COMMISSION OF THE EUROPEAN COMMUNITIES

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SECOND REPORT FROM THE COMMISSION

to the Council, the European Parliament,
the Economic and Social Committee and the Committee of the Regions
on the integration of health protection requirements in Community policies

(1995)

Executive Summary

1. This second report on the integration of health requirements in Community policies gives an overview of Community activities in 1995 with repercussions on health. Building on the first report, published in 1995, which took stock of health dimensions in all areas of Community policy, this report concentrates on a number of key policy areas. It is in these areas that the most important health-related developments have taken place:

   - social policy,
   - internal market,
   - agriculture, food and fisheries,
   - research and development,
   - environment and energy,
   - transport,
   - international cooperation.

   It includes the work of relevant agencies and other outside bodies connected to the Community which are working in these areas.

2. This annual report is one of the instruments the Commission has set up in order to monitor how the Community is meeting the obligation in Article 129 of the Treaty that health requirements shall form a constituent part of other Community policies. As set out in detail in the first report in 1995, this Treaty obligation is supplemented by a range of other references to health protection in the context of other Community policies. Their common aim is to ensure a high level of human health protection (Article 3 (o) of the Treaty).

   In the light of this goal, the Commission has also put into place other instruments which have more influence on the preparation of Community legislation and other activities than a retrospective report. These include the procedures of full interservice consultation on proposals in other fields which could have an impact on health being put forward by the Commission. In addition, the Interservice Group on Health provides opportunities for more general discussions of health-related topics among Commission services, while ad hoc groups have been created to allow more detailed examinations of particular problems or areas of policy from the health point of view.

3. Some progress has been made in raising awareness of the numerous links with and effects on health which the vast majority of Community policy areas have - and therefore of the importance of an early integration of health issues into the preparatory work for drawing up policies and action programmes - both within the Community institutions as well as in Member States. Moreover, the fact that health issues also tend to generate considerable media attention and raise major concerns among the population is another reason why they need to be taken into account at an early stage of policy formation.

It is not always evident how best to integrate health requirements in a given area of policy, or how and according to which criteria to judge success or failure. Work will have to continue to develop thinking on these areas. In publishing this report, the Commission wishes to stimulate public debate on these questions. In this sense, this report is an instrument to promote transparency and discussion on health issues within the Community.

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1. Introduction

1. This second report on the integration of health requirements in Community policies aims to provide an overview of developments in European Community policy pertaining to health. Read as a whole, it shows that a wide range of policy areas in the Community have considerable repercussions on health.

2. Article 129 of the Treaty stipulates that health considerations should form a constituent part of the Community's other policies. This annual report - following a Commission decision in the context of adopting the Commission Communication on the Framework of Action in the field of public health[1] - is designed to give an overview on how this obligation of the Treaty is taken into account in the different areas of Community policy.

3. This report is supplemented by other instruments of consultation and concertation within Commission services which aim to ensure that health requirements are properly taken into account. An Interservice Group on Health has been created which includes representatives from relevant Commission services and meets in plenary several times a year. Several subgroups follow specific issues. In application of regular Commission internal procedures, Commission services are required to consult on all proposals with a potential bearing on health with the responsible services for public health in the Directorate General for Employment, Industrial Relations and Social Affairs.

4. The first report on the integration of health requirements in other Community policies, covering activities in 1994, was adopted by the Commission on 29 May 1995[2]. As a first report of its kind, it aimed to give a complete overview of Community activities related to health. This second report focuses on health-related activities during the course of 1995. It does not include the recent debates on BSE and CJD which occurred in 1996 and will be dealt with in the third report. For a broader picture, it should be read in conjunction with the first report, particularly with its introduction, which includes a history of health-related activities at Community level.

5. The first report was met with great interest by the other Community Institutions and the public, while there was recognition of the difficulties associated with presenting such a wide range of topics in a coherent manner. The Council adopted a resolution on the integration of health requirements in Community policies which took the 1994 report as a point of departure.

   The Council welcomed the initiative taken by the Commission to present such reports, and invited the Commission to pay particular attention, in future reports, to certain areas of Community activity, namely, economic and in particular fiscal policy, social policy, including questions of employment, free movement of goods and persons, agricultural and food policy, consumer policy, research and technological development, environment and transport.[3]

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1 COM (93)559 fin. of 24.11.1993

2 COM (95)196 fin.

3 Council Resolution of 20.12.1995, OJ C 350/2, 30.12.1995

This report seeks to present an overview of all relevant activities whilst giving particular attention to the abovementioned areas of policy.

6. The European Parliament, in its Resolution on the medium-term social action programme, asked the Commission to present guidelines on incorporating health protection requirements in the other Community policies[4].

7. This year's report starts off with an overview of the public health programmes and activities of the Community, which in 1995 have been advanced considerably. This is followed by a summary of activities in a number of priority areas - areas which are important either because of the major activities which took place last year or because of the major impact they have on health in general. In a third section, the report outlines other health-related activities in additional areas of Community policy. In addition, some specific subjects (drugs, AIDS and tobacco) are presented in "boxes" inserted into the text. Legislative measures proposed or adopted in 1995 are summarised in an annex.

8. As in the first report, this report demonstrates that there is a diversity of areas of activity with an impact on health in the Community. In some areas, a remarkable degree of coherence has been achieved between the objectives in their own right and their impact on public health. In other areas, there is still progress to be made.

This report is designed to present as broad a picture as possible of political initiatives with a health perspective. It could serve to raise awareness on health-related issues and their likely impact, as well as to stimulate efforts aimed at ensuring that health becomes a fundamental consideration in the design and implementation of policies.

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4 Report on the Medium-Term Social Action Programme (HUGHES), Doc. A4-0311/95, p. 12

2. Public health programmes and activities

9. The Commission's Communication on the Framework of Action in the field of public health[5] identified eight policy areas necessitating particular attention and the development of specific programmes. As outlined in the 1994 report, proposals have been presented in the areas of the fight against cancer (Proposal for a European Parliament and Council Decision adopting an action plan 1996-2000 to combat cancer[6]), prevention of AIDS and other communicable diseases (Proposal for a European Parliament and Council Decision adopting a Community action programme on the prevention of AIDS and other communicable diseases[7]), prevention of drug dependence (Proposal for a European Parliament and Council Decision adopting a programme of Community action on the prevention of drug dependence[8]) and health promotion, information, education and training (Proposal for a European Parliament and Council Decision adopting a programme of Community action[9]).

10. On the programmes on cancer, AIDS and other communicable diseases, and health promotion, agreement was reached in the Conciliation Committee between Council and the European Parliament in December 1995 which led to the adoption of the relevant decisions in 1996. The Council adopted a Common Position on the Community action on drug dependence in December 1995[10].

11. In October 1995, the Commission adopted a Communication and Proposal for a Community action programme on health monitoring[11], which aims at developing a framework for the establishment of common health indicators among Member States and should establish a comparable basis for collecting and evaluating health data in the Community.

12. In addition to the 1994 report on the integration of health requirements in Community policies, the Commission adopted in July 1995 the first Report on the State of Health in the European Community[12], which gives an overview of health status in the Community, including a description of the main demographic trends and patterns of mortality and morbidity as well as the major determinants of health. The Commission intends to present annual health status reports, focusing on specific issues and population groups. At regular intervals, a general health status report will be produced.

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5 COM (93) 559 fin. of 24.11.1993

6 OJ C 139, 21.05.1994, p. 12, decision 646/96/EC of 29.03.1996, OJ L 95, 16.04.1996, p. 9

7 OJ C 333, 29.11.1994, p. 34, decision 647/96/EC of 29.03.1996, OJ L 95, 16.4.1996, p. 16

8 OJ C 257, 14.09.1994, p. 4

9 OJ C 252, 09.09.1994, p. 3, decision 645/96/EC of 29.03.1996, OJ L 95, 16.4.1996, p. 1

10 Common Position (EC) n° 1/96 adopted by the Council on 20.12.1995, OJ C 37, 09.02.1996, p. 1

11 COM (95) 449 fin. of 16.10.1995

12 COM (95) 357 fin. of 19.07.1995

13. In the context of its activities in the field of cancer prevention in 1995, the Commission supported the European Week against Cancer intended, notably, to promote the European Code against Cancer, a set of 10 simple but essential cancer prevention recommendations established by Europe's leading cancer experts.

During the week, a campaign aiming at the widest possible dissemination of the Code was carried out in all Member States, in close collaboration with organisations working in the field. The campaign was based on a common European concept and common supporting material (posters, leaflets, video spots, advertisements). 6.5 million information leaflets on the Code were distributed, and more than 250 million contacts were achieved through articles in the press and TV features as well as through (free) advertising space.

In parallel, a brochure on the Code was prepared geared to the particular information requirements of general practitioners, who play a vital role in raising their patients' awareness of the possibilities for cancer prevention; this brochure was mailed to all of Europe's 325 000 GPs and was widely welcomed.

Mental health

14. In 1995, the specific Community action providing exceptional financial support for Greece *inter alia* in the field of mental health from the European Social Funds was concluded. This was the first Community involvement in the field of mental health. The operations, involving 60 million ecus over eleven years, were designed to deal with the need to reform the Greek psychiatric care system through the development across the country of new structures and services aimed at the social and vocational rehabilitation of mentally ill and mentally handicapped persons and the improvement of care conditions for patients in public psychiatric hospitals. The impact of the programme has been significant. It led to the development of a structure for psychosocial rehabilitation services in Greece as well as a reduction in the size of the large psychiatric centres and hospitals and an improvement in the conditions found there[13].

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[13] cf. Final report, COM (95) 668 fin. of 15.12.1995

3. Integration of health requirements in Community policies

3.1 Social policy

15. Social and health policies are linked in many ways. Questions of employment and unemployment, labour laws, social protection systems and insurance, policy towards specific marginalised or vulnerable groups and regulations on health and safety at work all have broad repercussions on health.

The main orientation document for the Community's social policy is the Medium-Term Social Action Programme 1995-1997[14], which defines the creation of jobs and the fight against unemployment as the main priority of Community action.

A number of areas of social policy have a particular health dimension, i.e. the future of social protection, questions of solidarity and social exclusion, disability, questions of migration and of workers' mobility inside the Community, as well as the very concrete concerns on health and safety at work.

3.1.1 Social protection

16. In the debate on future orientations of social policy, social protection plays a central role. On 31 October 1995, the Commission adopted its Communication "The future of social protection - a framework for a European debate"[15], which identifies social protection as a fundamental component and a distinguishing feature of European societies. This is a contribution to the European debate on the future of social protection in the light of demographic changes as well as the economic and social challenges Europe is facing. An important factor in this debate is the future of health care systems, where the Community can help to exchange experiences on how to reconcile the objective of providing universal access to all necessary health care and prevention facilities with the need to contain rising costs.

Reforms in health care are also a specific topic in the report on social protection in Europe[16], which reports on the developments in this area in Member States.

3.1.2 European Social Fund

17. As outlined in the previous report, the European Social Fund supports projects both to encourage active measures in the labour market as well as to improve the general conditions for developing the full potential of participants in the labour market. Operations under Community Support Frameworks (CSFs) agreed with the Commission have started in the Member States. Results from the evaluation of these projects will be presented in later reports.

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14 COM (95) 134 fin. of 12.04.1995

15 COM (95) 466 fin. of 31.10.1995

16 Social protection in Europe, 1995

18. A first set of projects was selected for the Community Initiative "Employment" in December 1995 and will be carried out over the coming years. The Employment programme includes initiatives on the integration of people with disabilities (HORIZON) and people from excluded backgrounds (INCLUSION) into the labour market. In both initiatives, a number of projects selected involve a health dimension.

19. A certain amount of funds was set aside from general Social Fund financing to support innovative measures to achieve a more employment-intensive pattern of growth, to improve the workings of the labour market and to reinforce the training system. This includes specific measures for groups in danger of exclusion from the labour market. Of the more than 60 projects selected in 1995, four projects were particularly related to health, covering the integration of physically disabled people, health informatics and adapted workplaces for people with disabilities.

3.1.3 Solidarity - social exclusion

20. Health and social exclusion are inextricably linked. Poor health can be the cause of social exclusion (e.g. in the case in chronic sickness or invalidity leading to long-term unemployment, or in the case of the stigmatisation of a chronically ill or disabled person); it can be the consequence of social exclusion (e.g. depression, psychosomatic illness); it can be part of social exclusion (e.g. unhealthy housing, lack of running water, of accessible toilets, of a well-balanced diet, of access to quality health services), or it can be a factor preventing reintegration (e.g. depression, psychosomatic illness, lack of self-confidence if the person's physical health is weakened). Social exclusion may make access to health services more difficult.

21. The scheme of European funding for projects seeking to overcome social exclusion (1995) received some 2000 applications, many of which were concerned with different aspects of health. The aspects most frequently included were : drug and alcohol abuse, mental health and well-being (particularly of immigrants and refugees), disability (both mental and physical). Of the 86 projects finally adopted in December 1995, 15 concerned health, touching on the following areas: drug/alcohol addiction (8 projects), integration of sick and healthy people in housing development (2), help for women who have experienced violence (2), information about health services in immigrants' own languages (1), integration of prostitutes (2), integration of schizophrenics and their carers (1), improvement of mental health and well-being (1).

22. The European Initiative for the Prevention of Urban Delinquency and the Social Reintegration of Ex-Offenders (1995) included numerous health-related projects, in particular as regards drug abuse. Drug abuse is a health problem needing to be tackled among potential delinquents, and/or prisoners or ex-offenders. But it is also in many cases a crime itself, and often a major cause of further crime.

3.1.4 Free movement of workers

23. On 28 June 1995, the Commission submitted a proposal for a Council Regulation amending Regulation (EEC) 1408/71[17]. In particular, this proposal provides that the entitlement to urgently needed health care of a person who is insured in one Member State and temporarily resident in another be extended to all persons regardless of their nationality.

3.1.5 People with disabilities

24. As in health matters, policies concerning disabled people are tending increasingly to move away from strictly medical considerations towards the area of social welfare. While it is still important to look at how disabilities develop and at ways of preventing them, it is now essential to have a better understanding of their social effects. In this connection, we are now seeing the emergence of a new approach based on the need to take action directed not only at disabled individuals but also at the environment in which they live.

The third Community Action Programme to assist disabled people (HELIOS II)[18], covering the period January 1993-December 1996, is in line with this approach in that it develops exchanges and disseminates information at Community level so as to promote equality of opportunity for the disabled. Activities taking place under the programme in 1995 mainly concerned the following areas: anti-discrimination measures, raising public awareness, independent living, the creation of suitable jobs, and the role of NGOs.

3.1.6 Health and safety at work

25. The Communication from the Commission on a Community programme concerning safety, hygiene and health at work (1996-2000) was adopted on 12 July 1995[19], and included a proposal for a Council decision adopting a programme of non-legislative measures to improve health and safety at work.

The Commission intends that this programme should provide a sufficiently flexible, dynamic and realistic framework to enable the Community to meet the challenges posed by the profound economic, technological and social changes that are occurring. It includes non-legislative measures, a legislative programme and provisions concerning health and safety in other policies. As part of the programme the Commission has included SAFE (Safety Action for Europe), aimed at improving safety, hygiene and health at work especially in small and medium-sized enterprises.

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17 Amended proposal for a Council Regulation of 28.06.1995, OJ C 242 of 19.09.1995

18 Council Decision of 25.02.1993 establishing a third Community Action programme to promote equal opportunities and the integration of disabled people (HELIOS II), 93/136/EEC, OJ C 56, 09.03.1993, p. 30

19 COM(95) 282 final of 12.07.1995

The proposed decision of the Commission deals with the development of non-legislative measures such as guidance notes and information, education and training material and the SAFE programme.

26. In setting Occupational Exposure Limits (OELs) for the control of exposure to chemical substances the aim is to identify a level of exposure at which, according to the most up-to-date knowledge, the exposed worker's health should not be affected.

To further support the work of developing harmonized OELs, the Commission Decision on setting up a Scientific Committee for Occupational Exposure Limits to Chemical Agents (SCOEL)[20] established a formal basis for the scientific evaluation of the risk at the workplace related to chemical substances. By giving the Committee a formal basis, the European Commission has acknowledged the work already performed and significantly advanced its role in the European process, contributing to the global aim on the harmonisation of conditions in the working environment as specified by Article 118a of the European Community Treaty.

27. In September 1995 the Commission presented a proposal for a Council Directive amending for the first time Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work.[21] The main purpose of this proposal is to set limit values for occupational exposure to carcinogens, starting with benzene.

28. On 29 June 1995[22] the Council adopted a Regulation which amended the Regulation establishing a European Agency for Safety and Health at Work, located in Bilbao. The Agency's main tasks will be to collect and disseminate technical, economic and scientific information on health and safety at work and to promote and support exchanges of information and experience between Member States.

The Agency became operational in 1995. Two meetings of its Administrative Board were held. The recruitment of staff began with the publication of the Call for Applications for the post of Director[23].

29. In July 1995, the Commission decided to officially set up the Committee of Senior Labour Inspectors (SLIC)[24], which has existed informally since 1982. In 1995, the Committee discussed *inter alia* issues of free movement of workers, services and enterprises engaged in health and safety, and informatics support for labour inspectorates. SLIC has agreed on common principles of labour inspection. A process of evaluation of national systems was launched on the basis of these principles. Observers from Central and Eastern European countries and the Baltic States participated in parts of the Committee meetings.

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20 Commission Decision 95/320/EC of 12.07.1995 - O.J. N° L 188, 9.8.1995

21 O.J. N° C 317, 28.11.1995

22 Council Regulation N° 1643/95, OJ N° L 156, 07.07.1995, p.1

23 OJ N° C 338, 16.12.1995

24 Commission Decision 95/319/EC of 12.07.1995, OJ L 188/11, 09.08.1995

Drugs

1. Actions to combat drug dependence focus on reducing the supply of drugs (through measures such as police cooperation and border controls and incentives to producers to grow alternative crops) and on addressing the problems of drug users (through health and social support measures). Both approaches are prominent in the Community actions in the drugs sector, and are combined in the Community Action plan to combat drugs (1995-99)[25].

2. The reduction of drug dependence is a priority area for Community activities in the field of *public health* and is specifically mentioned in Article 129 of the Treaty. A corresponding Community action programme is currently under discussion. This is supplemented by high profile events, such as European Weeks against Drug Dependence.

   Social policy actions aimed at marginalised groups in society also reinforce preventive and support activities concerning potential and actual drug users.

   These actions are supplemented by other activities, e.g. *research, education and training* activities (particularly aimed at young people). Another important area is *medicinal products,* where issues of dependence are raised.

3. Drug supply reduction and activities preventing drug trafficking often extend beyond the territory of the Community and are therefore conducted in cooperation with third countries and international organisations. These issues are covered in several programmes of cooperation with third countries, e.g. Tacis/ Phare and the Lomé convention.

   Internally, drug supply reduction is a major topic in the area of cooperation between Member States in judicial and home affairs, particularly concerning police cooperation. Implementation of the first phase of EUROPOL also covers this topic.

   The Community is supporting relevant activities by the United Nations, its agencies and other international organisations.

   See the relevant sections of this report for further information on 1995 activities in these areas of policy.

3.2 Internal market - free movement of persons and goods, taxation

30. Community activities regarding the creation of the internal market have numerous consequences for health. These include the development of common rules and regulations concerning the markets for specific products, e.g. pharmaceuticals or medical devices, as well as the rules on free movement of goods as such. A

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25 COM (94) 234 fin.

specific area of activity - under the auspices of consumer protection - is the field of cosmetics. Indirect taxation of goods such as tobacco or alcohol can have immediate health effects. An important requisite enabling the free movement of persons is the recognition of diplomas, e.g. in medical professions. Finally, data protection is an area of Community policy where health-related concerns - both of the citizen interested in protecting his/her medical and other data and the medical researcher - need to be taken into account.

3.2.1 Medicinal products

31. Starting with the first directive in 1965, Community legislation on pharmaceuticals has usually been designed to promote and protect public health. By 1993 there was a harmonised legal framework for marketing authorisations. Under the rules, every medicinal product must meet strict quality, safety and efficacy criteria before it can be authorised. This legislation covers all industrially-manufactured medicinal products: vaccines, blood products, radiopharmaceuticals. The criteria are regularly revised to take account of scientific and technical progress.

1995 saw the introduction of the new European system for authorising and monitoring medicinal products in the European Community. Under this new system the Commission has already authorised the marketing of three innovative products.

This new system for registering medicinal products in the European Community represents a decisive step towards the establishment of the Single Market. It helps to promote the free movement of medicines within the European Community while ensuring optimum protection for public health.

32. The main innovation in this area in 1995 was the establishment of the European Medicines Evaluation Agency (EMEA) in London, whose aim is to encourage cooperation between, and coordinate the resources of, national drug registration agencies.

There are now two licensing procedures for medicinal products: a centralised procedure, which is compulsory for high-technology products and optional for innovatory new medicines, and a decentralised procedure that is based on the principle of mutual recognition of national authorisations. Under the latter procedure, the Agency intervenes if there are conflicting scientific evaluations by national authorities when application is made for mutual recognition of authorisations.

Once the evaluation process has been completed, the European Commission is responsible for making the scientific opinions binding (for human and veterinary uses).

This new system provides all patients in the European Community with more rapid, and simultaneous, access to innovatory medicines. When an authorisation is issued, health professionals and consumers are provided with clear and reliable information in the form of labels and package leaflets. In addition, the monitoring of medicinal products after their authorisation is being improved through coordination by the Agency of national pharmacovigilance activities.

By coordinating national resources devoted to drugs registration, this system helps to ensure that the quality, safety and efficacy of medicines which are to be marketed in the European Community or exported to third countries are of an optimum standard.

Finally, this system coincides with the emergence of the European Community onto the international scene. It provides third countries with a public health guarantee for evaluations carried out in the Community and strengthens the latter's position vis-à-vis these countries.

33. In 1995, the institutions discussed the Communication from the Commission to the Council and the European Parliament on the outlines of an industrial policy for the pharmaceutical sector in the European Community[26]. Although in other areas the Commission advocates a global approach to industrial policy, a sectoral approach seemed appropriate in this particular area given the public health and social policy issues that it raises. In its communication, the Commission proposes a set of guidelines reconciling effective control of health care expenditure with continuation of the long-term efforts by the European pharmaceutical industry to develop therapeutically innovative medicines. However, it is the Council which should take the lead here since most of the subjects discussed in the Commission's communication lie within the competence of the Member States.

34. The Commission has launched an information society programme for the pharmaceutical sector to encourage transparency and the rapid exchange of information. This is particularly important as regards pharmacovigilance. The databases to which the network will give access will include scientific and economic information on all medicines sold on the Community market.

3.2.2 Medical devices

35. Community legislation on medical devices removes technical barriers to trade, thus enabling the single market to be brought about in this particular sector. It is also designed to ensure a high level of safety and health in the Community and, for this purpose, introduces a coherent approach to the establishment and implementation of requirements for the design, manufacture and marketing of such devices. The gains in terms of protection of public health are real and quite considerable.

36. 1 January 1995 saw the compulsory application - following the end of the transition period - of Council Directive 90/385/EEC on active implantable medical devices. It also marked the optional application - at the beginning of the transition period - of Council Directive 93/42/EEC, which covers all other medical devices (except those used for *in vitro* diagnosis). During 1995, the Commission's efforts aimed at implementing these two directives had a positive effect as regards the protection of public health. Its activities included:

- consultations with authorities in the Member States which are responsible for implementing the two directives;

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26 COM (93) 718 fin. of 02.03.1994

- coordination and monitoring of the activities of the certification bodies concerned (notified bodies) to ensure that the latter adopt a uniform, consistent approach[27]
- monitoring performance of the tasks assigned to international standardisation organisations (CEN and CENELEC). In this connection, the titles and references of important "horizontal" standards have been published in the OJ, giving them the status of European harmonised standards[28]
- encouraging and coordinating work to set up a Community monitoring system so as to avoid the occurrence and/or recurrence of events with negative repercussions on public health; in 1995, the issuing of public warnings concerning certain types of devices and the use of the safeguard clause by certain Member states, as provided for in the directives, showed how valuable and important the concept of Community monitoring is in an area as sensitive as that of health.

37. Finally, mention should be made of the Commission's proposal for a directive on *in vitro* diagnostic medical devices[29], which completes the set of directives covering all medical devices. This proposal has received a favourable opinion from the Economic and Social Committee. It is currently undergoing the initial consultation procedure at the Parliament and will be discussed by the Council's Working Party on Economic Questions at the beginning of 1996.

3.2.3 Consumer protection - cosmetics

38. In July 1995, the Commission adopted the 18th Directive adapting to technical progress the annexes of the basic directive on cosmetic products[30]. These annexes contain lists of substances which must not form part of the composition of cosmetic products, substances which cosmetic products can contain only subject to restrictions or special conditions, and substances which cosmetic products may contain (UV-filters, preservatives and colouring agents). Before being added to one of these lists, the safety of the substance for human health is assessed by the Scientific Committee on Cosmetology, which gives an opinion. The Commission takes this opinion into account when preparing its draft proposal, which is subsequently submitted to the Committee for Adaptation to Technical Progress. In July 1995, the Commission adopted a 6th Directive on methods of analysis for checking the composition of cosmetic products[31].

39. The Commission has adopted a directive establishing the criteria and conditions under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients in the list of ingredients to be indicated on the packaging of cosmetic products[32]. These criteria take into account the safety of the consumer as well as the justified commercial interests of the manufacturer.

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27 OJ C 280/12 of 25.10.1995

28 OJ C 277/6 of 4.10.1994, C 204/22 of 9.8.1995, C 307/14 of 18.11.1995

29 OJ C 172/21 of 7.7.1995, p. 21

30 Commission Directive 95/34/EC of 10.07.1995, OJ L 167 of 18.07.1995, p. 19

31 Directive 95/32/EC of 07.07.1995, OJ L 178, 28.07.1995, p. 20

32 Directive 95/17/EC of 19.06.1995, OJ L 140, 23.06.1995, p. 26

40. The Commission is currently finalising an inventory of ingredients employed in cosmetic products and a common nomenclature of these ingredients. These are linked with the full labelling of ingredients in cosmetic products required after January 1997. The idea is to enable the consumer to identify substances he should avoid, e.g. because of personal allergy, when buying a cosmetic product.

3.2.4 Taxation

41. Fiscal policy concerning the indirect taxation of goods has an effect on the price of goods such as tobacco, alcoholic beverages and petrol. On 13 September 1995, the Commission adopted a report on the approximation of excise duties[33]. In this report, the Commission clearly demonstrates how fiscal policy has to take into account the general objectives of the Treaty, including health protection requirements as well as environmental questions.

Regarding the consumption of tobacco products, the report underlines that fiscal measures represent a means of dissuasion. The revenue generated could contribute towards compensation for the "social cost" of smoking, i.e. health care costs and costs of scientific research. On alcohol and alcoholic beverages, from a social and health policy point of view, taxation could be a means of discouraging excessive consumption. It could contribute to reduce the problems associated with the abuse of alcohol.

3.2.5 Jurisdiction on free movement of goods

42. Protecting public health is one of the legitimate objectives recognised by the Treaty as justifying, where necessary and appropriate, measures that do not accord with one of the basic principles of the internal market, i.e. the free movement of goods. It is, in fact, often invoked by Member States to justify the adoption of national regulations laying down technical specifications that affect the free movement of goods within the single market.

43. In 1995, the Court of Justice delivered two judgments regarding the application of the rules on free movement in the light of health protection requirements.

In its judgment of 23.02.1995[34], the Court ruled that Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin does not preclude national legislation - in this instance, Italian regulations - from setting maximum permissible levels for residues of Chlorpropham and Propham and providing for procedures for checking compliance with those levels, on condition that such provisions do not contravene Articles 30 and 36 of the Treaty.

In its judgment of 28.03.1995[35], the Court held that a national practice - in this instance, a British one - of prohibiting importation of narcotic drugs (diamorphine, in this particular case) is covered by Article 30 of the Treaty. Moreover, an import

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[33] COM (95) 285 fin. of 13.09.1995

[34] Judgment of 23.02.1995, Joined Cases C-54/94 and C-74/94, [1995] ECR I - 391

[35] Judgment of 28.03.1995, Case C-324/93, [1995] ECR I - 563

ban would not be admissible under Article 36 if it were based on the need to safeguard an undertaking's survival. On the other hand, such a ban may benefit from the derogation provided for in Article 36 of the EEC Treaty if protection of the health and life of humans is at issue and this objective cannot be achieved as effectively by measures less restrictive of intra-Community trade.

3.2.6 Free movement of persons
Recognition of diplomas in health professions

44. Health protection has always been an important consideration when it comes to the mutual recognition of diplomas in the health professions (doctors, nurses, midwives, pharmacists, dentists and veterinarians, in particular). The directives concerning these diplomas are based on the free-movement articles of the Treaty, 49, 54 and 63, and aim to facilitate the free movement of professionals trained in the Community in accordance with comparable standards of training. These standards are being harmonised by drawing up common minimum requirements.

In addition, advisory committees on the training of these professionals, set up to support the directives, help to ensure comparably high skill levels by issuing opinions and recommendation on training matters.

In so doing, they also contribute to the framing of health policies in the Community.

45. Finally, the Committee of Senior Officials on Public Health, consisting of senior officials from the Member States with direct responsibilities in the public health field, has the task *inter alia* of gathering any useful information on arrangements for providing medical and general care in the Member States and of issuing opinions that help to guide the Commission's work as far as doctors, dentists, nurses and midwives are concerned. For pharmacists and veterinaries, this task is assured by two specific bodies. A proposal for a directive submitted by the Commission to the European Parliament and the Council on 16 December 1994 is designed to enable this committee to assist the Commission by means of a special committee procedure with a view to amending the lists of medical specialisations and the length of the corresponding training courses set out in Directive 93/16/EEC on facilitating the free movement of doctors. The Commission has presented a modified proposal of the directive following the opinion of Parliament[36].

[36] 27.11.1995, JOC C 28, 01.02.1996

3.2.7 Data protection

46. 1995 saw the final adoption of the European Parliament and Council directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data[37]. The text establishes a framework of general principles for the processing of data relating to individuals, and will apply generally to all data processing covered by Community law, including that in the health sector.

The needs of public health are recognised specifically in the text in a number of places, most notably in a recital which cites public health as an area where an exemption to the prohibition on the processing of certain sensitive categories of data may be granted on grounds of important public interest.

The overall effect of the directive, which Member States have 3 years to transpose into national law, will be to harmonise data protection legislation so that personal data may move freely within the European Community on the basis of a shared framework of rules. In the public health field this will facilitate data processing which involves bringing together personal data from a number of different Member States. Epidemiology and clinical trials are two areas which are likely to be particularly affected in this regard.

3.2.8 Education and training - KAROLUS

47. The KAROLUS Programme is a scheme for training officials from the Member States through the exchange of national officials between Member State administrations. Its purpose is to facilitate cooperation, and promote mutual confidence, between national administrations, and to ensure a uniform and proper application of Community legislation on the internal market. Among the sectors covered by the exchange programme are some with a direct or indirect bearing on health, such as medicinal products, foodstuffs, product safety, etc.

3.3 Agricultural and foods policy, fisheries

48. The links between the quality of food and health are obvious. Therefore, the different aspects of agricultural, fisheries and foodstuffs policies are crucial areas where health requirements need to be integrated into Community policy. It is impossible to give a complete overview of all day-to-day activities of the Commission in this field. In this section, major developments in 1995 concerning the veterinary sector, pesticides, tobacco, wine and alcohol, foodstuffs, milk, and the fisheries sector will be presented.

[37] EP and Council Directive 95/46/CE of 24.10.1995, OJ L 281 of 23.11.1995

3.3.1 Veterinary sector

49. A series of decisions were taken during 1995 by the Council and the Commission, developing legislation on health and hygiene, concerning animals and products of animal origin.

50. In June, the Council adopted a directive amending Directive 64/433/EEC concerning health conditions for the production and marketing of fresh meat[38]. It also adopted a series of decisions concerning tests for salmonella in certain animals and animal products destined for Finland and Sweden[39].

The Commission adopted a number of proposals for presentation to the Council including in particular a proposal on the marketing of meat products[40] and a proposal for a Council directive amending Directive 92/117/EEC concerning measures for protection against certain zoonoses (diseases transmissible between animals and man, such as rabies)[41].

51. The Commission took many decisions to establish common health requirements to be applied to the import of animals and products of animal origin from third countries.

In addition, it was necessary to take a number of emergency safeguard measures to limit imports of products from certain third countries where the health situation was considered unsatisfactory. The import of fish from Japan was restricted after an inspection revealed serious deficiencies in inspections and controls of products to be exported to the European Community[42]. A Commission decision based on a report from the Scientific Veterinary Committee authorised special heat treatment to decontaminate bivalve molluscs in southern Spain containing low levels of the PSP toxin. This decision applies only to Spain and is limited to a particular species. Its purpose is ensure that this type of product is safe for human consumption. Following the outbreak of Ebola disease in Zaïre, the Commission banned the importation of apes originating in or coming from Zaïre[43]. Both these decisions form part of the measures to protect human and animal health in the Community.

52. The veterinary and phytosanitary office continued its programme of inspections within the Community and in third countries to monitor the application of and compliance with Community health rules in the veterinary sector. Apart from the fresh meat and meat products sector, checks were also initiated in the poultrymeat and fish and fishery products sector. In addition, special visits were also made in

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38 Directive 95/23/EC, OJ L 243, 11.10.1995, p.7

39 Directives 95/409 to 411/EC, OJ L 243, 11.10.1995, pp. 21, 25, 29

40 OJ C 269, 16.10.199

41 COM (95) 491 fin. of 23.10.1995

42 95/119/EC of 07.04.1995

43 Decisions 95/171/EC of 18.05.1995, OJ L 112 of 19.05.1995, p. 30, and 95/313/EC of 24.07.1995, OJ L 187, 08.08.1995, p. 23

Member States and third countries in case of outbreaks of certain diseases to study the epidemiology and check the health controls applied.

53. From 30 November to 1 December 1995, the Commission organised a major scientific conference on growth promotion in meat production. The conference came to the conclusion that the accumulation of experiences and published data on the use of natural and sex hormones and related compounds (Zeranol and Trenbolene) has shown no evidence of human health risk arising from their use, when used under prescribed conditions. Further scrutiny is required to evaluate effects on animal health. Substantial concerns about the potential risk for human and animal health remain concerning the possible use of beta-2-antagonists as growth promoters. The conference concluded in addition that the illicit use of a variety of growth promoters has become a serious problem. It saw therefore a need for coordinating national control systems, to target surveillance systems more effectively, and to enhance the efficacy of detection systems and methods.

3.3.2 Pesticide residues

54. In 1995, as part of the ongoing harmonisation of maximum levels of pesticide residues in and on certain products of plant or animal origin, the Council adopted three directives harmonising maximum residue levels for nine pesticide active substances and amending existing maximum residue levels for some 20 pesticide active substances[44]

3.3.3 Tobacco

55. The Community fund for tobacco research and information decided to fund a number of projects, to commence in March 1996, both on informing the public about the health effects of tobacco and on agricultural research aimed at reducing the harm caused by tobacco[45].

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[44] Council directives 95/38/EC, OJ L 197, 22.08.1995, p. 14; 95/39/EC, OJ L 197, 22.08.1995, p. 29. 95/61/EC, OJ L 292, 07.12.1995, p. 27

[45] cf. call for tenders published in OJ C 179/8 of 01.07.1994

Tobacco and alcohol

1. Tobacco and alcohol abuse are among the major determinants for important health scourges such as cancer and cardio-vascular diseases. In addition, excessive consumption of alcohol is a major factor in accidents, be it on the road, in the workplace or at home. Several areas of Community policy address tobacco and alcohol issues.

2. In *public health,* there is a strong focus on the need to stop smoking and moderate alcohol consumption in the context of activities to combat cancer. Alcohol and tobacco were two major focuses of European Cancer Week in October 1995.

   Specific *social policy* actions aim at improving the situation of excluded and disadvantaged groups in society. This may involve victims of severe alcohol abuse.

3. *Community agricultural policy* covers tobacco, which is as an important agricultural product of southern Member States. It has taken steps to encourage the production of less harmful products, e.g. tobacco yielding low levels of nicotine. The Community funds for tobacco research and information will become operational in 1996 to support research and public awareness campaigns in this area.

   The production of alcoholic beverages also involves agricultural products (grapes, hops, malt, etc.), and common market regulations exist for hops, wine and spirits.

4. *Fiscal policy*, particularly concerning indirect taxation, has a major effect on the pricing of tobacco and alcohol products and on choices made by consumers. While indirect taxation levels have not been harmonised at the EC level, there is an awareness that tax revenues from the sale of alcohol and tobacco could provide important resources for preventive activities.

5. Alcohol and driving is a major concern for *transport policy* in the context of road safety campaigns.

   See the relevant sections in this report for more details on policy developments in these sectors in 1995.

3.3.4 Foodstuffs

56. In the area of foodstuffs legislation, the Commission adopted a directive amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs[46].

57. The Commission also adopted the updated inventory of scientific cooperation tasks on questions related to food[47]. Scientific cooperation provides a mechanism allowing the Member States to assist the Commission with the scientific examination of questions related to food. Many of the tasks undertaken relate to subjects of direct relevance to public health.

The Scientific Committee for Food delivered a substantial number of opinions relating to food safety covering additives, contaminants, materials and articles in contact with foods and adverse reactions to food and food ingredients. Their opinions and reports will serve as the basis for future legislative initiatives of the Commission.

3.3.5 Milk promotion campaigns

58. Under the EC's school milk scheme, subsidies are provided so that schoolchildren can receive certain milk products at reduced prices. Although the prime objective of this programme is to promote the consumption of milk products, its contribution to achieving a balanced diet for schoolchildren has proved to be equally important. In recent years, Member States have been encouraged to supply suitable nutritional information on milk and milk products in schools, in order to enhance the efficiency of the school milk scheme.

The range of milk products eligible for subsidy is sufficiently wide to comply with the need for a varied and balanced diet in different circumstances. Within this range, there is a clear trend towards those products with a reduced fat content. In the school year 1988/89, whole milk products still accounted for some 77% of the total quantity distributed ; for the 1994/95 period, this figure was reduced to less than 65%.

3.3.6 Fisheries

59. There is a general consensus that the consumption of fish contributes to the prevention of cardio-vascular diseases. Accordingly, the Commission has continued its efforts to promote the consumption of fisheries products and to improve the quality of products sold to the public.

60. After the merging (in late 1993) of all the structural financial tools in a unique financial instrument for fisheries guidance (FIFG), the Community action in

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[46] Directive 95/3/EC of 14.02.1995, OJ L 41, 23.02.1995, p. 44

[47] Commission decision amending Decision 94/652/EC establishing the inventory and distribution of tasks to be undertaken within the framework of cooperation by Member States in the scientific examination of questions related to food (95/492/EC of 15.11.1995)

supporting these measures is carried out in the framework of the Structural Funds reform, i.e. in integrated, coherent structural development plans covering the period 1994-99, established in partnership between the Commission and Member States, and implemented at local level. The new financial instrument has special provisions for the promotion of consumption, including operations associated with quality certification, promotion campaigns based on quality, and studies. Moreover, all physical investment intended to improve conditions of hygiene or human or animal health and to improve quality is eligible for aid in the sectors of aquaculture, fish processing and marketing of fisheries products.

The total FIFG budget allocated to national plans for the period 1994-99 is 2 671 million ecus. Of this, 84 million is allocated to promotion and 859 million to aquaculture, processing and marketing (this sum includes financing for measures not directly linked to health requirements).

The FIFG also finances studies on an annual basis; in the period 1994-95, six studies directly relating to quality or health matters were financed, with a Community contribution in excess of 530 000 ecus.

3.4 Research and development

61. Research and development activities in the European Community take place in the context of Framework Programmes for research and technological development (RTD). The 4th Framework Programme[48], which currently is the basis of RTD activities, encompasses a number of specific RTD programmes which are either health-related or include projects with a health dimension.

3.4.1 BIOMED

62. Health-related research and development activities take place mainly within the Biomedicine and Health Programme (1994-1998 - BIOMED 2) within the 4th RTD Framework Programme[49]. With a total budget of 336 million ecus, it covers the following eight target areas:

Area 1: Pharmaceuticals research;
Area 2: Research on biomedical technology and engineering;
Area 3: Brain research;
Area 4: Research on other diseases with a major socio-economic impact;
Area 5: Human genome research;
Area 6: Public health research, including health services research;
Area 7: Research on biomedical ethics;
Area 8: Ethical, legal and social aspects.

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[48] Decision 94/1110/EC of 26.04.1994, OJ L 126, 18.05.1994, p. 1, as amended by Decision 96/616/EC of 25.03.1996, OJ L 86, 04.04.1996, p. 69

[49] Council decision 94/913/EC of 15.12.1994 adopting a specific programme of research and technological development, including demonstration, in the field of biomedicine and health (1994-1998), OJ L 361, 31.12.1994, p.40

63. A first call for proposals was launched in January 1995 with all thematic areas of the work programme open to submission of research proposals. After scientific and technical evaluation by independent experts, 307 out of 1709 proposals have been selected for Community support with a financial contribution totalling 153.7 million ecus.

The selected proposals, notably in the fields of AIDS, cancer, occupational health research and in particular public health research, are expected to underpin the public health initiatives in the context of Article 129 of the Treaty.

Likewise, the BIOMED 2 programme will be supporting demonstration projects in order to prove the techno-economic viability of new medical practices (e.g. *ex vivo* AIDS treatment, restoration of movement of paraplegic patients by electrical stimulation) and to disseminate these practices to users, industry, public entities and other targeted interest groupings.

64. Vaccination is widely recognised as one of the most efficient tools of public health policy showing evident cost-benefit advantages for all the target populations involved.

With more than 5 million patients in western Europe, hepatitis C is the most important chronic viral infection in the region. Development of a vaccine for hepatitis C is extremely complicated because of the lack of knowledge regarding immunological parameters, and can be accomplished only through a collaborative effort of multidisciplinary approaches involving several laboratories. The BIOMED 2 programme is currently supporting a project for developing a vaccine in which laboratories from five countries are participating.

It now appears feasible to develop cancer vaccines that induce cancer rejection responses and stimulate the immune system to produce antibodies against cancer cells. The BIOMED 2 programme is supporting a transnational project involving seven leading laboratories, the main aim of which is to identify antigens recognised by T-lymphocytes on human tumours.

A number of research teams are devoting their efforts to develop vaccines against chronic diseases by the development of highly immunogenic recombinant/peptide vaccines and generation of new adjuvants.

The Task Force on Vaccines and Viral Diseases which has been established aims at strengthening the European effort on vaccine development by fostering partnership and cooperation in research and transposing the latest scientific advances.

65. Research on the human genome - the genetic material contained in every cell in the human body - aims at determining the structure of human DNA and the identification and function of all the genes. The rationale for coordinated European activities related to human genome research is based on its potential contribution to the understanding of the processes underlying human disease, hence to improve diagnostics, treatment and eventually disease prevention. This objective is met through the improvement of research infrastructure, availability

of resources and cooperation of leading research groups in Europe in order to put Europe on the map of the international human genome programme.

Particular progress was achieved through EUROGEM, the European Gene Mapping Project, which includes 23 laboratories. This network enabled European researchers from all Member States, in particular those without national programmes, to organise human genome research at a European level and to come up with a European Genetic Map based on the CEPH reference families. At the international level, the work on chromosomes 11 and 21 has been particularly successful.

Thanks to a European initiative there are the so-called "Single Chromosome Workshops" for exchange of information and data and reaching agreement on nomenclature with regard to progress in the study of individual chromosomes. The EC pays for the European organisers and participants; the U.S. (DOE and NIH) eventually agreed to follow the scheme and pay for the U.S. participants or organisers. These workshops turned out to be extremely valuable in the development of scientific collaboration and the establishment of research policies in this field.

66. From a broader health perspective, a meeting was held in 1995 under the auspices of the BIOMED programme in Delft/NL on "Individual responsibility for health - moral issues regarding lifestyle and a just distribution of medical resources", bringing together experts from different Member States in the fields of public health, sociology and ethics.

3.4.2 Telematics

67. Another area of RTD activities with an important health dimension is telematics. The telematics applications programme[50] includes specific activities on health care telematics as well as for the disabled and the elderly among the 15 sectors in the programme. It has an overall budget of 843 million ecus for 1994 to 1998. Health care telematics has an indicative budget of 135 million ecus, while the sector concerning the disabled and elderly has an indicative budget of 65 million ecus.

68. Most of the 42 health telematics RTD projects initiated during the 3rd Framework Programme came to an end in 1995. Seventy new projects with a total Community contribution of 77 million ecus were negotiated in 1995 under the 4th framework programme budget. As in other sectors of the telematics application programme, stress is now put on actual validation of applications by "user groups" in order to have effective up-take and deployment of results once the programme has been completed.

Some of the fields covered by the programme are: development and inter-operation of regional networks for a better integration and continuity of care, cooperation of professionals in areas important for public health such as cancer,

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[50] Council Decision 94/801/EC of 23.11.1994, adopting a specific programme of research and technological development, including demonstration in the field of telematics applications of common interest, OJ L 334 of 22.11.1994, p.1

cardio-vascular diseases and chronic illnesses. Inter-operability of telematics services on a European scale is also covered, for example concerning emergencies. In all cases, the objective is to increase the efficiency of the natural circulation of information in the health sector, improving access while maintaining security and strict confidentiality. Management of feasibility studies in support of national policies and of other Community policies is also a significant part of the activities.

3.4.3 G-7 Global Information Society Initiative

69. In February 1995, the G7 group of major industrialised nations launched a "Global Information Society" initiative in Brussels. Among the 11 projects included in this initiative, the project on Global Healthcare Applications consists of six sub-projects:

1. Towards a Global Public Health Network
2. Improving prevention, early detection, diagnosis and treatment of cancer
3. Improving prevention, diagnosis and treatment of cardiovascular diseases
4. A 24 hour multilingual telemedicine surveillance and emergency service around the world
5. Enabling mechanisms for global health networks
6. International harmonisation of the use of data cards in health care.

A global healthcare project meeting in Ottawa/Canada in November 1995 launched a number of European feasibility studies in preparation for these initiatives.

3.4.4 Targeted socio-economic research

70. The programme on targeted socio-economic research is divided into three main areas: research into science and technology options in Europe, research on education and training, and research on social integration and social exclusion in Europe[51]. A number of projects funded under these headings - particularly in the third area of action - are related to health.

3.4.5 Research on agriculture, fisheries and agro-industrial processing

71. The work programme of the FAIR (food and agro-industrial research) programme for 1994-1998, which is the specific RTD programme for agriculture and fisheries[52], includes a number of references to health issues. The section on agricultural environmental interaction also foresees health-related research, such as minimising the passage of agrochemicals into the water table and thence to

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[51] Council decision 94/915/EC of 15.12.1994 adopting a specific programme of research and technological development, including demonstration, in the field of targeted socio-economic research (1994-1998), OJ L 361 of 31.12.1994, p.77

[52] Council Decision 94/805/EC of 23.11.1994 adopting a specific programme of research and technological development and demonstration in the field of agriculture and fisheries...(1994-1998), OJ L 334 of 22.11.1994, p. 73

human drinking-water supply. A large part of the programme is dedicated to the role of food in consumer nutrition and well-being.

In addition, four research projects in the field of fisheries products upgrading, which have connections to human health requirements, have been financed in 1995. The Community contribution to these projects exceeded two million ecus.

3.4.6 Transport research

72. The Specific Programme for research and technological development in the field of Transport within the 4th Framework Programme[53] continues to address safety issues in all modes of transport. From an extensive list of tasks, the following safety issues are particularly noteworthy: 'the safety aspects of human management' (rail), 'passenger survivability' (air), 'methodology of safety in maritime operations', and 'traffic management and vessel traffic system' (waterborne) as well as 'improvements in passive vehicle safety' and 'driver behaviour' (road).

3.4.7 Environment and climate

73. The Environment and climate programme (1994-1998)[54] has a total budget of 532 million ecus and covers four themes:

1. Research into the natural environment, environmental quality and global change,
2. Environmental technologies,
3. Space technologies applied to environmental monitoring and research,
4. Human dimensions of environmental change.

A first call for proposals was launched for themes 1, 2 and 4 in January 1995 and after scientific and technical evaluation by independent experts, 315 out of 1601 proposals were selected for Community support with a Community financial contribution totalling 216 million ecus. 18 of 88 health-related proposals were retained with a Community financial support of 12 million ecus. These projects complemented the 46 health-related projects financed in the preceding ENVIRONMENT Programme which were still running in 1995.

Health-related research underpins the environmental health policies of the Community and is consistent with the conclusions of the Intergovernmental Conference on Chemical Safety (Stockholm, April 1994) and the Declaration of the Ministers of Health and the Environment (Helsinki, June 1994).

74. The main research priorities are to assess the impact of environmental factors (e.g. ozone depletion, air quality pollutants) on the health status of populations

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[53] Council Decision 94/914/EC of 15.12.1994 adopting a specific programme for research and technological development, including demonstration in the field of transport (1994 to 1998), OJ L 361, 31.12.1994, p. 56

[54] Council Decision 94/911/EC of 15.12.1994 adopting a specific programme of research and technological development in field of environment and climate (1994-1998), OJ L 361 of 31.12.1994, p. 1

(neurological, immunological, genotoxic, endocrine-disrupting effects, etc.) and to improve risk management of chemical substances by developing more efficent testing methods (with an emphasis on reducing the number of animals required for testing), by critically appraising the risk assessment process itself, by developing new methodologies for hazard identification and exposure assessment and by identifying vulnerable or susceptible groups in the population. The research is implemented in close cooperation with international organisations in the field. More than 200 European laboratories are currently involved.

3.4.8 Industrial and Material Technologies

75. Concerning the production technologies area, the Industrial and Material Technologies Programme[55] deals with the development of clean production technologies emphasizing the efficent use of material and energy ressources, and reduction or elimination of polluting wastes at their source. Reduction of emissions is also a high priority within research related to transport means. Specific attention is given to the health of the workforce employed in the manufacturing industries by developing safe and reliable production systems and paying attention to human and organisational factors.

76. The research area on Materials and technologies for product innovation contributes on a more long term scale to health, as it deals with basic research in materials (e.g. surface behaviour, biocompability and strength of materials for implants), development of special coatings (e.g. for targeted drug release and dental or orthepeadic applications), research on medical devices and instruments for diagnosis. The result will produce new applications and new methods (diagnosis and treatment) for medicine.

77. A third area of the programme covers technologies for means of transport, including all aspects of design, integration, production, efficency, environment, safety and operation of the transport vehicle, be it an aircraft or any form of surface vehicle. The aim of projects selected is to contribute to reduce the environmental impact of production systems, products and means of transport and to improve the safety of products and vehicles. This includes the reduction of noise and pollutant emission from engines as well as primary vehicle safety technologies - accident prevention - and secondary safety - the mitigation of effects of accidents. Other projects aim to prevent contamination caused by the exit of goods being transported in case of an accident.

3.4.9 Standards, Measurements and Testing

78. The Standards, Measurements and Testing Programme[56] has set up a specific management tool - the Dedicated Call - to allow targeted research on some

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[55] Council Decision 94/571/CE of 27.07.1994 adopting a specific programme for research and technological development, including demonstration, in the field of industrial and materials technologies (1994-1998), OJ L 222 of 26.08.1994, p. 19

[56] Council Decision 94/803/CE of 23.11.1994 adopting a specific programme for research and technological development, including demonstration, in the field of standards, measurements and testing (1994-1998), OJ L 334, 22.12.1994, p. 47

specific subjects in support of European policies on standardisation. In 1995, 15 projects related to health, safety and environmental topics have been selected, amounting to some 13 million ecus.

3.5 Environmental policy, energy

79. In the framework of the Community Programme on Environment and Sustainable Development[57], Community policy in the environmental field aims to integrate environmental considerations into Community policies. Among the environmental challenges and priorities of the programme, the improvement of public health and of health and safety (particularly the evaluation of industrial risks, nuclear security and radiation protection) are explicitly mentioned.

The direct and indirect effects of the environment on health are becoming more and more evident. A number of interrelated factors have already been identified as influencing health:

- climate changes and global warming,
- shrinking of the ozone layer,
- atmospheric pollution (concentration of ozone in the atmosphere, increased concentration of sulphur and nitrogen oxides, particulate matter),
- soil pollution and acidification,
- surface and ground water pollution,
- exposure to man-made chemical agents and substances.

In the majority of cases, legislation in these areas takes health considerations into account.

3.5.1 Air pollution

80. A proposal for a European Parliament and Council directive was adopted on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery[58]. In addition, a number of proposals were considered by the institutions in 1995: a directive on the quality of ambient air[59], a revision of the directive on air pollution from motor vehicle emissions[60] and a directive on diesel motor emissions in heavy vehicles[61].

Apart from legislation, reports on the implementation of the ambient air directives and on developments concerning ozone were published.

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[57] Fifth Programme - OJ C 138 - 17.05.1993

[58] COM (95) 350 fin. of 06.09.1995

[59] COM (94) 109 fin. of 04.07.1994

[60] COM (94) 558 fin. of 16.12.1994

[61] COM (94) 559 fin. of 16.12.1994

3.5.2 Radiation protection

81. In the framework of Chapter III (Health and Safety) of the Euratom Treaty the revision of two important directives directly related to health protection continued in 1995.

First, a revision of the Basic Safety Standards Directive (80/836/EURATOM) for the protection of workers and the public against the dangers arising from ionising radiation was made, in order to take into account the latest scientific data. The revision reinforces radiation protection, for example by reducing dose limits for workers and the public, and by including in the scope of the directive exposure to natural sources of radiation at work. The Commission's proposal was accepted by the Permanent Representatives on 21 December 1995 and was formally adopted at the beginning of 1996.

82. Secondly, the revision of the Directive on the protection of persons undergoing medical examination or treatment involving ionising radiation (84/466/EURATOM) continued. A formal opinion of the group of experts set up under Article 31 of the Euratom Treaty was obtained on a Commission proposal for revision of the directive. This proposal largely extends the existing directive in order to take account of new techniques used in medicine and to clarify and specify radiation protection aspects in this field.

83. Chapter III (Health and Safety) of the Euratom Treaty was applied to the nuclear tests in French Polynesia: the Commission, in accordance with its responsibilities, asked the French authorities for information on the radiation protection measures taken to protect both workers at the nuclear site and the public, and visited the area.

The Commission asked the French authorities to continue the monitoring of environmental radioactivity in the area on a long-term basis and to communicate the results to the Commission. It also asked an independent institute to make an evaluation of the worst case scenario as regards geological accidents, which confirmed the sound basis of the calculations made by the French authorities.

84. Besides these regulatory activities, the Commission is participating in research on optimisation of radiation protection of the patient in diagnostic radiology. Scientifically based guidance is established to fulfil clinical and technical requirements for adequate diagnostic information obtained at reasonable dose to the patient. The principle of safety culture is thus promoted both in the clinical environment and on the manufacturer's side.

3.5.3 Chemical products

85. Concerning chemical products, the Commission put forward an amended proposal for a Council Directive concerning integrated pollution prevention and control[62]. An amendment was also proposed concerning the draft directive on the marketing

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[62] COM (95) 88 fin. of 15.05.1995

of biocidal products[63], which provides for an authorization procedure for each biocidal product put on the market, based on an evaluation of risks for human health and the environment.

3.5.4 Civil protection

86. A process of reflection has been launched in the area of civil protection concerning, on the one hand, emergency medicine in cases of disasters (organisation at the moment of disaster, psychological follow-up) and, on the other hand, the environmental impact of natural and technological disasters with a view to reducing, or even avoiding, their serious consequences for human health and the environment.

3.5.5 European Environment Agency

87. The European Environment Agency based in Copenhagen has recently become operational. It has now published a monograph "Environment & Health (1): Overview and main European Issues" in the framework of the "Threats to Human Health" project.

3.5.6 Energy policy

88. The relationship between energy and health is mainly based on the direct effects which production and the use of energy have on the environment, since pollution directly influences individuals' health. At the end of 1995, the Commission presented a White Paper on "An Energy Policy for the European Community"[64]; Among the common objectives outlined, the objective of the protection of the environment will have a positive and direct impact on human health. Moreover, an integrated energy/environmental framework will contribute to the achievement of sustainable development.

The White Paper states that all problems related to spills, waste, noise, amenity damage and atmospheric pollution produced by local emissions or the increased emissions of CO_2 and other greenhouse gases must be dealt with increasingly at the Community level, as their direct negative effects on public health are obvious. This will particularly be done by making use of new technologies.

89. The Commission's proposals for two new programmes under discussion in 1995 - THERMIE II for the promotion and dissemination of new clean technologies[65] and SAVE II concerning a multi-annual programme for the promotion of energy efficiency in the Community[66] - will, when adopted by the Council, greatly contribute to alleviating global environmental problems.

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[63] COM (95) 387 fin. of 20.07.1995
[64] COM (95) 682 fin. of 13.12.1995
[65] COM (94) 654 fin. of 12.12.1994
[66] COM (95) 225 fin. of 31.05.1995

3.6 *Transport*

90. The importance of transport safety was reinforced by the Treaty on European Union, which amended Article 75 to extend Community activities to "measures to improve transport safety". All measures increasing transport safety contribute to attaining a high level of health protection in the Community. In July 1995, the Commission adopted a Communication on the Common Transport Policy: Action Programme 1995-2000[67]. Elaborating on the White Paper on the Future Development of the Common Transport Policy[68], the Action programme maintains safety as an integral component of the Common Transport Policy.

The Action Programme sets out in detail proposals and actions for the period 1995-1996 and identifies issues to be addressed in the period 1997-2000 and beyond. Safety is prominent in the list of these measures.

3.6.1 Ships

91. The loss of the "Estonia" with over 900 lives in the Baltic Sea in September 1994 highlighted the urgent need to improve the safety of roll-on/roll-off ferries. The Commission prepared a proposal for a Council Regulation on the Safety Management of Ro-Ro Passenger Vessels, which was adopted by Council on 8 December 1995[69]. The Regulation seeks mandatory application by 1 July 1996 of the International Maritime Organisation's "International Safety Management Code" (ISM Code) for regular ro-ro passenger ferry services to and from ports of the Community. In addition, it includes a provision for strict verification of compliance by Member States. The development of a safety culture by means of a Safety Management System under the ISM code can only have positive effects on the safety of passengers and seafarers alike.

92. Although it is recognised that some 80% of accidents at sea can be attributed to human factors, it remains the case that vessels and equipment on board vessels may also be at fault. Conversely, safe and reliable equipment can often be the very factor which prevents tragedy at sea. In June, the Commission adopted a proposal for a Council Directive on Marine Equipment[70] which aims to submit an extensive range of equipment to compliance with existing international testing standards, or where these do not exist, with future standards to be agreed within the IMO. Compliance would have to be verified by notified bodies fulfilling common quality criteria.

3.6.2 Transport of dangerous goods

93. During 1995, the European Parliament and Council discussed the Commission's proposal for a Council Directive on the approximation of laws of the Member States with regard to the transport of dangerous goods by rail. In December 1995,

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[67] COM (95) 302 fin. of 12.07.1995

[68] COM (92) 494 fin. of 02.12.1992

[69] Council regulation 3051/95/EC of 08.12.1995 - OJ L 320/14 of 30.12.1995

[70] COM (95) 269 fin. of 21.06.1995

Council adopted its Common Position on the proposal[71]. The potential health risks associated with the transport of such goods by rail are significant, particularly given the fact that these goods are often transported in quantity through urban areas. Moreover, the gradual opening of rail transport markets requires the development of a framework of safety legislation to cover the transport of dangerous goods by rail.

94. In October 1995, the Council adopted a Common Position on a long-standing proposal for a Council Directive on the appointment and vocational qualification of a safety advisor for the transport of dangerous goods[72]. This proposal seeks to ensure that undertakings carrying out the transport of dangerous goods and related activities appoint advisors to safeguard against risks to public health and safety, property and the environment, who would facilitate the carrying-out of the undertaking's activities in the safest possible way.

3.6.3 Road transport

95. The Commission brought forward a proposal for a Council Directive on the approximation of laws of the Member States relating to roadworthiness tests for motor vehicles and their trailers[73]. Its purpose includes the amendment of the basic Directive 77/143/EEC[74] to include effective and regular testing of speed limitation devices on certain heavy goods vehicles and buses, thereby contributing to general road safety and to the health of the population. Opportunity was also taken to consolidate the texts of this Directive, which guarantees that vehicles concerned are sufficiently regulated and maintained to ensure road safety.

3.7 International cooperation, relations with third countries and international organisations

96. Provisions on cooperation in the areas of health and health and safety at work are included in cooperation agreements between the EC and third countries.

97. The Euro-Mediterranean Conference in Barcelona identified health in its final declaration as one of the areas of future cooperation in the region. In the work programme adopted in Barcelona, the partners agreed to cooperate, in particular, on information and prevention activities, the development of public health services, the training of personnel, and medical assistance in the event of natural disasters[75].

98. In the trade relations between the European Community and third countries, health protection is included in both bilateral and regional programmes, including the transatlantic dialogue and activities in the framework of the Community's Specific Commitments to the General Agreement on Trade in Services.

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71 COM (94) 573 fin. of 09.12.1994

72 COM (91) 4 fin.

73 COM (95) 415 fin of 08.09.1995

74 OJ L 47 of 18.02.1977

75 Barcelona Declaration, adopted at the Euro-Mediterranean Conference (27/28.11.1995), final version, Barcelona, 28.11.1995

99. In research cooperation with third countries, and international organisations[76], significant progress has been made on drug, diagnostic and vaccine research aimed at providing the tools to combat the predominant disease problems of many developing countries. For studies of malaria, the STD-3 programme involved the participation of over 80 teams in 33 different countries. Reflecting the importance of this disease, malaria research, and in particular malaria vaccine studies, also feature within the new INCO-DC programme. Discussions on possible cooperation with the United States on malaria vaccine development are underway.

3.7.1 EC-USA cooperation

100. In the framework of the joint EC-USA Action Plan adopted at the EC-USA summit in Madrid on 9 December 1995, the two parties pledged to establish a task force to develop and implement an effective global early warning system and response network for communicable diseases. Furthermore, they have undertaken to cooperate, bilaterally and within the framework of the WHO and other international organisations as appropriate, on programmes on health-related matters (AIDS and other communicable diseases, cancer, drug addiction), and to identify specific areas for cooperation, especially in the research field.

101. The two parties have also pledged to explore the scope for an agreement for the exchange of information on issues affecting health and safety at work, such as occupational safety and health standards, the development of regulations, high-risk activities, carcinogenic substances at the workplace, toxicology, testing programmes, education and information programmes, and the collection of statistics and data. In addition, they are expected to explore the establishment of improved mechanisms for the timely exchange of information related to the general safety of products, including the withdrawal of products from the market.

102. In the area of the environment - directly related to the protection of health - the Community and the USA have pledged to strengthen the exchange of information and reporting on global environmental issues such as climate change, biodiversity, ozone layer depletion, persistent organic pollutants, desertification and erosion, water quality and quantity, land-based sources of marine pollution, hazardous wastes and contaminated soils, and forests. Furthermore, they have undertaken to enhance their bilateral dialogue on regulatory cooperation, including:

- extending cooperation on chemical issues;
- continuing work on biotechnology issues, such as the mutual acceptance of data for assessment and the release of genetically modified organisms;
- enhancing work on air pollution.

[76] Council Decision 94/807/CE of 23.11.1994 adopting a specific programme of research and technological development, including demonstration in the field of cooperation with third countries and international organisations, OJ L 334, 22.12.1994, p. 109

3.7.2 Cooperation with Central Europe and the Community of Independent States - PHARE/Tacis

103. Phare has concentrated its support on key areas of reform along the lines of the Health Strategy Paper revised in 1994 (health financing, reorganisation of health services with special emphasis on primary health care, pharmaceuticals policy, human resources management and training, and preventive measures), areas which were already mentioned in the first strategy paper. In programme design and adaptation of ongoing programmes, while pursuing the specific objectives of health sector reform, Phare has paid special attention to the wider objective of integrating countries with association agreements. A total amount of over 130 million ecus was committed to health sector restructuring in the period 1991-1995. During 1995, implementation of the ongoing programmes in all the Phare-eligible CEECs, except Slovenia, continued, while new programmes were approved for four other CEECs.
With regard to Tacis, in 1995 a start was made on work under the 4.5 million ecu programme for Russia approved in 1994 involving support for health sector reform in 4 pilot areas.
In 1995, new programmes with a health component were developed for Russia and Moldova.

104. a) Ongoing Phare/Tacis activities in 1995

In Albania, ongoing activities are taking place under two programmes (1993 and 1994) and concern: i) primary health care development through strategy design and re-training of 500 general practitioners and 1800 nurses; ii) reform of the hospital system through twinning with EC hospitals and training to streamline management practices, the creation of a maintenance service for biomedical equipment, improving the diagnostic and follow-up capacity of hospital laboratories, and restructuring the emergency services; iii) technical assistance with setting up a legal framework for the health sector; iv) restructuring of the pharmaceuticals sector involving the creation of an infusion fluid production line and assistance in establishing a pharmaceuticals inspectorate; v) preventive medicine, with the restructuring of the network of public health laboratories. Most of the work under the 1993 programme was completed during 1995.

In Bulgaria, activities comprise two programmes (1992 and 1993) and concern: i) health financing, including assessment of costs for medical procedures, and health insurance issues; ii) training in devising a training policy for medical and para-medical staff, training of medical personnel and officials involved in the decentralisation process, creating a faculty of nursing in the University of Sofia, improving training in general medicine (post-graduate and continuing education); iii) pharmaceuticals policy involving *inter alia* harmonisation of national legislation and practice with those found in the EC; iv) a framework for private practice aimed at the development of a well-balanced mixed public/private health care system; vi) health and safety at work with collaboration between the Ministry of Health and the Ministry of Labour. Most of the activities under the 1992 programme were completed in 1995.

In Hungary, the 1993 programme aims at: i) the development of a modern primary health care system covering all aspects (legislation, policy and implementation strategy, training, operational research, communication strategy, etc.), combined with an innovation fund providing grants for public or private PHC initiatives; ii) harmonisation with EC legislation and best EC practices as regards health and safety at work and the training of health professionals. Work is still continuing.

In Romania, some work on health financing reform was continued under the health component of the social programme.

In FYROM, assistance in preparing a pharmaceuticals policy was continued as part of a humanitarian aid package which initially included the supply of pharmaceuticals.

Existing programmes were completed in the Czech Republic (health care financing and health insurance administration, health information system) and Slovakia (devising methods for assessing and managing medical equipment, designing a strategy for primary health care development and for health care management including coverage of the immediate continuing education needs of existing staff) as well as in the Baltic States.

In Russia, the activities initiated in 1995 under the 1994 programme covered the development of primary health care (PHC) services in the form of "pilot oblasts", the modernisation of hospital practices and management as well as a demonstration project on maternal and child health in one pilot area.

105. b)New Phare/Tacis programmes in 1995

New Phare programmes were prepared for Slovakia and the three Baltic States, partly as a continuation of previous support:

In Slovakia, the programme focuses on 4 areas: i) health financing reform addressing issues such as pricing and payment systems, accountancy and information flow between care providers and financing bodies, resource allocation criteria and the development of investment strategies for health care infrastructures and equipment; ii) preparation of a framework for private practice with a view to developing a well-balanced mixed public/private health care system; iii) implementation of a PHC strategy; iv) implementation of a health management strategy.

In the Baltic States the focus remains mainly on previous priority areas: health care financing reform in all 3 countries; in Latvia and Lithuania support is also given to human resources and training, primary health care development and pharmaceuticals policy, while in Estonia support is also provided for information systems.

In all these new programmes, it is planned to devise and implement a communication strategy on health reform directed at health professionals and the general public.

106. In addition to these national programmes, a 10 million ecu multi-country programme initiated by the Commission, named CONSENSUS, was launched in 1995 to provide policy advice and support for social protection reform in Phare-eligible countries. Inter-Institutional Reform Committees have been set up in the CEECs and a Programme Advisory Board, composed of the 15 EC Members States and all the Phare-eligible CEECs, advises on programme policy and selection of project proposals. The scope of this programme includes health care financing issues and health care delivery. It is being implemented in close collaboration with DGV.

With regard to Tacis, in 1995 new programmes with a health component were drawn up for Russia and Moldova:

Russia: two actions were initiated
* A 2.6 million ecu programme, aimed at the coherent implementation of social and health care reforms, was finalised for the Republic of Karelia. It deals with the management of social protection by the Ministry of Social Welfare in cooperation with other ministries such as the Ministry of Labour and the Ministry of Health, as well as management of the health care systems, which remains under the responsibility of the Ministry of Health but is in practice exercised by local government agencies.
* 500 000 ecus were made available for policy advice for the Russian Government concerning both the demand and the supply side of pharmaceuticals, with a view to improving their distribution and production.

Moldova: In the framework of the programme "Technical Assistance on Human Resource Development" a sum of 500 000 ecus was approved to cover primary health care development and health care management.

107. Furthermore, health considerations played an important role in the ongoing contacts and cooperation activities with Central and Eastern European countries, aimed in particular at evaluating the situation and specific needs as well as the scope for cooperation in the social and health fields, including the possibility of opening Community programmes in the field of health to the participation of these countries.

108. The Link Inter-European NGOs (LIEN) programme, initiated in 1994 and covering both Phare and Tacis countries, is aimed at stimulating activities of NGOs in favour of deprived communities. In the health field, the actions can cover:

- assistance to women having limited access to health and social services;
- sustainable health and social support for the most disadvantaged target groups, such as the disabled, victims of addiction, people with HIV/AIDS, street children, the elderly, etc.

Health projects for over 1 million ecus have been approved in Bulgaria, Hungary, Lithuania, Poland and Slovakia. Among these projects the following deserve mention:

- establishment of a centre providing palliative home care in the region of Sofia (for persons suffering from incurable illnesses such as cancer and AIDS);
- professional training for young people with drug problems and criminal records;
- improving women's health in Slovakia through the development of sustainable reproductive health care services;
- rehabilitation of children with cerebral palsy;
- AIDS centre: assistance, education, information and documentation;
- model for community-based health care for vulnerable older people (mental illness and dementia).

Coordination and coherence is maintained between these activities and the European Community programmes in public health such as cancer, AIDS, drug dependence and health promotion.

3.7.3 Cooperation with international organisations

109. The European Community continued to follow health-related activities in the Council of Europe and was represented on several relevant committees and groups. In 1995, the major items under consideration related to blood (blood safety and self-sufficiency, including the proposed revision of the technical protocol to Agreement No. 26), the proposed Bioethics Convention and a number of other subjects, including organ transplantation, the organisation of health care services for persons in custody, recommendations on nursing research, health information in hospitals, health problems of single-parent families, and health, dignity and social exclusion.

110. Cooperation with the World Health Organisation (including the European Region and the International Agency for Research on Cancer) has continued at a satisfactory level. The WHO Director General, Dr Nakajima, visited the Commission in June 1995.

The Commission participated in the World Health Assembly, the Executive Board of WHO and the European Regional Committee meetings. The meeting of the Regional Committee in Jerusalem (September 1995) recognised the importance of placing statements from the European Commission on its activities in the health field high on its agenda.

3.7.4 Cooperation with ACP countries in the health field

111. 1995 saw the revision of the Fourth Lomé Convention, which since 1990 has governed cooperation between the European Community and African, Caribbean and Pacific (ACP) countries. The new agreement, signed on Mauritius on 4 November 1995, does not represent a new departure but strengthens and partly recasts a convention that will remain in force until the year 2000.

In this connection, a start has been made on work preceding the negotiations leading to the adoption of the indicative programmes. In 1995, this work mainly involved an examination of cooperation strategies at region and country level.

In the course of this examination, questions of health and AIDS were given greater consideration than in the past. Thus, even though it is of course impossible to anticipate the results of the negotiations on the indicative programmes, the signs are that funding for the health sector will continue to rise when the 8th Lomé financial protocol is implemented.

112. The work carried out over the past few years in the fields of health and AIDS continued in 1995. Apart from the monitoring of the development projects funded under the 7th EDF which are now underway and assistance given under the structural adjustment facility, several new and important financing decisions were taken. Particular mention should be made of those relating to:

* Mozambique, where 22 million ecus were allocated to a programme for improving the health system in rural areas

* Kenya, for a "family health" programme (drawn up jointly with the ODA in the UK) to which the Commission contributed 14.8 million ecus.

A number of other operations were decided upon, Burkina Faso (support for reform of the pharmaceutical sector, 1.6 million ecus) and Central Africa (support to improve primary health care, 1.8 million ecus) deserving particular mention.

113. As regards STDs/HIV/AIDS, the Commission continued to implement its main strategies by focusing on prevention, the strengthening of health services, consideration of the socio-economic impact of the epidemic, and scientific training.

Major programmes were adopted in 1995, relating in particular to the incorporation of the STD/HIV/AIDS strategy into health systems (including a 5 million ecu project in Mozambique and a 4 million ecu scheme in Tanzania). As for operational research, 1995 saw the completion of an important project at Mwanza in Tanzania showing how treating STDs reduces HIV transmission. Finally, at regional level, a number of HIV/AIDS awareness campaigns aimed at the general public were organised via the mass media. These included radio campaigns in some Asian countries as well as television campaigns (advertising spots during the African Nations Cup).

114. Meetings of technicians and national experts from ACP countries were organised in Brussels to discuss "decentralisation of health systems".

The first of these, held in November 1995 and dealing with the situation in French-speaking countries, brought together over 30 participants from west and central Africa.

Its purpose was to review the situation in these countries and to examine the constraints, limits and consequences associated with the decentralisation process, which is an important factor in the health system reforms now taking place.

115. The process of improving coordination with the Member States, the main features of which were decided upon by the Council in 1994, continued in 1995.

Activities in this area included further meetings of the expert groups "health and development" and "STD/AIDS" as well as efforts to progressively improve operational coordination in the countries themselves.

Action was also taken to extend joint consultation on policies and strategies and to improve operational coordination with, in particular, USAID and the World Bank.

116. 1995 also saw the convening of the second meeting of health ministers of countries in the franc area and associated countries on medicines policy, which was held in Brussels in April.

This meeting is part of a process initiated by the Ivory Coast with the support of the EC following the devaluation of the CFA franc in 1994, the aim being to promote joint discussion and action with regard to policies on medicines.

The meeting adopted an action plan with the following objectives:

* setting up an information network on medicines and their prices in Africa;
* strengthening mechanisms for the quality control of medicines;
* speeding up the introduction of generic medicines in the private sector;
* harmonising legislation;
* improving the way in which medicines are prescribed and dispensed.

AIDS

1. HIV/AIDS today poses a major scientific and social challenge.

Addressing the problem of HIV/AIDS calls for a multi-disciplinary response that combines the best of biological and medical research, effective interventions to deal with the socio-economic causes and consequences, particularly for the most disadvantaged groups and the poorest countries, actions to monitor and reduce the spread of HIV infection, notably by education and information, and provision of support for those living with HIV/AIDS and their families.

The European Community has played and continues to play a major part in the international HIV/AIDS effort. The actions implemented by the European Commission range across the whole span of the responsibilities of the Community, but focus mainly on the following three areas of activity: research, development assistance, and public health.

2. HIV/AIDS prevention in Europe : the European Community's priorities

By 31 December 1995, a cumulative total of 159 343 AIDS cases had been reported in the fifteen countries of the European Community since the epidemic began. Cases tend to be geographically clustered with a gradient of decreasing incidence rates from the south-western to the north-eastern countries. Against the background of rapid increase of AIDS cases, a consensus has emerged that the Community needs to play a significant role in the response to the epidemic.

Since 1988 the European Community has tackled the issue of AIDS in the framework of public health. A "Europe against AIDS" programme was set up in June 1991. Under the Treaty on European Union of 1993, the European Community was given a new competence in public health, namely that Community action should be directed towards "the prevention of diseases", in particular the major health scourges. Up to 1995 about 360 transnational projects involving NGO's have been funded for approximately 40 million ecus.

A new draft programme of Community action on the prevention of AIDS and certain other communicable diseases for the years 1996-2000 was discussed by the institutions in 1995, with a view of adoption in 1996[77].

This new programme, with a budget of 49.6 million ecus, will have four key priorities:

[77] The programme was adopted on 29.03.1996 - Decision 645/96/EC - cf. OJ L 95 of 16.04.1996

- surveillance and control of AIDS and certain other communicable diseases,
- combatting transmission of HIV,
- information, education and training,
- support for persons with HIV/AIDS and combatting discrimination.

The programme is implemented through:
- support for Community wide projects,
- support for innovative projects,
- support for NGOs' activities, including the establishment of inter-country links,
- setting up of networks.

This programme is open to the participation of countries in association agreements with the European Community and promotes cooperation with international organisations active in this field.

3. The HIV/AIDS programme for developing countries

The Commission began its work concerning HIV/AIDS in developing countries back in 1987 and has endeavoured from the start to ensure that its activities are closely coordinated with the WHO's special programme dating from the same year.

Over the years, the programmes have evolved from preventive measures taken in an emergency situation towards strategies and policies which deal with HIV/AIDS as a structural problem requiring a long-term strategy and a multisectoral response.

This response must first come from the health and welfare sectors, which in many countries are undergoing reforms aimed at greater efficiency in the provision of services while at the same time having to cope with a significant increase in the demand for HIV/AIDS-related care. However, the consequences of the epidemic and the responses called for go well beyond the health sector, involving as they do respect for human rights, non-discrimination towards persons with HIV/AIDS, and the social and family structures affected by the epidemic.

It is against this background that the Commission has, in close collaboration with the EC Member States, endeavoured to develop an appropriate policy and strategy for dealing with the HIV/AIDS problem. If Community support and bilateral aid are taken together, the EC is the largest contributor to the fight against HIV/AIDS in developing countries. Efforts to improve coordination led in 1994 to the submission of a Commission communication to the Council and the European Parliament on policies and strategies to deal with HIV/AIDS. On the basis of this communication, a Council resolution was adopted in 1994 followed by a Parliament resolution in 1995. Four action priorities were identified:

- controlling the spread of the epidemic by means of preventive measures;
- strengthening the health sector to enable it to cope with the additional burden resulting from the epidemic;
- helping countries to pay more attention to the social and economic consequences of AIDS;
- developing scientific knowledge and skills.

Close coordination is taking place both with the Member States and with the UN AIDS programme as well as with other international organisations working in this field.

In overall terms, when all countries and all financial resources are included (excluding co-funding by NGOs and research), Community spending in this area since July 1987 amounts to over 160 million ecus.

4. The Biomedical and Health Research Programme

The European Commission's activities in the area of research in biomedicine and health dates back to the launching of the First Medical and Health Research Programme in 1978. It has ever since steadily grown both in its research ambitions as well as in its budget available for supporting European research in areas of high priority.

Medical research at the EC level aims at: pooling of data, avoiding duplication of effort, standardization of methods and reagents, better selection of cohorts for clinical trials, bringing together complementary skills in multi-faceted projects, improved training possibilities for young researchers in specialized fields, better utilisation of results in the public health sector, creating better access to research results for all parts of Europe, establishment of European shared facilities for animal experimentation in order to reduce the overall number of animals used in experimentation and increase cost-effectiveness.

Ever since 1983, only two years after the first case of AIDS was diagnosed, the European Commission has taken on an active role in the fight against the AIDS epidemic. Funding of research on AIDS began in 1987 under the Fourth Medical and Health Research Programme. The ambitions of the programme as well as the budget available have been significantly increased over the years. At present, the programme is supporting a total of 51 projects including over 600 research teams with a budget of 32 million ecus under the BIOMED 1 and BIOMED 2 research work on AIDS - figures which will grow shortly as the Commission has made its selection for funding among the recently submitted project proposals.

The projects are all closely related to the three main priorities of the programme:

- development of safe and effective vaccines against HIV infection
- development of therapeutic agents suppressing progression of the disease in infected individuals
- research on the epidemiology of the virus in Europe

5. The International Scientific Collaboration Programme - Health Research for Development

This programme, concerning research collaboration between European groups and scientists in developing countries, contains an important component on health research in which some activity on HIV takes place as well.

16 joint research projects have been funded with partners in Africa and Asia with a budget over 5 million ecus.

The programme invests in research on the epidemiology of HIV in developing countries, mechanisms of vertical HIV transmission, longitudinal studies of HIV infection profiles, biology and epidemiology of HIV/IBC co-infection, role of other STDs in the epidemiology of HIV, international research against STDs and HIV with particular regard to evaluation of upgraded STD patient and clinical services.

See the relevant sections of this report for further information on 1995 activities in these areas of policy.

3.7.5 Cooperation with South and South East Asia, Latin America

117. In Asian countries, a number of important health programmes have been launched. They were concentrated, on the one hand on an extensive malaria control programme (Cambodia, Laos and Vietnam, 29 MECU) and on women's health and safe motherhood (Philippines, 17 MECU) on the other. Two smaller projects concerned primary health care (Bangladesh, 9.95 MECU) and reproductive health (Nepal, 0.9 MECU).

118. Support to the health sector is increasing rapidly with Latin America. In 1995, the health sector represented 6 % of the total amount of all the on-going projects from this budget line, and there will be a significant increase in the future. Among the financial proposals approved in 1995, 30 % constituted support to the health sector. This implies that in 1996 the share will raise to 9 % of all projects under implementation. In addition, the majority of rural development programmes include components related to health, such as water and sanitation and construction of health centres, etc.

In 1995, the total amount disbursed to the health sector was 54,5 MECU, the support being mainly concentrated to Central America (27 MECU to health projects in El Salvador and 21 MECU to regional projects); Among the regional projects it is worth mentioning the Project "Salud materno-infantil" (16,0 MECU), which is addressing specific problems related to reproductive health.

3.7.6 Fight against drugs

119. The Phare Multi-country Drugs Programme covers all countries of Central and Eastern Europe (11 countries) and has been operational since 1993. Health education, training and other preventive measures, as well as treatment and rehabilitation components represent a significant part of the programme. It is a multidisciplinary programme promoting cooperation among the Phare partner countries in the fields of drug demand and supply reduction and the development of a global approach towards the drugs phenomenon. The programme has helped to raise official awareness of the problem of drug use and to initiate the creation of structures at national level to coordinate actions and bring together all actors in the field.

Regional training activities have been organised on topics such as schools, the family, the community and the media.

A second regional report on drug demand reduction was prepared in 1995; it shows both an increase in drug use and the development of local awareness and facilities to deal with the problem. The report was discussed at a joint CEEC-EC seminar in Luxembourg in September 1995, thus enhancing the cooperation which was established in 1994 between this programme and the drug-related activities carried out inside the Community.

Approximately 2 million ecus have been spent so far on this activity.

120. In the context of North-South activities, particular emphasis is placed on the fight against drugs and drug dependence. A total of 8.7 million ecus was utilised to support actions to reduce drug supplies (trafficking controls, alternative developments) and demand (prevention, treatment and rehabilitation).

3.7.7 Humanitarian aid

121. The European Community Humanitarian Office, ECHO, which has been operating since 1992, plans, implements, finances, monitors and evaluates operations and decisions concerning humanitarian aid. When health systems are clearly

inadequate, preventive humanitarian measures may be taken to stop epidemics and assist the population. Given the limited resources available to ECHO, this type of assistance is only provided in a serious situation.

122. In 1995, man-made disasters accounted for 96% of ECHO's work, the remaining 4% relating to epidemics or natural disasters and their prevention. During the year, ECHO followed the same approach as in 1994 in respect of its emergency health protection measures:

- supply of medicines and medical equipment (the most important health measure taken by the Office);
- vaccination campaigns;
- checking the quality of distributed foodstuffs;
- infrastructure work to improve the general standard of health, and training of local medical personnel.

123. The main emergency operations undertaken by ECHO in 1995 in the health field were predominantly directed at the Great Lakes Region (Rwanda, Burundi). But they also concerned the vaccination of, and support for, cholera victims in Liberia, Guinea, Nicaragua and Peru. In addition, a major contribution (15 million ecu) mainly in form of medicines and food, was made to a global campaign launched by UNICEF aimed at combatting a renewed outbreak of diphtheria and tuberculosis in Russia, the Community of Independent States and the Baltic States.

3.7.8 Environment and health

124. The Community plays an important international role also in the area of environment and health. It is participating in the activities of the UNCED Commission on Sustainable Development and is represented on the European Committee for Environment and Health (ECEH), which is responsible for the follow-up of the Second European Conference on Environment and Health held in Helsinki in 1994. The next meeting is due to take place in London in 1999.

3.8 Integration of health requirements in other Community policies

3.8.1 Statistics

125. A condition for Community action in any field is the existence of reliable, accurate and accessible data. Under the Framework programme for priority actions in the field of statistical information 1993-1997[78] and with close involvement of the Statistical Programme Committee[79], sectoral programmes for social policy statistics are being further developed.

126. In close cooperation with the Member States, Eurostat (the Statistical Office of the European Community) is collecting, analysing and disseminating statistical information on a wide range of items related to social and economic aspects, such

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[78] Council Decision 93/464/EEC, 22.07.1993, OJ L 219, 28.08.1993, p.1

[79] Established by Council Decision 94/382/EEC, Euratom, OJ L 181, 28.06.1989, p.47

as demography, environment, poverty and social exclusion, social protection, public health, and health and safety at work. A number of publications containing *inter alia* statistical information on health and safety were published in 1995 (Eurostat Yearbook, Social Portrait of Europe, Women and Men in the EC, Disabled persons: Statistical data - second edition).

127. Data on accidents at work (ESAW: European Statistics on Accidents at Work) are collected on a regular basis and a database has been designed. A task force has been set up to discuss methodological issues such as coverage and under-reporting, as well as changes to certain classification systems. A pilot project on developing comparable studies on occupational diseases (EODS: European Occupational Diseases Statistics) for 31 substances and diseases has been launched and a prototype database has been created. A technical sub-committee to develop new classification systems for factors on biological, physical and chemical exposure has been established. The basic variables for which data are being collected will provide the first reliable Community-wide statistics on working conditions.

128. On the collection at Community level of data on home and leisure accidents (EHLASS), Eurostat has provided assistance in the preparation of summary reports and the revision of methodologies.

129. In 1995, the second wave of the European Community household panel took place. The first wave (1994) data of this multidimensional panel survey, which provide information on a wide range of socio-economic issues including health and medical consumption, are currently being analyzed.

130. These health-related activities will be coordinated with the forthcoming programme on health monitoring[80]. In close cooperation with other Commission services and with international organisations active in the field of health statistics (WHO, OECD), existing projects on 'causes of death statistics', 'health interview surveys' and 'health resources' will be further improved in view of this coming programme.

3.8.2 Youth and education

131. The SOCRATES Community action programme (1995-1999) is designed to contribute to the development of quality education and training.

Chapter I, relating to higher education (ERASMUS), provides for measures to promote student and teacher mobility, the setting up of thematic networks, and the development of curricula for various subject areas. The latter include medical sciences such as medicine, psychiatry, dentistry, public health, pharmacology, medical technologies, etc.

Chapter II, covering school education (COMENIUS), has a section on "partnerships between schools" (Action 1) that is aimed at encouraging the creation of partnerships between several schools in different Member States which

[80] COM (95) 449 fin. of 16.10.1995 - see above, Public health

will cooperate on European education projects (EEP). The latter aim to develop subjects of European interest (culturage heritage, the environment, science and technology, etc.). One such subject could be health promotion in schools.

132. The Youth for Europe programme gives financial support to projects and exchanges organised by youth initiatives and organisations. Specific actions support periods of voluntary service and exchanges outside the European Community, including CEECs, the NIS, Latin America and the Mediterranean region.

While health is not a specific programme target, a number of projects receiving financial assistance in 1995 had a health dimension, relating for example to drug prevention and abuse, alcohol, AIDS prevention and the provision of care and support for people with HIV/AIDS, health education and young people with disabilities. One project relates to health in the context of basic youth rights to be accorded to all young people[81].

3.8.3 Information activities

133. The Citizens First campaign, designed to help to bring Europe closer to the individual citizen, was adopted by the Commission in October 1995. In the run up to the Intergovernmental Conference, the Commission intends this campaign to demonstrate the benefits of the internal market to citizens. This general objective will be developed in the context of ten specific themes. When the information campaign on one of the themes is launched, the Commission will publish both a guide and a factsheet. Two of the themes have a particular relevance for health: health provisions in the single market, and health and safety at the workplace.

3.8.4 Regional policy

134. As outlined in the 1994 report, investments in education and health in objective I regions are now included in the scope of the European Regional Development Fund (ERDF). While it is too early to provide any detailed assessment of the effect on health of this expenditure (the Commission does not yet have a complete overview of all projects funded according to target area), it is clear that, in qualitative terms, significant health benefits are expected from improvements in the overall environment and infrastructure of the regions concerned.

3.8.5 Drugs

135. The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in Lisbon became operational in the first half of 1995. As the centre's physical infrastructure was not in place before mid-year, activities concentrated on gearing up for the tasks assigned to the Centre and on launching work in the main priority areas defined by the Centre's 1995-97 work plan.

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[81] cf. Youth for Europe statistics 1995, DG XXII, Doc. YfE-D95-006E

136. The Centre has concentrated on the following objectives: 1. Definition of a set of principles for information collection, 2. Identification of key indicators and core data, 3. Identification of mechanisms for providing appropriately analyzed information, 4. Establishment of effective working relationships with competent international institutions and bodies, 5. Establishment of working relationships with the main research groups and centres in the Member States, and, finally, 6. Establishment of recommendations for the Management Board concerning action to be taken in these fields. The completion of this work is a precondition for preparing the Annual Report on the Drugs Situation in Europe.

137. Taking into account these objectives, the centre focused its activities in 1995 on reviewing the diverse studies and initiatives undertaken by the Community prior to its creation. These covered three main areas: demand reduction and epidemiology, implementation and coordination of the REITOX network and the national focal points, and a restructuring of relations with the Centre's institutional and scientific partners. The work of the REITOX network was reviewed in 1995, with a view to improving this successful cooperation between Member States concerning drugs questions.

4. Conclusions

138. This second annual report on the integration of health requirements in Community policies shows clearly how almost all main policy areas in the Community have repercussions on health and take health considerations into account.

139. It shows that a number of subjects are being addressed by several different policy areas: work on tobacco, for example, takes place in the context of the preventive activities of the Europe against cancer programme. In addition, agricultural policy deals with the growth of tobacco plants; research is being conducted on less harmful tobacco varieties and indirect taxation of tobacco products is being considered within the context of taxation policy. A similar situation exists concerning drugs, which are a topic for action in public health (with a programme proposal being discussed by Council), for cooperation in internal and justice affairs, or in North-South work. Drugs-related projects are also funded by programmes directed at the fight against social exclusion and by the Youth for Europe programme. The specific programmes targeted at Central and Eastern Europe all include a health dimension.

140. Several important health-related issues on the EC level are not being administered by the Community institutions themselves, but have become the task of independent agencies. In this report, there have been references to the European Agency for Safety and Health at Work (Bilbao), the European Medicines Evaluation Agency (EMEA) in London, the European Environment Agency (Copenhagen), and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in Lisbon. In their work, these agencies, while formally independent, are still required to respect the provisions of Article 129 of the Treaty.

141. The emphasis which the first report put on the need for complementarity - public health policy needs to be complementary to other policies, and other Community policies may need to be complemented by public health measures - remains a continual challenge for Community policies[82]. Particularly in areas where the legislative groundwork has been laid, it is important to realise that legislative or other measures in that context may also have important public health aspects which need to be considered.

142. All in all, health protection and disease prevention requirements are steadily taking on more importance both as a result of the consultation processes installed inside the Commission - including the Interservice Group on Health - and because of growing public awareness of the health implications of other areas of policy.

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[82] Report on the integration of health requirements in Community policies (1994), COM (95) 196 fin. of 29.05.1995, p. 40f.

143. This report is intended to be a contribution to the transparent functioning of the Community. This is, however, a two-way process. The Commission would therefore hope that the publication of this report will also provide important pointers to all those involved and interested in decision-making in various policy areas to ways and directions of intervention aiming at ensuring that health requirements are properly integrated into the various Community policies.

Article 129 of the Treaty places the obligation to integrate health requirements in Community policies on all the institutions involved in the shaping and implementation of Community policies. Some Member States and regions in the Community have launched similar initiatives. The Commission hopes that this report will stimulate other Member States and regions to follow suit.

ANNEX

Proposals for and adoption of major health-related legislation in 1995

Legislation proposed in 1995

Public health

Communication and Proposal for a European Parliament and Council Decision on Health Monitoring, COM (95) 449 fin. of 16.10.1995

Social policy

Amended proposal for a Regulation amending Council Regulation (EEC) 1408/71, OJ C 242, 19.09.1995

Proposal for a Council Directive amending Directive 90/349/EEC on the protection of workers from the risks related to the exposure to carcinogens at work, OJ C 317, 28.11.1995

Environment

Proposal for a European Parliament and Council Directive on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, COM (95) 350 fin. of 06.09.1995

Amended proposal for a Council Directive concerning integrated pollution prevention and control, COM (95) 88 fin. of 15.05.1995

Amended proposal for a Council Directive on the marketing of biocidal products, COM (95) 387 fin. of 20.07.1995

Agriculture

Proposal for a Council Directive in relation to the marketing of meat products, OJ C 269 of 16.10.1995

Proposal for a Council Directive amending Directive 92/117/EEC concerning measures for protection against certain zoonoses, COM (95) 491 fin. of 23.10.1995

Transport

Proposal for a Council Directive on maritime equipment, COM (95) 269 fin. of 21.06.1995

Proposal for a Council Directive on the approximation of laws of the Member States relating to roadworthiness tests for motor vehicles and their trailers, COM (95) 415 fin. of 08.09.1995

Energy

Proposal for a Council Decision concerning a multi-annual programme for the promotion of energy efficiency in the European Union - SAVE II, COM (95) 225 fin. of 31.05.1995

Legislation adopted in 1995

Social policy

Medium-Term Social Action Programme, COM (95) 134 fin. of 12.04.1995

The Future of Social Protection - a framework for a European debate, COM (95) 466 fin. of 31.10.1995

Commission Communication on a Community programme concerning safety, hygiene and health at work (1996-2000), COM (95) 282 fin. of 12.07.1995

Commission Decision 95/230/EC of 12.07.1995 setting up a Scientific Committee for Occupational Exposure Limits to Chemical Agents, OJ L 188, 09.08.1995

Commission Decision 95/319/EC of 12.07.1995 setting up a Committee of Senior Labour Inspectors, OJ L 188, 09.08.1995

Single Market

18th Directive adapting to technical progress the annexes of the basic Directive on cosmetics products, Commission Directive 95/34/EC of 10.07.1995, OJ L 167 of 18.07.1995

6th Directive on methods of analysis for checking the composition of cosmetic products, Commission Directive 95/32/EC of 07.07.1995, OJ L 178, 28.07.1995

Directive establishing the criteria and conditions under which a manufacturer may apply not to include one or more ingredients on the list of ingredients to be indicated on the packaging of cosmetic products, Commission Directive 95/17/EC of 19.06.1995, OJ L 140, 23.06.1995

Directive 95/46/EC of the European Parliament and of the Council of 24.10.1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ L 281, 23.11.1995

Agriculture

Council Directive 95/23/EC of 22.06.1995 amending Directive 64/433/EEC on conditions for the production and marketing of fresh meat, OJ L 243, 11.10.1995

Council Directives harmonising maximum residue levels for nine pesticide active substances and amending existing maximum residue levels for other pesticide active substances, Council Directives 95/38/EC, OJ L 197, 22.08.1995; 95/39/EC, OJ L 197, 22.08.1995; 95/61/EC, OJ L 292, 07.12.1995

Commission Directive 95/3/EC of 14.02.1995 amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs, OJ L 41, 23.02.1995

Commission Decision 95/492/EC of 15.11.1995 amending Decision 94/652/EC establishing the inventory and distribution of tasks to be undertaken within the framework of cooperation by Member States in the scientific examination of questions related to food, OJ L 282, 24.11.1995

Transport

Commission Communication on a common transport policy: Action programme 1995-2000, COM (95) 302 fin. of 12.07.1995

Council Regulation (EC) No 3051/95 of 08.12.1995 on the safety management of roll-on/roll-off passenger ferries, OJ L 320, 30.12.1995

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