impact on other sectors. There is a need, however, to maintain a balance between the three objectives of the programme, allocating budget resources fairly between them.
- (38) Practical measures are essential in order to attain the objectives of the programme. Consequently, when implementing the programme and earmarking resources under it, the importance of practical measures should be emphasised.
- (39) The measures necessary for the implementation of this Decision should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(2)</sup>.
- (40) The Agreement on the European Economic Area (EEA Agreement) provides for greater cooperation in the field of public health between the European Community and its Member States, on the one hand, and the countries of the European Free Trade Association participating in the European Economic Area (EFTA/EEA countries), on the other. Provision should also be made to open the programme to participation of the associated Central and Eastern European countries in accordance with the conditions established in the Europe Agreements, in their additional protocols and in the decisions of the respective Association Councils, of Cyprus, funded by additional appropriations in accordance with the procedures to be agreed with that country, as well as of Malta and Turkey, funded by additional appropriations, in accordance with the provisions of the Treaty.

<sup>(1)</sup> OJ C 172, 18.6.1999, p. 3.

<sup>(2)</sup> OJ L 184, 17.7.1999, p. 23.

- (41) The applicant countries should be actively involved in the development and implementation of the programme and consideration should be given to a strategic approach to health in those countries, and especially to their specific problems.
- (42) On the accession of new Member States, the Commission should report on the consequences of these accessions for the programme.
- (43) Cooperation with third countries and the competent international organisations in the sphere of health, such as the WHO, the Council of Europe and the OECD, should be fostered, not only in the field of collecting and analysing data (including indicators) but also in the field of intersectoral health promotion, in order to ensure cost effectiveness, avoid overlapping of activities and programmes and enforce synergy and interaction, taking particular account of specific arrangements for cooperation such as that between the WHO and the Commission.
- (44) In order to increase the value and impact of the programme there should be regular monitoring and evaluation, including independent external evaluations, of the measures taken. It should be possible to adjust or modify the programme in the light of these evaluations and of developments that may take place in the general context of Community action in health and health-related fields. The European Parliament should be informed of the annual work plans which will be drawn up by the Commission.
- (45) The programme of Community action in the field of public health builds on the activities and the eight programmes under the previous framework and on the work of the network for epidemiological surveillance and control of communicable diseases in the Community, and pursues all the objectives and measures therein in the form of a global and integrated health strategy. The decisions concerning those eight programmes are covered by the new programme and should therefore be repealed with effect from 31 December 2002,

HAVE DECIDED AS FOLLOWS:

#### Article 1

##### Establishment of the programme

1. This Decision establishes a programme of Community action in the field of public health, hereinafter referred to as 'the programme'.
2. The programme shall be implemented in the period starting on 1 January 2003 and ending on 31 December 2008.

#### Article 2

##### Overall aim and general objectives

1. The programme, which shall complement national policies, shall aim to protect human health and improve public health.
2. The general objectives of the programme shall be:
  - (a) to improve information and knowledge for the development of public health;
  - (b) to enhance the capability of responding rapidly and in a coordinated fashion to threats to health;
  - (c) to promote health and prevent disease through addressing health determinants across all policies and activities.
3. The programme shall thereby contribute to:
  - (a) ensuring a high level of human health protection in the definition and implementation of all Community policies and activities, through the promotion of an integrated and intersectoral health strategy;
  - (b) tackling inequalities in health;
  - (c) encouraging cooperation between Member States in the areas covered by Article 152 of the Treaty.

#### Article 3

##### Community actions and activities

1. The general objectives of the programme as set out in Article 2 shall be pursued by means of the actions listed in the Annex.
2. These actions shall be implemented in close cooperation with Member States through support to activities of a transversal nature, which may be used to implement all or part of the actions and which may, where appropriate, be combined. These activities are the following:
  - (a) Activities related to the monitoring and rapid reaction systems
    - (i) network activities operated through structures designated by Member States and other activities of Community interest for the purposes of public health monitoring and providing national information, as well as data at Community level, in furtherance of the objectives of the programme;
    - (ii) activities to counter health threats, including major diseases, and react to unforeseen events, enable investigations and coordinate response;
    - (iii) preparation, establishment and operation of appropriate structural arrangements coordinating and integrating networks for health monitoring and for rapid reaction to health threats;
    - (iv) development of appropriate links between the actions concerning the monitoring and rapid reaction systems.

## (b) Activities on health determinants

## Article 4

development and implementation of health promotion and disease prevention activities across all Community policies and involving, as appropriate, non-governmental organisations, innovative or pilot projects and networks between national institutions and activities.

## (c) Activities related to legislation

- (i) preparatory work for Community legislative instruments in the field of public health;
- (ii) health impact assessment of Community legislation;
- (iii) coordination of the position of the Community and its Member States in fora in which health-related matters are discussed.

## (d) Activities related to consultation, knowledge and information

- (i) development and dissemination to competent authorities in Member States, to health and other professionals and, where appropriate, to other stakeholders and the general public of health information, knowledge, including statistics, reports, reviews, analysis, and advice on issues of common interest to the Community and to Member States;
  - (ii) information and consultation on health and health-related matters at the Community level, involving all stakeholders such as patients' organisations, health professionals, health care providers, trade unions, social partners and NGOs in the field of public health;
  - (iii) sharing of experience and exchange of information on health-related matters between the Community and authorities and competent organisations of Member States;
  - (iv) encouraging education and vocational training in the field of public health relevant to the objectives of the programme;
  - (v) developing and maintaining networks for the exchange of information on best practice in public health and the effectiveness of health policies;
  - (vi) obtaining scientific information and advice from high-level scientists and experts;
  - (vii) supporting and promoting activities by the Community and the Member States with regard to good practice and to sound guidelines for public health based on scientific data.
- (e) Promotion of coordination at the European level of non-governmental organisations which are developing activities defined as priorities under the programme. They may be operating either singly or in the form of several coordinated associations.

**Joint strategies and actions**

To ensure a high level of human health protection in the definition and implementation of all Community policies and activities, the objectives of the programme may be implemented as joint strategies and joint actions by creating links with relevant Community programmes and actions, notably in the areas of consumer protection, social protection, health and safety at work, employment, research and technological development, internal market, information society and information technology, statistics, agriculture, education, transport, industry and environment, and with actions undertaken by the Joint Research Centre and relevant Community bodies with which cooperation shall be fostered.

## Article 5

**Implementation of the programme**

1. The Commission shall ensure the implementation, in close cooperation with the Member States, of the actions set out in the programme, in accordance with the provisions of Article 9 and ensuring its harmonious and balanced development.

2. In order to assist implementation, the Commission shall ensure, through appropriate structural arrangements closely associating the Member States, the coordination and integration of networks for health monitoring and rapid reaction to health threats.

3. The Commission and Member States shall take appropriate action, within their respective areas of competence, to ensure the efficient running of the programme and to develop mechanisms at Community and Member State level to achieve the objectives of the programme. They shall ensure that appropriate information is provided about actions supported by the programme and that the widest possible participation is obtained in actions requiring implementation through local and regional authorities and non-governmental organisations.

4. The Commission shall, in close cooperation with the Member States, pursue the comparability of data and information and, where possible, the compatibility and interoperability of the systems and networks for exchange of data and information on health.

5. In implementing the programme the Commission, together with the Member States, shall ensure compliance with all relevant legal provisions regarding personal data protection and, where appropriate, the introduction of mechanisms to ensure the confidentiality and safety of such data.

6. The Commission, in close cooperation with the Member States, shall ensure the transition between those actions developed within the public health programmes adopted by the Decisions referred to in Article 13 which contribute to the priorities set out in this programme, and those to be implemented under this programme.



*Article 6***Consistency and complementarity**

The Commission shall ensure that there is consistency and complementarity between the actions to be implemented under the programme and those implemented under other Community policies and activities, including the policies mentioned in Article 4. In particular, the Commission shall identify those proposals of particular relevance to the objectives and actions of the programme, and inform the Committee referred to in Article 9 of how health considerations are taken into account in these proposals and of their expected health impact.

*Article 7***Funding**

1. The financial framework for the implementation of the programme for the period specified in Article 1 is hereby set at EUR 312 million.

Expenditure on technical and administrative assistance related to the structural arrangements referred to under Article 3(2)(a)(iii), and activities arising therefrom, shall be met from the overall budget of the programme.

2. The annual appropriations shall be authorised by the budgetary authority within the limits of the financial perspective.

*Article 8***Implementation measures**

1. The measures necessary for the implementation of this Decision relating to the matters referred to below shall be adopted in accordance with the management procedure referred to in Article 9(2):

- (a) the annual plan of work for the implementation of the programme, setting out priorities and actions to be undertaken, including allocation of resources;
- (b) the arrangements, criteria and procedures for selecting and financing the actions of the programme;
- (c) the arrangements for implementing the joint strategies and actions referred to in Article 4;
- (d) the arrangements for evaluating the programme referred to in Article 12;
- (e) the arrangements for the preparation of any structural arrangements for the coordination of health monitoring and rapid reaction to health threats;
- (f) the arrangements for transmitting, exchanging and disseminating information and for rapid reaction on health threats under the programme, without prejudice to the implementation measures carried out under Decision 2119/98/EC.

2. The measures necessary for the implementation of this Decision relating to all other matters shall be adopted in accordance with the advisory procedure referred to in Article 9(3).

*Article 9***Committee**

1. The Commission shall be assisted by a Committee.
2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
4. The Committee shall adopt its rules of procedure.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at two months.

*Article 10***Participation of the EFTA/EEA countries, the associated central and eastern European countries, Cyprus, Malta and Turkey**

The programme shall be open to the participation of:

- (a) the EFTA/EEA countries in accordance with the conditions established in the EEA Agreement;
- (b) the associated countries of central and eastern Europe, in accordance with the conditions laid down in the Europe Agreements, in their Additional Protocols and in the Decisions of the respective Association Councils;
- (c) Cyprus, funded by additional appropriations in accordance with the procedures to be agreed with that country;
- (d) Malta and Turkey, funded by additional appropriations in accordance with the provisions of the Treaty.

*Article 11***International cooperation**

In the course of implementing the programme, cooperation with third countries and with international organisations competent in the sphere of public health, in particular the World Health Organisation, the Council of Europe and the Organisation for Economic Cooperation and Development, or able to have an impact on public health such as the World Trade Organisation and the United Nations Food and Agriculture Organisation shall be encouraged in accordance with the procedure laid down in Article 9(3). In particular, the health information system and the capacity to respond to health threats should be, where appropriate and possible, coordinated with the activities of the World Health Organisation.

*Article 12***Monitoring, evaluation and dissemination of results**

1. The Commission, in close cooperation with the Member States, shall regularly monitor, where appropriate with the help of experts, the implementation of the actions of the programme in the light of the objectives. It shall report annually to the Committee. The Commission shall transmit a copy of its main findings to the European Parliament and to the Council.

2. At the request of the Commission, Member States shall submit information on the implementation and the impact of this programme.

3. By the end of the fourth year of the programme, the Commission shall have an external assessment conducted by independent qualified experts of the implementation and achievements during the three first years of the programme. It shall also assess the impact achieved on health and the efficiency of the use of resources, as well as the consistency and complementarity with other relevant programmes, actions and initiatives implemented under other Community policies and activities. The Commission shall communicate the conclusions thereof, accompanied by its comments, to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions. The Commission shall also submit to those institutions and bodies a final report on the implementation of the programme by the end of the year which follows the end of the programme.

4. The Commission shall make the results of actions undertaken and the evaluation reports publicly available.

*Article 13***Repeal**

The following Decisions are hereby repealed on 31 December 2002:

Decision No 645/96/EC, Decision No 646/96/EC, Decision No 647/96/EC, Decision No 102/97/EC, Decision No 1400/97/EC, Decision No 372/1999/EC, Decision No 1295/1999/EC, Decision No 1296/1999/EC.

*Article 14***Entry into force**

This Decision shall enter into force on the date of its publication in the *Official Journal of the European Communities*.

Done at Brussels, 23 September 2002.

*For the European Parliament*

*The President*

P. COX

*For the Council*

*The President*

M. FISCHER BOEL

## ANNEX

## ACTIONS AND SUPPORT MEASURES

1. To improve health information and knowledge for the development of public health by:
  - 1.1. developing and operating a sustainable health monitoring system to establish comparable quantitative and qualitative indicators at Community level on the basis of existing work and of accomplished results, and to collect, analyse and disseminate comparable and compatible age- and gender-specific information on human health at Community level concerning health status, health policies and health determinants, including demography, geography and socioeconomic situations, personal and biological factors, health behaviours such as substance abuse, nutrition, physical activity, sexual behaviour, and living, working and environmental conditions, paying special attention to inequalities in health;
  - 1.2. developing an information system for the early warning, detection and surveillance of health threats, both on communicable diseases, including with regard to the danger of cross-border spread of diseases (including resistant pathogens), and on non-communicable diseases;
  - 1.3. improving the system for the transfer and sharing of information and health data including public access;
  - 1.4. developing and using mechanisms for analysis, advice, reporting, information and consultation with Member States and stakeholders on health issues relevant at Community level;
  - 1.5. improving analysis and knowledge of the impact of health policy developments and of other Community policies and activities, such as the internal market as it affects health systems, in contributing to a high level of human health protection, including developing criteria and methodologies for assessing policies for their impact on health and developing other links between public health and other policies;
  - 1.6. reviewing, analysing, and supporting the exchange of experiences on, health technologies, including new information technologies;
  - 1.7. supporting the exchange of information and experiences on good practice;
  - 1.8. developing and operating a joint action with the plans drawn up under e-Europe to improve availability to the general public on the Internet of information on health matters, and considering the possibilities for establishing a system of recognisable Community seals of approval for Internet sites.

The existing data and the information provided by the system is to be easily accessible to the Community, relevant users in Member States and, as appropriate, international organisations.

The statistical element of the system will be developed, in collaboration with Member States, using as necessary the Community Statistical Programme to promote synergy and avoid duplication.

2. To enhance the capability of responding rapidly and in a coordinated fashion to threats to health by:
  - 2.1. enhancing the capacity to tackle communicable diseases by supporting the further implementation of Decision No 2119/98/EC on the Community network on the epidemiological surveillance and control of communicable diseases;
  - 2.2. supporting the network's operation, in the Member States and the countries participating on the basis of Article 10 of this decision, in particular in relation to common investigations, training, continuous assessment, quality assurance and, where appropriate, in relation to its contribution to the actions described in the Annex, points 1.2 and 1.3;
  - 2.3. developing strategies and mechanisms for preventing, exchanging information on and responding to non-communicable disease threats, including gender-specific health threats and rare diseases;
  - 2.4. exchanging information concerning strategies in order to counter health threats from physical, chemical or biological sources in emergency situations, including those relating to terrorist acts, and developing or using, when appropriate, Community approaches and mechanisms;
  - 2.5. exchanging information on vaccination and immunisation strategies;
  - 2.6. enhancing the safety and quality of organs and substances of human origin, including blood, blood components and blood precursors by developing high standards of quality and safety for the collection, processing, storage and distribution and use of these substances;

- 2.7. implementing vigilance networks for human products, such as blood, blood components and blood precursors;
  - 2.8. promoting strategies and measures concerning the protection of human health from possible adverse effects from environmental agents such as ionising and non-ionising radiation and noise;
  - 2.9. developing strategies for reducing antibiotic resistance.
3. To promote health and prevent disease through action on health determinants across all Community policies and activities by:
- 3.1. preparing and implementing strategies and measures, including those related to public awareness, on life-style related health determinants, such as nutrition, physical activity, tobacco, alcohol, drugs and other substances and on mental health, including measures to take in all Community policies and age- and gender-specific strategies;
  - 3.2. analysing the situation and developing strategies on social and economic health determinants, in order to identify and combat inequalities in health and to assess the impact of social and economic factors on health;
  - 3.3. analysing the situation and developing strategies on health determinants related to the environment and contributing to the identification and assessment of the health consequences of environmental factors;
  - 3.4. analysing the situation and exchange information on genetic determinants and the use of genetic screening;
  - 3.5. developing methods to evaluate quality and efficiency of health promotion strategies and measures;
  - 3.6. encouraging relevant training activities related to the above measures.
4. Support measures
- 4.1. Community assistance may be provided to support the actions and activities referred to in Article 3.
  - 4.2. In carrying out the programme, the Commission may require additional resources, including recourse to experts, for instance for the monitoring system, the evaluation of the programme or the preparation of new legislation. It may also require experts to work for the Community structural arrangements for the coordination and integration of networks for health monitoring and for rapid reaction to health threats. The report referred to in Article 12(1) shall be accompanied, if need be, by any proposal regarding adjustment of the requirements.
  - 4.3. The Commission may also undertake information, publication and dissemination of actions. It may also undertake evaluation studies and organise seminars, colloquia or other meetings of experts.
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## COMMISSION STATEMENTS

### Declaration on structural arrangements

in order to ensure the effective implementation of the programme, in conformity with Article 5 of the Decision, the Commission intends to proceed as follows:

1. it will take the necessary steps to ensure the functioning of the Committee established under Articles 8 and 9 of the Decision. This Committee will be composed of representatives designated by the Member States, as laid down in Decision 1999/468/EC;
2. in full respect of the provisions of Article 218(2) of the EC treaty, it will operate its departments in the best way in order to facilitate attaining the three general objectives of the programme set out in Article 2 of the Decision;
3. in accordance with point 4 of the Annex to the Decision, the Commission will make use of scientific and technical experts to reinforce its capacity in the specific areas of action of the programme. Such experts will work with the Commission services in conformity with the relevant administrative rules;
4. the Commission also intends to make full use of the possibilities described in its Communication on externalisation (COM(2000) 788) and proposed regulation (COM(2001) 808). This may include examining the setting up of an executive agency in order to assist the Commission in implementing certain tasks of the programme once the proposed Regulation currently before the Council, is adopted.

The Commission further declares that the actions envisaged in points 1 and 2 will be implemented not later than the beginning of 2003, when the programme comes into effect; point 3 will begin early in the programme as soon as the relevant arrangements can be made, and point 4 will be considered later in the programme once the proposed Regulation is adopted.

### Declaration on Article 7

The financial framework of the programme shall be reviewed in the context both of the accession of new Member States and the preparation for the revision of the financial perspective, taking account of the establishment of the structural arrangements, and of developments concerning key priorities; financial proposals will be made, if appropriate.

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**COMMISSION REGULATION (EC) No 1787/2002**  
**of 8 October 2002**  
**establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 3223/94 of 21 December 1994 on detailed rules for the application of the import arrangements for fruit and vegetables <sup>(1)</sup>, as last amended by Regulation (EC) No 1498/98 <sup>(2)</sup>, and in particular Article 4(1) thereof,

Whereas:

- (1) Regulation (EC) No 3223/94 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in the Annex thereto.

- (2) In compliance with the above criteria, the standard import values must be fixed at the levels set out in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

*Article 1*

The standard import values referred to in Article 4 of Regulation (EC) No 3223/94 shall be fixed as indicated in the Annex hereto.

*Article 2*

This Regulation shall enter into force on 9 October 2002.

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

Done at Brussels, 8 October 2002.

*For the Commission*

J. M. SILVA RODRÍGUEZ  
*Agriculture Director-General*

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<sup>(1)</sup> OJ L 337, 24.12.1994, p. 66.

<sup>(2)</sup> OJ L 198, 15.7.1998, p. 4.

## ANNEX

**to the Commission Regulation of 8 October 2002 establishing the standard import values for determining the entry price of certain fruit and vegetables**

(EUR/100 kg)

CN code	Third country code <sup>(1)</sup>	Standard import value
0702 00 00	052	70,6
	060	93,0
	096	33,6
	999	65,7
0707 00 05	052	95,3
	999	95,3
0709 90 70	052	84,0
	999	84,0
0805 50 10	052	69,4
	388	60,1
	524	58,0
	528	48,4
	999	59,0
0806 10 10	052	113,0
	064	124,7
	400	204,0
	999	147,2
0808 10 20, 0808 10 50, 0808 10 90	096	41,3
	388	72,7
	400	58,9
	512	85,1
	804	74,7
0808 20 50	999	66,5
	052	94,2
	999	94,2

<sup>(1)</sup> Country nomenclature as fixed by Commission Regulation (EC) No 2020/2001 (OJ L 273, 16.10.2001, p. 6). Code '999' stands for 'of other origin'.

**COMMISSION REGULATION (EC) No 1788/2002****of 8 October 2002****prohibiting fishing for deepwater prawn by vessels flying the flag of Sweden**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2847/93 of 12 October 1993 establishing a control system applicable to the common fisheries policy <sup>(1)</sup>, as last amended by Regulation (EC) No 2846/98 <sup>(2)</sup>, and in particular Article 21(3) thereof,

Whereas:

- (1) Council Regulation (EC) No 2555/2001 of 18 December 2001 fixing for 2002 the fishing opportunities and associated conditions for certain fish stocks and groups of fish stocks, applicable in Community waters and, for Community vessels, in waters where limitations in catch are required <sup>(3)</sup>, lays down quotas for deepwater prawn for 2002.
- (2) In order to ensure compliance with the provisions relating to the quantity limits on catches of stocks subject to quotas, the Commission must fix the date by which catches made by vessels flying the flag of a Member State are deemed to have exhausted the quota allocated.
- (3) According to the information received by the Commission, catches of deepwater prawn in Norwegian waters

South of 62°00'N by vessels flying the flag of Sweden or registered in Sweden have exhausted the quota allocated for 2002. Sweden has prohibited fishing for this stock from 8 April 2002. This date should be adopted in this Regulation also,

HAS ADOPTED THIS REGULATION:

*Article 1*

Catches of deepwater prawn in Norwegian waters South of 62°00'N by vessels flying the flag of Sweden or registered in Sweden are hereby deemed to have exhausted the quota allocated to Sweden for 2002.

Fishing for deepwater prawn in Norwegian waters South of 62°00'N by vessels flying the flag of Sweden or registered in Sweden is hereby prohibited, as are the retention on board, transhipment and landing of this stock caught by the above vessels after the date of application of this Regulation.

*Article 2*

This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Communities*.

It shall apply from 8 April 2002.

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

Done at Brussels, 8 October 2002.

*For the Commission*

Franz FISCHLER

*Member of the Commission*

<sup>(1)</sup> OJ L 261, 20.10.1993, p. 1.

<sup>(2)</sup> OJ L 358, 31.12.1998, p. 5.

<sup>(3)</sup> OJ L 347, 31.12.2001, p. 1.



**DIRECTIVE 2002/65/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**of 23 September 2002**  
**concerning the distance marketing of consumer financial services and amending Council Directive**  
**90/619/EEC and Directives 97/7/EC and 98/27/EC**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 47(2), Article 55 and Article 95 thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(2)</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(3)</sup>,

Whereas:

- (1) It is important, in the context of achieving the aims of the single market, to adopt measures designed to consolidate progressively this market and those measures must contribute to attaining a high level of consumer protection, in accordance with Articles 95 and 153 of the Treaty.
- (2) Both for consumers and suppliers of financial services, the distance marketing of financial services will constitute one of the main tangible results of the completion of the internal market.
- (3) Within the framework of the internal market, it is in the interest of consumers to have access without discrimination to the widest possible range of financial services available in the Community so that they can choose those that are best suited to their needs. In order to safeguard freedom of choice, which is an essential consumer right, a high degree of consumer protection is required in order to enhance consumer confidence in distance selling.
- (4) It is essential to the smooth operation of the internal market for consumers to be able to negotiate and conclude contracts with a supplier established in other Member States, regardless of whether the supplier is also established in the Member State in which the consumer resides.

(5) Because of their intangible nature, financial services are particularly suited to distance selling and the establishment of a legal framework governing the distance marketing of financial services should increase consumer confidence in the use of new techniques for the distance marketing of financial services, such as electronic commerce.

(6) This Directive should be applied in conformity with the Treaty and with secondary law, including Directive 2000/31/EC <sup>(4)</sup> on electronic commerce, the latter being applicable solely to the transactions which it covers.

(7) This Directive aims to achieve the objectives set forth above without prejudice to Community or national law governing freedom to provide services or, where applicable, host Member State control and/or authorisation or supervision systems in the Member States where this is compatible with Community legislation.

(8) Moreover, this Directive, and in particular its provisions relating to information about any contractual clause on law applicable to the contract and/or on the competent court does not affect the applicability to the distance marketing of consumer financial services of Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgements in civil and commercial matters <sup>(5)</sup> or of the 1980 Rome Convention on the law applicable to contractual obligations.

(9) The achievement of the objectives of the Financial Services Action Plan requires a higher level of consumer protection in certain areas. This implies a greater convergence, in particular, in non harmonised collective investment funds, rules of conduct applicable to investment services and consumer credits. Pending the achievement of the above convergence, a high level of consumer protection should be maintained.

(10) Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts <sup>(6)</sup>, lays down the main rules applicable to distance contracts for goods or services concluded between a supplier and a consumer. However, that Directive does not cover financial services.

<sup>(1)</sup> OJ C 385, 11.12.1998, p. 10 and OJ C 177 E, 27.6.2000, p. 21.

<sup>(2)</sup> OJ C 169, 16.6.1999, p. 43.

<sup>(3)</sup> Opinion of the European Parliament of 5 May 1999 (OJ C 279, 1.10.1999, p. 207), Council Common Position of 19 December 2001 (OJ C 58 E, 5.3.2002, p. 32) and Decision of the European Parliament of 14 May 2002 (not yet published in the Official Journal). Council Decision of 26 June 2002 (not yet published in the Official Journal).

<sup>(4)</sup> OJ L 178, 17.7.2000, p. 1.

<sup>(5)</sup> OJ L 12, 16.1.2001, p. 1.

<sup>(6)</sup> OJ L 144, 4.6.1997, p. 19.

- (11) In the context of the analysis conducted by the Commission with a view to ascertaining the need for specific measures in the field of financial services, the Commission invited all the interested parties to transmit their comments, notably in connection with the preparation of its Green Paper entitled 'Financial Services — Meeting Consumers' Expectations'. The consultations in this context showed that there is a need to strengthen consumer protection in this area. The Commission therefore decided to present a specific proposal concerning the distance marketing of financial services.
- (12) The adoption by the Member States of conflicting or different consumer protection rules governing the distance marketing of consumer financial services could impede the functioning of the internal market and competition between firms in the market. It is therefore necessary to enact common rules at Community level in this area, consistent with no reduction in overall consumer protection in the Member States.
- (13) A high level of consumer protection should be guaranteed by this Directive, with a view to ensuring the free movement of financial services. Member States should not be able to adopt provisions other than those laid down in this Directive in the fields it harmonises, unless otherwise specifically indicated in it.
- (14) This Directive covers all financial services liable to be provided at a distance. However, certain financial services are governed by specific provisions of Community legislation which continue to apply to those financial services. However, principles governing the distance marketing of such services should be laid down.
- (15) Contracts negotiated at a distance involve the use of means of distance communication which are used as part of a distance sales or service-provision scheme not involving the simultaneous presence of the supplier and the consumer. The constant development of those means of communication requires principles to be defined that are valid even for those means which are not yet in widespread use. Therefore, distance contracts are those the offer, negotiation and conclusion of which are carried out at a distance.
- (16) A single contract involving successive operations or separate operations of the same nature performed over time may be subject to different legal treatment in the different Member States, but it is important that this Directive be applied in the same way in all the Member States. To that end, it is appropriate that this Directive should be considered to apply to the first of a series of successive operations or separate operations of the same nature performed over time which may be considered as forming a whole, irrespective of whether that operation or series of operations is the subject of a single contract or several successive contracts.
- (17) An 'initial service agreement' may be considered to be for example the opening of a bank account, acquiring a credit card, concluding a portfolio management contract, and 'operations' may be considered to be for example the deposit or withdrawal of funds to or from the bank account, payment by credit card, transactions made within the framework of a portfolio management contract. Adding new elements to an initial service agreement, such as a possibility to use an electronic payment instrument together with one's existing bank account, does not constitute an 'operation' but an additional contract to which this Directive applies. The subscription to new units of the same collective investment fund is considered to be one of 'successive operations of the same nature'.
- (18) By covering a service-provision scheme organised by the financial services provider, this Directive aims to exclude from its scope services provided on a strictly occasional basis and outside a commercial structure dedicated to the conclusion of distance contracts.
- (19) The supplier is the person providing services at a distance. This Directive should however also apply when one of the marketing stages involves an intermediary. Having regard to the nature and degree of that involvement, the pertinent provisions of this Directive should apply to such an intermediary, irrespective of his or her legal status.
- (20) Durable mediums include in particular floppy discs, CD-ROMs, DVDs and the hard drive of the consumer's computer on which the electronic mail is stored, but they do not include Internet websites unless they fulfil the criteria contained in the definition of a durable medium.
- (21) The use of means of distance communications should not lead to an unwarranted restriction on the information provided to the client. In the interests of transparency this Directive lays down the requirements needed to ensure that an appropriate level of information is provided to the consumer both before and after conclusion of the contract. The consumer should receive, before conclusion of the contract, the prior information needed so as to properly appraise the financial service offered to him and hence make a well-informed choice. The supplier should specify how long his offer applies as it stands.
- (22) Information items listed in this Directive cover information of a general nature applicable to all kinds of financial services. Other information requirements concerning a given financial service, such as the coverage of an insurance policy, are not solely specified in this Directive. This kind of information should be provided in accordance, where applicable, with relevant Community legislation or national legislation in conformity with Community law.

- (23) With a view to optimum protection of the consumer, it is important that the consumer is adequately informed of the provisions of this Directive and of any codes of conduct existing in this area and that he has a right of withdrawal.
- (24) When the right of withdrawal does not apply because the consumer has expressly requested the performance of a contract, the supplier should inform the consumer of this fact.
- (25) Consumers should be protected against unsolicited services. Consumers should be exempt from any obligation in the case of unsolicited services, the absence of a reply not being construed as signifying consent on their part. However, this rule should be without prejudice to the tacit renewal of contracts validly concluded between the parties whenever the law of the Member States permits such tacit renewal.
- (26) Member States should take appropriate measures to protect effectively consumers who do not wish to be contacted through certain means of communication or at certain times. This Directive should be without prejudice to the particular safeguards available to consumers under Community legislation concerning the protection of personal data and privacy.
- (27) With a view to protecting consumers, there is a need for suitable and effective complaint and redress procedures in the Member States with a view to settling potential disputes between suppliers and consumers, by using, where appropriate, existing procedures.
- (28) Member States should encourage public or private bodies established with a view to settling disputes out of court to cooperate in resolving cross-border disputes. Such cooperation could in particular entail allowing consumers to submit to extra-judicial bodies in the Member State of their residence complaints concerning suppliers established in other Member States. The establishment of FIN-NET offers increased assistance to consumers when using cross-border services.
- (29) This Directive is without prejudice to extension by Member States, in accordance with Community law, of the protection provided by this Directive to non-profit organisations and persons making use of financial services in order to become entrepreneurs.
- (30) This Directive should also cover cases where the national legislation includes the concept of a consumer making a binding contractual statement.
- (31) The provisions in this Directive on the supplier's choice of language should be without prejudice to provisions of national legislation, adopted in conformity with Community law governing the choice of language.
- (32) The Community and the Member States have entered into commitments in the context of the General Agreement on Trade in Services (GATS) concerning the possibility for consumers to purchase banking and investment services abroad. The GATS entitles Member States to adopt measures for prudential reasons, including measures to protect investors, depositors, policy-holders and persons to whom a financial service is owed by the supplier of the financial service. Such measures should not impose restrictions going beyond what is required to ensure the protection of consumers.
- (33) In view of the adoption of this Directive, the scope of Directive 97/7/EC and Directive 98/27/EC of the European Parliament and of the Council of 19 May 1998 on injunctions for the protection of consumers' interests <sup>(1)</sup> and the scope of the cancellation period in Council Directive 90/619/EEC of 8 November 1990 on the coordination of laws, regulations and administrative provisions relating to direct life assurance, laying down provisions to facilitate the effective exercise of freedom to provide services <sup>(2)</sup> should be adapted.
- (34) Since the objectives of this Directive, namely the establishment of common rules on the distance marketing of consumer financial services cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principles of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary to achieve that objective.

HAVE ADOPTED THIS DIRECTIVE:

#### Article 1

#### Object and scope

1. The object of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning the distance marketing of consumer financial services.
2. In the case of contracts for financial services comprising an initial service agreement followed by successive operations or a series of separate operations of the same nature performed over time, the provisions of this Directive shall apply only to the initial agreement.

<sup>(1)</sup> OJ L 166, 11.6.1998, p. 51. Directive as last amended by Directive 2000/31/EC (OJ L 178, 17.7.2001, p. 1).

<sup>(2)</sup> OJ L 330, 29.11.1990, p. 50. Directive as last amended by Directive 92/96/EEC (OJ L 360, 9.12.1992, p. 1).

In case there is no initial service agreement but the successive operations or the separate operations of the same nature performed over time are performed between the same contractual parties, Articles 3 and 4 apply only when the first operation is performed. Where, however, no operation of the same nature is performed for more than one year, the next operation will be deemed to be the first in a new series of operations and, accordingly, Articles 3 and 4 shall apply.

## Article 2

### Definitions

For the purposes of this Directive:

- (a) 'distance contract' means any contract concerning financial services concluded between a supplier and a consumer under an organised distance sales or service-provision scheme run by the supplier, who, for the purpose of that contract, makes exclusive use of one or more means of distance communication up to and including the time at which the contract is concluded;
- (b) 'financial service' means any service of a banking, credit, insurance, personal pension, investment or payment nature;
- (c) 'supplier' means any natural or legal person, public or private, who, acting in his commercial or professional capacity, is the contractual provider of services subject to distance contracts;
- (d) 'consumer' means any natural person who, in distance contracts covered by this Directive, is acting for purposes which are outside his trade, business or profession;
- (e) 'means of distance communication' refers to any means which, without the simultaneous physical presence of the supplier and the consumer, may be used for the distance marketing of a service between those parties;
- (f) 'durable medium' means any instrument which enables the consumer to store information addressed personally to him in a way accessible for future reference for a period of time adequate for the purposes of the information and which allows the unchanged reproduction of the information stored;
- (g) 'operator or supplier of a means of distance communication' means any public or private, natural or legal person whose trade, business or profession involves making one or more means of distance communication available to suppliers.

## Article 3

### Information to the consumer prior to the conclusion of the distance contract

1. In good time before the consumer is bound by any distance contract or offer, he shall be provided with the following information concerning:

#### (1) the supplier

- (a) the identity and the main business of the supplier, the geographical address at which the supplier is established and any other geographical address relevant for the customer's relations with the supplier;
- (b) the identity of the representative of the supplier established in the consumer's Member State of residence and the geographical address relevant for the customer's relations with the representative, if such a representative exists;
- (c) when the consumer's dealings are with any professional other than the supplier, the identity of this professional, the capacity in which he is acting vis-à-vis the consumer, and the geographical address relevant for the customer's relations with this professional;
- (d) where the supplier is registered in a trade or similar public register, the trade register in which the supplier is entered and his registration number or an equivalent means of identification in that register;
- (e) where the supplier's activity is subject to an authorisation scheme, the particulars of the relevant supervisory authority;

#### (2) the financial service

- (a) a description of the main characteristics of the financial service;
- (b) the total price to be paid by the consumer to the supplier for the financial service, including all related fees, charges and expenses, and all taxes paid via the supplier or, when an exact price cannot be indicated, the basis for the calculation of the price enabling the consumer to verify it;
- (c) where relevant notice indicating that the financial service is related to instruments involving special risks related to their specific features or the operations to be executed or whose price depends on fluctuations in the financial markets outside the supplier's control and that historical performances are no indicators for future performances;
- (d) notice of the possibility that other taxes and/or costs may exist that are not paid via the supplier or imposed by him;
- (e) any limitations of the period for which the information provided is valid;
- (f) the arrangements for payment and for performance;
- (g) any specific additional cost for the consumer of using the means of distance communication, if such additional cost is charged;

#### (3) the distance contract

- (a) the existence or absence of a right of withdrawal in accordance with Article 6 and, where the right of withdrawal exists, its duration and the conditions for exercising it, including information on the amount which the consumer may be required to pay on the basis of Article 7(1), as well as the consequences of non-exercise of that right;



- (b) the minimum duration of the distance contract in the case of financial services to be performed permanently or recurrently;
- (c) information on any rights the parties may have to terminate the contract early or unilaterally by virtue of the terms of the distance contract, including any penalties imposed by the contract in such cases;
- (d) practical instructions for exercising the right of withdrawal indicating, *inter alia*, the address to which the notification of a withdrawal should be sent;
- (e) the Member State or States whose laws are taken by the supplier as a basis for the establishment of relations with the consumer prior to the conclusion of the distance contract;
- (f) any contractual clause on law applicable to the distance contract and/or on competent court;
- (g) in which language, or languages, the contractual terms and conditions, and the prior information referred to in this Article are supplied, and furthermore in which language, or languages, the supplier, with the agreement of the consumer, undertakes to communicate during the duration of this distance contract;

#### (4) redress

- (a) whether or not there is an out-of-court complaint and redress mechanism for the consumer that is party to the distance contract and, if so, the methods for having access to it;
- (b) the existence of guarantee funds or other compensation arrangements, not covered by Directive 94/19/EC of the European Parliament and of the Council of 30 May 1994 on deposit guarantee schemes<sup>(1)</sup> and Directive 97/9/EC of the European Parliament and of the Council of 3 March 1997 on investor compensation schemes<sup>(2)</sup>.

2. The information referred to in paragraph 1, the commercial purpose of which must be made clear, shall be provided in a clear and comprehensible manner in any way appropriate to the means of distance communication used, with due regard, in particular, to the principles of good faith in commercial transactions, and the principles governing the protection of those who are unable, pursuant to the legislation of the Member States, to give their consent, such as minors.

#### 3. In the case of voice telephony communications

- (a) the identity of the supplier and the commercial purpose of the call initiated by the supplier shall be made explicitly clear at the beginning of any conversation with the consumer;
- (b) subject to the explicit consent of the consumer only the following information needs to be given:
  - the identity of the person in contact with the consumer and his link with the supplier,
  - a description of the main characteristics of the financial service,

- the total price to be paid by the consumer to the supplier for the financial service including all taxes paid via the supplier or, when an exact price cannot be indicated, the basis for the calculation of the price enabling the consumer to verify it,
- notice of the possibility that other taxes and/or costs may exist that are not paid via the supplier or imposed by him,
- the existence or absence of a right of withdrawal in accordance with Article 6 and, where the right of withdrawal exists, its duration and the conditions for exercising it, including information on the amount which the consumer may be required to pay on the basis of Article 7(1).

The supplier shall inform the consumer that other information is available on request and of what nature this information is. In any case the supplier shall provide the full information when he fulfils his obligations under Article 5.

4. Information on contractual obligations, to be communicated to the consumer during the pre-contractual phase, shall be in conformity with the contractual obligations which would result from the law presumed to be applicable to the distance contract if the latter were concluded.

#### Article 4

##### Additional information requirements

1. Where there are provisions in the Community legislation governing financial services which contain prior information requirements additional to those listed in Article 3(1), these requirements shall continue to apply.
2. Pending further harmonisation, Member States may maintain or introduce more stringent provisions on prior information requirements when the provisions are in conformity with Community law.
3. Member States shall communicate to the Commission national provisions on prior information requirements under paragraphs 1 and 2 of this Article when these requirements are additional to those listed in Article 3(1). The Commission shall take account of the communicated national provisions when drawing up the report referred to in Article 20(2).
4. The Commission shall, with a view to creating a high level of transparency by all appropriate means, ensure that information, on the national provisions communicated to it, is made available to consumers and suppliers.

#### Article 5

##### Communication of the contractual terms and conditions and of the prior information

1. The supplier shall communicate to the consumer all the contractual terms and conditions and the information referred to in Article 3(1) and Article 4 on paper or on another durable medium available and accessible to the consumer in good time before the consumer is bound by any distance contract or offer.

<sup>(1)</sup> OJ L 135, 31.5.1994, p. 5.

<sup>(2)</sup> OJ L 84, 26.3.1997, p. 22.

2. The supplier shall fulfil his obligation under paragraph 1 immediately after the conclusion of the contract, if the contract has been concluded at the consumer's request using a means of distance communication which does not enable providing the contractual terms and conditions and the information in conformity with paragraph 1.

3. At any time during the contractual relationship the consumer is entitled, at his request, to receive the contractual terms and conditions on paper. In addition, the consumer is entitled to change the means of distance communication used, unless this is incompatible with the contract concluded or the nature of the financial service provided.

#### Article 6

#### Right of withdrawal

1. The Member States shall ensure that the consumer shall have a period of 14 calendar days to withdraw from the contract without penalty and without giving any reason. However, this period shall be extended to 30 calendar days in distance contracts relating to life insurance covered by Directive 90/619/EEC and personal pension operations.

The period for withdrawal shall begin:

- either from the day of the conclusion of the distance contract, except in respect of the said life assurance, where the time limit will begin from the time when the consumer is informed that the distance contract has been concluded, or
- from the day on which the consumer receives the contractual terms and conditions and the information in accordance with Article 5(1) or (2), if that is later than the date referred to in the first indent.

Member States, in addition to the right of withdrawal, may provide that the enforceability of contracts relating to investment services is suspended for the same period provided for in this paragraph.

2. The right of withdrawal shall not apply to:

- (a) financial services whose price depends on fluctuations in the financial market outside the suppliers control, which may occur during the withdrawal period, such as services related to:
  - foreign exchange,
  - money market instruments,
  - transferable securities,
  - units in collective investment undertakings,
  - financial-futures contracts, including equivalent cash-settled instruments,

- forward interest-rate agreements (FRAs),
- interest-rate, currency and equity swaps,
- options to acquire or dispose of any instruments referred to in this point including equivalent cash-settled instruments. This category includes in particular options on currency and on interest rates;

- (b) travel and baggage insurance policies or similar short-term insurance policies of less than one month's duration;
- (c) contracts whose performance has been fully completed by both parties at the consumer's express request before the consumer exercises his right of withdrawal.

3. Member States may provide that the right of withdrawal shall not apply to:

- (a) any credit intended primarily for the purpose of acquiring or retaining property rights in land or in an existing or projected building, or for the purpose of renovating or improving a building, or
- (b) any credit secured either by mortgage on immovable property or by a right related to immovable property, or
- (c) declarations by consumers using the services of an official, provided that the official confirms that the consumer is guaranteed the rights under Article 5(1).

This paragraph shall be without prejudice to the right to a reflection time to the benefit of the consumers that are resident in those Member States where it exists, at the time of the adoption of this Directive.

4. Member States making use of the possibility set out in paragraph 3 shall communicate it to the Commission.

5. The Commission shall make available the information communicated by Member States to the European Parliament and the Council and shall ensure that it is also available to consumers and suppliers who request it.

6. If the consumer exercises his right of withdrawal he shall, before the expiry of the relevant deadline, notify this following the practical instructions given to him in accordance with Article 3(1)(3)(d) by means which can be proved in accordance with national law. The deadline shall be deemed to have been observed if the notification, if it is on paper or on another durable medium available and accessible to the recipient, is dispatched before the deadline expires.

7. This Article does not apply to credit agreements cancelled under the conditions of Article 6(4) of Directive 97/7/EC or Article 7 of Directive 94/47/EC of the European Parliament and of the Council of 26 October 1994 on the protection of purchasers in respect of certain aspects of contracts relating to the purchase of the right to use immovable properties on a timeshare basis <sup>(1)</sup>.

<sup>(1)</sup> OJ L 280, 29.10.1994, p. 83.

If to a distance contract of a given financial service another distance contract has been attached concerning services provided by the supplier or by a third party on the basis of an agreement between the third party and the supplier, this additional distance contract shall be cancelled, without any penalty, if the consumer exercises his right of withdrawal as provided for in Article 6(1).

8. The provisions of this Article are without prejudice to the Member States' laws and regulations governing the cancellation or termination or non-enforceability of a distance contract or the right of a consumer to fulfil his contractual obligations before the time fixed in the distance contract. This applies irrespective of the conditions for and the legal effects of the winding-up of the contract.

#### Article 7

##### **Payment of the service provided before withdrawal**

1. When the consumer exercises his right of withdrawal under Article 6(1) he may only be required to pay, without any undue delay, for the service actually provided by the supplier in accordance with the contract. The performance of the contract may only begin after the consumer has given his approval. The amount payable shall not:

- exceed an amount which is in proportion to the extent of the service already provided in comparison with the full coverage of the contract,
- in any case be such that it could be construed as a penalty.

2. Member States may provide that the consumer cannot be required to pay any amount when withdrawing from an insurance contract.

3. The supplier may not require the consumer to pay any amount on the basis of paragraph 1 unless he can prove that the consumer was duly informed about the amount payable, in conformity with Article 3(1)(3)(a). However, in no case may he require such payment if he has commenced the performance of the contract before the expiry of the withdrawal period provided for in Article 6(1) without the consumer's prior request.

4. The supplier shall, without any undue delay and no later than within 30 calendar days, return to the consumer any sums he has received from him in accordance with the distance contract, except for the amount referred to in paragraph 1. This period shall begin from the day on which the supplier receives the notification of withdrawal.

5. The consumer shall return to the supplier any sums and/or property he has received from the supplier without any undue delay and no later than within 30 calendar days. This period shall begin from the day on which the consumer dispatches the notification of withdrawal.

#### Article 8

##### **Payment by card**

Member States shall ensure that appropriate measures exist to allow a consumer:

- to request cancellation of a payment where fraudulent use has been made of his payment card in connection with distance contracts,
- in the event of such fraudulent use, to be re-credited with the sum paid or have them returned.

#### Article 9

##### **Unsolicited services**

Without prejudice to Member States provisions on the tacit renewal of distance contracts, when such rules permit tacit renewal, Member States shall take the necessary measures to:

- prohibit the supply of financial services to a consumer without a prior request on his part, when this supply includes a request for immediate or deferred payment,
- exempt the consumer from any obligation in the event of unsolicited supplies, the absence of a reply not constituting consent.

#### Article 10

##### **Unsolicited communications**

1. The use by a supplier of the following distance communication techniques shall require the consumer's prior consent:

- (a) automated calling systems without human intervention (automatic calling machines);
- (b) fax machines.

2. Member States shall ensure that means of distance communication other than those referred to in paragraph 1, when they allow individual communications:

- (a) shall not be authorised unless the consent of the consumers concerned has been obtained, or
- (b) may only be used if the consumer has not expressed his manifest objection.

3. The measures referred to in paragraphs 1 and 2 shall not entail costs for consumers.

#### Article 11

##### **Sanctions**

Member States shall provide for appropriate sanctions in the event of the supplier's failure to comply with national provisions adopted pursuant to this Directive.

They may provide for this purpose in particular that the consumer may cancel the contract at any time, free of charge and without penalty.

These sanctions must be effective, proportional and dissuasive.

*Article 12***Imperative nature of this Directive's provisions**

1. Consumers may not waive the rights conferred on them by this Directive.
2. Member States shall take the measures needed to ensure that the consumer does not lose the protection granted by this Directive by virtue of the choice of the law of a non-member country as the law applicable to the contract, if this contract has a close link with the territory of one or more Member States.

*Article 13***Judicial and administrative redress**

1. Member States shall ensure that adequate and effective means exist to ensure compliance with this Directive in the interests of consumers.
2. The means referred to in paragraph 1 shall include provisions whereby one or more of the following bodies, as determined by national law, may take action in accordance with national law before the courts or competent administrative bodies to ensure that the national provisions for the implementation of this Directive are applied:
  - (a) public bodies or their representatives;
  - (b) consumer organisations having a legitimate interest in protecting consumers;
  - (c) professional organisations having a legitimate interest in acting.
3. Member States shall take the measures necessary to ensure that operators and suppliers of means of distance communication put an end to practices that have been declared to be contrary to this Directive, on the basis of a judicial decision, an administrative decision or a decision issued by a supervisory authority notified to them, where those operators or suppliers are in a position to do so.

*Article 14***Out-of-court redress**

1. Member States shall promote the setting up or development of adequate and effective out-of-court complaints and redress procedures for the settlement of consumer disputes concerning financial services provided at distance.
2. Member States shall, in particular, encourage the bodies responsible for out-of-court settlement of disputes to cooperate in the resolution of cross-border disputes concerning financial services provided at distance.

*Article 15***Burden of proof**

Without prejudice to Article 7(3), Member States may stipulate that the burden of proof in respect of the supplier's obligations to inform the consumer and the consumer's consent to conclusion of the contract and, where appropriate, its performance, can be placed on the supplier.

Any contractual term or condition providing that the burden of proof of the respect by the supplier of all or part of the obligations incumbent on him pursuant to this Directive should lie with the consumer shall be an unfair term within the meaning of Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts<sup>(1)</sup>.

*Article 16***Transitional measures**

Member States may impose national rules which are in conformity with this Directive on suppliers established in a Member State which has not yet transposed this Directive and whose law has no obligations corresponding to those provided for in this Directive.

*Article 17***Directive 90/619/EC**

In Article 15(1) of Directive 90/619/EEC the first subparagraph shall be replaced by the following:

'1. Each Member State shall prescribe that a policyholder who concludes an individual life-assurance contract shall have a period of 30 calendar days, from the time when he was informed that the contract had been concluded, within which to cancel the contract.'

*Article 18***Directive 97/7/EC**

Directive 97/7/EC is hereby amended as follows:

1. the first indent of Article 3(1) shall be replaced by the following:

— relating to any financial service to which Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the distance marketing of consumer financial services and amending Council Directive 90/619/EEC and Directives 97/7/EC and 98/27/EC (\*) applies,

(\*) OJ L 271, 9.10.2002, p. 16.;

2. Annex II shall be deleted.

(1) OJ L 95, 21.4.1993, p. 29.



## Article 19

**Directive 98/27/EC**

The following point shall be added to the Annex of Directive 98/27/EC:

- '11. Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the distance marketing of consumer financial services and amending Council Directive 90/619/EEC and Directives 97/7/EC and 98/27/EC (\*).

(\*) OJ L 271, 9.10.2002, p. 16.'

## Article 20

**Review**

1. Following the implementation of this Directive, the Commission shall examine the functioning of the internal market in financial services in respect of the marketing of those services. It should seek to analyse and detail the difficulties that are, or might be faced by both consumers and suppliers, in particular arising from differences between national provisions regarding information and right of withdrawal.

2. Not later than 9 April 2006 the Commission shall report to the European Parliament and the Council on the problems facing both consumers and suppliers seeking to buy and sell financial services, and shall submit, where appropriate, proposals to amend and/or further harmonise the information and right of withdrawal provisions in Community legislation concerning financial services and/or those covered in Article 3.

## Article 21

**Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 9 October 2004. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field governed by this Directive together with a table showing how the provisions of this Directive correspond to the national provisions adopted.

## Article 22

**Entry into force**

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

## Article 23

**Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 23 September 2002.

*For the European Parliament*

*The President*

P. COX

*For the Council*

*The President*

M. FISCHER BOEL