COMMISSION OF THE EUROPEAN COMMUNITIES

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# REPORT FROM THE COMMISSION

**to the Council, the European Parliament and the Economic and Social Committee**

**on the integration of health protection requirements in Community policies**

TABLE OF CONTENTS

# INTRODUCTION

This report aims to provide a survey of issues relating to health in Community policies as a whole. It is the first of its kind, and is designed to give effect to the commitment of the Commission to report on the way health requirements form a constituent part of the Community's other policies, in accordance with Article 129 of the E.C. Treaty.

The large number of current Community actions and policies which either directly relate to public health or have implications for it are described in the report. From the description of all these measures it is possible to draw out several major themes in relation to the development of health-related activities in the Community.

**Health considerations in the first Community Treaties**

The first such theme is that health considerations have been present in the policies of the Community right from the outset. One of the underlining objectives of the EEC Treaty is that of raising *the standard of living* (Article 2) which is clearly of major significance for health. Moreover, the Treaty contains a number of provisions which have formed the basis for important health-related actions. Article 39, for example, on the Common Agricultural policy has led to the harmonisation of *health rules for animals, products of animal origin, and products of plant origin* in order to ensure their free movement in the Community while at the same time protecting consumers' health.

Further relevant provisions are the various Articles governing free movement. Article 48 ensures freedom of movement of workers, Articles 52 to 58 provide for the right of establishment, and Article 59 guarantees the free movement of services. These apply to the health sector - to health services, patients and health professionals - just as much as to other parts of society. Under Article 100, health protection provisions relating to foodstuffs and pharmaceuticals have been adopted, and Article 118 makes specific mention of *health and safety at work*.

Finally, in a particularly striking example of the weight given to health considerations, under Article 36 the basic principle of the free movement of goods is limited so that certain restrictions on imports, exports and goods in transit can be imposed in order to protect human health and life.

Health is also explicitly covered by the Euratom Treaty which in Chapter III sets out provisions for the protection of the health of workers and the general public *against the dangers arising from ionising radiation.*

**The Single Act**

Not only has the Community always been concerned with health issues, but that concern has over the years gradually developed and crystallised. This process was given a great impetus by the adoption of the Single Act in 1986, which strengthened the legal basis for Community action in relation to health protection. The Act in particular extended the scope

for Community action on health and safety of workers (Article 118a) and in relation to approximation of laws (Article 100a). Under Article 130r Community action on the environment had to contribute towards human health and consumer protection. Also by virtue of Article 100a, proposals for measures establishing the *internal market* were to have as a base a high level of health protection.

On the foundations laid by this Act much work has been carried out to improve consumers' health protection, for example through the adoption of directives on safety of toys (1988) and general product safety (1992). Similarly, using Article 118a as a basis, the framework directive 89/391/EEC covering the principal aspects of health and safety at work and a vast body of specific directives on particular aspects of occupational safety and health has been elaborated.

**The Treaty on European Union**

The Treaty on European Union, which came into force on 1 November 1993, continued the gradual evolution of Community involvement in health. The Treaty built upon the existing Community competences in the health field in two important ways. First, it introduced or strengthened provision in a number of policy areas with an impact on health. Relevant provisions include :

- Article 75(c) on measures to improve transport safety,
- Article 129a, on the contribution to the attainment of a high level of consumer protection,
- Articles 126 and 127 on the development of quality education and vocational training,
- Title VI on cooperation in the fields of Justice and Home Affairs.

Second, in Articles 3(o) and Article 129 the Treaty introduced a specific Community competence on public health. The Community was given the objective of making *a contribution to the attainment of a high level of health protection.* This opened up for the first time the prospect of developing a fully consistent and planned Community approach to public health which would integrate the various strands of action being taken in this area into a coherent overall strategy with established priorities and aims.

At the same time, by providing a clear framework for Community actions in this field and by placing a firm emphasis on prevention of disease as the core of Community work, Article 129 can be seen as helping to define and circumscribe the scope of future action. Previously the public health actions taken, based on specific Council requests, differed in their scope and objectives. With the new Treaty provisions it will be much easier than hitherto to establish a clear direction and focus for the Community's public health actions.

One of the principal provisions of Article 129 is *that health protection requirements shall form a constituent part of the Community's other policies.* This provision has consequences for the formulation of Community policies in other areas and for the measures and instruments proposed by the Commission to give effect to these policies. It requires the Commission to check that proposals for policies, and implementing measures and instruments, do not have an adverse impact on health, or create conditions which undermine the promotion of health. It will in addition be possible to promote health protection requirements in the context of other policies, on the basis of this Article 129. Article 129 in its paragraph 3, also provides for the cooperation with third countries and the competent organizations in the sphere of public health.

## The Commission's communication on public health

In November 1993 the Commission adopted a *Communication on the framework for action in the field of public health*[1] setting out its strategy for implementing the Treaty provisions. At the same time, in order to ensure that health considerations were properly taken into account in other Community policies, the Commission also decided on the following arrangements :

- the reinforcement of interservice consultation prior to Commission decisions whenever a decision might have implications for public health;
- the setting up of an Inter-Service Group on Health to ensure mutual exchange of information and internal coordination with regard to health and health protection aspects of policies and legislative proposals; and finally,
- the production of an annual report in which there would be information on the health implications of other policies.

## The report on health protection requirements in Community policies

This Commission report is the first annual report on the health implications of other policies. As well as being a response to the obligations of the Treaty, it also provides a method of fulfilling the wishes expressed by the Council, the European Parliament, and the Economic and Social Committee, for an overview of health-related Community action. The Council[2] and the European Parliament[3][4] have in recent months both underlined the need to ensure an effective intersectoral cooperation in health-related areas and a better integration of health protection aspects in Community and Member States' policies. Similarly, in July 1994, the European and Social Committee recommended[5] that a suitable link be made between health policy and the socio-economic dimension of the Community's work.

Health protection requirements are dealt with in this report within the context of the whole range of health matters in which the Community is involved. This is both in order to provide a broad overview of such work and a proper perspective in which to view health protection activities, and also to demonstrate that in many areas Community work on health goes well beyond the parameters for public health activities established by Article 129. For example, activities with regard to research, training of professionals, pharmaceuticals, telematics and social security all have an impact on the provision and organisation of health care.

The report illustrates how the Community has tackled health-related issues in different ways and in different contexts. A wide variety of areas of Community competence have been involved, such as the internal market, competition policy, research, education, energy and agriculture policy. For each area of Community policy with an impact on health the health aspects are analysed and the specific actions which implement the health protection requirement in the Treaty are summarised.

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(1) COM(93)559 final of 24 November 1993

(2) Council Resolution of 2 June 1994 on the framework for Community action in the field of public health, OJ C 165, 17.6.1994, p.1

(3) Resolution of the European Parliament of 19 November 1993 on public health policy after Maastricht, OJ N° C 329, 6.12.1993, p. 375

(4) Resolution of the European Parliament of 6 May 1994 on the submission of the European Parliament to the World Health Organisation's European Conference on environment and health OJ C 205 of 25.07.1994, p. 521.

(5) Opinion on the Commission Communication on the framework for action in the field of public health, OJ C 388 of 31 December 1994, p.3

In this way the report shows how deeply embedded health considerations are throughout the spectrum of the Community's work and reveals the close and intricate links between health activities and those in other areas.

**Interaction between public health and other activities**

In the first place it can clearly be seen that other Community policies can have considerable impact on public health. This is the case for policies which are not primarily directed at health protection, but rather at very different areas such as transport and energy, which can nonetheless have an important impact on health. Other policies may have a more direct influence such as the measures leading to improvements in the quality of the environment which thus may benefit citizen's health. On the other hand, certain Community actions in agriculture, say, may have both a positive influence and a less positive influence. Actions to promote fresh fruit and vegetables are particularly important, whereas support for the production, import and promotion of tobacco, or for the preferential promotion of full fat milk without the appropriate warnings of total fat intake, might have a negative effect on health.

Secondly, the report demonstrates that other Community policies which have an impact on health may themselves need to be complemented by public health measures to ensure that their consequences for health are as beneficial and effective as possible.

One example is the area of pharmaceuticals where the Community has achieved major accomplishment in the area of public health, while taking account of industry's interests. The criteria and procedures for the authorisation of medicines have been extensively harmonised together with other important aspects of pharmaceutical legislation such as the rational use of medicines. Equally, much scientific work has been supported within the large-scale Community research and development framework programme. With the new Treaty competence the existing achievements can be complemented by activities relating to the public health dimension of pharmaceuticals - their role within the health system, their rational use by health professionals, understanding by the public, and so on.

Similarly, existing Community pharmaceutical legislation does not cover labile blood components and the relevant national legislation and rules vary. In this field, therefore, additional Community public health action is desirable to ensure the safety and free movement of blood within the Community, and to improve the confidence of the citizens in the safety of the blood transfusion chain.

Thirdly, the report demonstrates clearly that the converse is also true, namely that public health actions themselves need to be accompanied by measures in other areas if they are to be fully effective. The issue of drug dependence is a notable example of this. Public health actions aimed at reducing demand for drugs and minimising dependence must be complemented by measures to tackle the supply of drugs and the various judicial, police and external relations questions that arise. The Global Action Plan for the European Union to combat drugs contains all these elements.

HIV/AIDS provides another example. As a global and multi-faceted phenomenon AIDS requires a response spanning a number of areas. The Community's public health actions, which cover the areas of prevention, education and support are therefore complemented both by a large-scale research commitment within the BIOMED programme and by a programme of AIDS-related developmental assistance.

Finally, the report illustrates how Community policies can contribute to improving human health while maintaining a balance between economic and social interests. The varied actions taken by the Community have helped to improve health not least by increasing citizen's awareness and understanding of their health and its determinants which has had a positive impact on lifestyles. For example, the "Europe Against Cancer" programme[6] has contributed towards beneficial changes in patterns of nutrition, such as an increase in consumption of fresh fruit and vegetables and a reduced intake of saturated fat in Member States. The promotion of the consumption of olive oil and of fish products in the context of Community agricultural and fisheries policies is a further example of such an action.

**A contribution to transparency**

The growing attention given by the media to an enormous number of health topics ranging from AIDS and cancer to the quality of medical care, the effects of environmental pollution and stress at work is a reflection of people's deep interest in and concern about health matters. By providing information on the impact of Community action and policies on the health of the population of the Community, this report is intended to contribute to reinforcing the transparency and openness of the Union, thus increasing its acceptance by its citizens and bringing the Community Institutions closer to them.

(6) Council Decision of 17 May 1990, OJ L 137 of 30.5.1990

# I. PREAMBLE

On 24 November 1993, the Commission approved a *Commission Communication on the framework for action in the field of public health*[7] in order to meet the objectives introduced by Articles 3(o) and 129 of the EC Treaty.

In order to respond to the obligation in Article 129 that health protection requirements shall form a constituent part of the Community's other policies, the Commission decided to submit an annual report on related aspects in Community policies, programmes and actions.

This report is the first of such annual reports, covering the question of the health aspects of other policies as described by the various Commission departments involved.

The structure followed in this report follows the lines of the Commission's annual General Report on the Activities of the European Communities.

Future reports on health protection, starting with that for 1995, will report on new initiatives in the different areas of Community policy involved, review the progress made, and consider the possibilities and issues that lie ahead.

(7) COM(93)559 final

## II. HEALTH PROTECTION ASPECTS OF THE SINGLE MARKET AND THE COMMUNITY ECONOMIC AND SOCIAL AREA

### 2.1 Statistics

1. Reliable and comparable statistical data are an essential tool for the European Union in defining, implementing, monitoring and evaluating its policies. It is Eurostat's mandate to provide official statistics to ensure a common statistical language at the level of the EU and to disseminate the results to interested parties in and outside the Commission services.

2. By its Decision 93/464/EEC of 22 July 1993[1], the Council agreed on the framework programme for priority actions in the field of statistical information 1993-1997; sectoral programmes for social policy, including *statistics on health and safety,* are an essential element in this framework programme. Close involvement of the National Statistical Institutes in the execution of this programme is assured through the Statistical Programme Committee, established by Decision 89/382/EEC, Euratom[2].

   Eurostat's activities in the context of this new programme and previous statistical programmes have led *inter alia* to the collection, analysis and dissemination of statistics on health and safety, its determinants and consequences in the following fields :
   - demography (e.g. fertility, mortality, population projections, causes of death);
   - transport (e.g. road accidents and railway casualties);
   - working conditions (accidents at work (ESAW) and occupational diseases (EODS));
   - statistics on persons with IDH (impairments, disabilities and handicaps);
   - poverty and social exclusion;
   - health resources statistics (e.g. health personnel and hospital beds);
   - family budget surveys (e.g. household consumption expenditure on medical care and health, on food, alcohol and tobacco);
   - labour market characteristics : Labour Force Survey (e.g. numbers of days/hours lost at work due to sickness);
   - education and training (e.g. enrolment for and graduates in "medical science and health-related studies");
   - environment (e.g. air emissions, waste, inland waters, noise)
   - social protection : ESSPROS (social security benefits for "sickness", "maternity" and "invalidity/disability");
   - national accounts : ESA (e.g. general government expenditure on health affairs).
   - home and leisure accidents : EHLASS (assistance on methodological aspects).

   In addition, data on health and safety will become available via the time use survey (in preparation). Statistics on a variety of socio-economic items such as income, labour,

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(1) OJ No L 219, 28.8.1993, p. 1
(2) OJ No L 181, 28.6.1989, p. 47

housing, health, social relations and sociability will be obtained via the European Community Household Panel (first wave data will be available in 1995).

3. In 1994, Eurostat started to develop a new framework for health statistics at Community level, including statistics on health status, on health determinants and on health services and health resources. Future activities on health statistics will continue to be developed in close collaboration with international organisations active in this field (WHO, OECD).

In line with the above mentioned framework programme 1993-1997 and in cooperation with international organisations active in this field (WHO, OECD) future activities on health and safety statistics will cover *inter alia* a more detailed analysis of mortality and morbidity by cause. Eurostat is also involved in the preparatory work for Commission proposals concerning a programme on "Health data and indicators" in the context of its framework for action in the field of public health.

## 2.2 Internal market

### 2.2.1 Free movement of goods

#### 2.2.1.1 Dangerous substances, pharmaceutical products, foodstuffs, medical devices

4. • **Dangerous substances and preparations**

Health implications or considerations are fully taken into account when EC legislation in this field is drafted and adopted. This position varies according to the activity involved. Protection of health can be included in the "essential requirements" that should be fulfilled by processes or by products before going on the market[3]. Moreover, specific pieces of legislation contain provisions regarding the marketing or use of certain *dangerous substances* and preparations[4], the classification, packaging and labelling of dangerous preparations[5] or the manufacturing and the placing on the market of narcotic drugs and psychotropic substances[6].

The legislation on dangerous substances and preparations, which spans a period of nearly 30 years, is very extensive. It provides for the classification, packaging and labelling of many thousands of dangerous substances and for about a million dangerous preparations. It also provides for limitations on the marketing and use of forty substances and groups of substances where risks cannot be controlled by simpler means. This adds up to an extensive package of health protection measures.
In the legislative field, the major achievement of 1994 was the final adoption by the Council and European Parliament of three Directives. These related to protection of consumers from the dangers to health posed by nickel-notably in jewellery[7], to the

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(3) See Communication on Construction of February of 28 1994 (OJ No C 62) or COM(93)646 on cableway installations to carry passengers

(4) See Council Directive 76/769/EEC of 27/7/76 (OJ No L 262 of 27.6.1976)

(5) See Council Directive 88/379/EEC of 7/6/88 (OJ No L 187 of 16.7.1988)

(6) See Council Directive 92/109/EEC of 14/12/92 (OJ No L 370, 19.12.1992)

(7) OJ L 188 of 22.07.94 p.1

protection of consumers (especially children) from the dangers associated with use of flammable gases in certain aerosol products [8] and to the protection of consumers from creosote, chlorinated solvents and substances classified as cancerogenic, mutagenic and toxic to reproduction[9].

An important new development is the desire of certain Member States to apply their own national rules in place of Community legislation. Thus the Commission decided to allow Germany to keep its national rules on Pentachlorophenol (PCP) in place of the PCP Directive and to take account, thereby, of a special danger to health posed by this substance to German consumers[10]. A further three applications to derogate from Community Directives on dangerous substances for reasons of health protection are under active examination. There is every sign that differences between Member States will be further aggravated by the recent enlargement of the Union. The services of the Commission will try to build a better consensus among Member States by introducing a more planned approach to legislation on dangerous substances and preparations and by promoting scientific evaluation at all stages in the legislative process.

5. **•Pharmaceutical products**

*EC pharmaceutical legislation*, since the first directive in 1965, has constantly aimed at the promotion and protection of public health. By requiring strict quality, safety and efficacy criteria to be complied with before a medicinal product can be authorised, patients have been given protection which did not previously exist. The gradual extension of this legislation to all types of medicinal products (e.g. vaccines, blood products, radiopharmaceuticals, etc.) and the constant adaptation of testing requirements to progress in scientific and technical knowledge have given the Community a comprehensive legislative framework for marketing authorisation of medicinal products and other important issues such as the rational use of medicines.

6. The harmonization of pharmaceutical legislation was completed in 1993, but the decisions on the authorisation of individual medicinal products had also to be addressed. The Council of the European Union adopted in June and July 1993 a regulation[11] and 3 directives [12] concerning the creation of two new Community authorisation procedures for human and veterinary medicines and the establishment of a European Medicines Evaluation Agency (EMEA).

Under the new system for marketing authorization in the European Union, innovatory medicinal products will be authorised centrally via the EMEA, and marketed in all the Member States of the European Union. Conventional medicinal products will be subject to a decentralised procedure mutually recognised by the Member States.

The supervision of medicinal products circulating in or exported from the European Union (inspections and pharmacovigilance) will be coordinated by the EMEA in close liaison with the Member States.

This will give all patients throughout the Community earlier and simultaneous access to important innovative medicinal products, such as anti-cancer agents, products for the

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(8) OJ L 331 of 21.12.94 p. 7
(9) OJ L 365 of 31.12.94 p. 1
(10) OJ L 316 of 09.12.94 p. 43
(11) Regulation (EEC) n° 2309/93 of 22.07.93, O. J. n° L 214, 24.08.93, p. 1
(12) Directives 93/39/EEC, 93/40/EEC and 93/41/EEC of 14.06.93, O. J. n° L 214, 24.08.93, p. 22 to 40

treatment of AIDS, new vaccines, etc. Pharmaceuticals will be marketed in the whole European Union under identical conditions of use and public confidence will no longer be undermined by national differences in safety evaluation of the same drug.

7. In the Communication from the Commission on the outlines of an industrial policy for the pharmaceutical sector in the European Community[13], it is made clear that it is essential to ensure that the Community's pharmaceutical industry retains its competitiveness while taking into account the specificity of this industry: the vital role played by medicinal products in public health, and the cost of such products, which represents a large proportion of social security budgets. In this connection the Commission's communication includes a proposal to intensify the dialogue already initiated in the pharmaceutical field with the Member States, for example through measures aimed at health professionals and consumers to promote the rational use of medicinal products.

8. In 1989, the Council decided that medicinal products derived from human blood or plasma should be subject to the strict criteria laid down for other medicinal products, in order to ensure their quality and their safety from viral contamination[14]. This topic has remained a constant concern of the highest priority; all developments in this area are kept under review and the relevant provisions and recommendations are continuously updated in the light of scientific and technical progress.

9. In 1992, the Council adopted four directives designed to promote a more rational use of medicines in the European Union, namely :
   - Directive 92/25/EEC[15] on the wholesale distribution of medicines, which aims at eliminating obstacles to their free circulation through the control of the wholesale channel of distribution of medicinal products, including the recall of defective products.
   - Directive 92/26/EEC[16] on the legal status of classification for the supply of medicinal products to the patient, distinguishing between those available on prescription only and those available without a prescription.
   - Directive 92/27/EEC[17] designed to improve patient information, harmonising the content of the labelling and the package leaflets of pharmaceuticals.
   - Directive 92/28/EEC[18] concerning the advertising of medicinal products which provides for separate rules for advertising to the general public, allowed only with respect to self medication products, and for advertising to health professionals which is subject to a more complete system of rules.

10. With regard to veterinary medicinal products, Regulation (EEC) Nr. 2377/90[19] has a major impact on public health protection by requiring legally binding maximum residue

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(13) COM (93) 718 final of 2.3.1994
(14) Directive 89/381/EEC, OJ No L 181, 28.6.1989
(15) OJ N° L 113, 30.04.1992, P. 1
(16) OJ N° L 113, 30.04.1992, P. 5
(17) OJ N° L 113, 30.04.92, p. 8
(18) OJ N° L 113, 30.04.92, p. 13
(19) OJ N° L 224 of 18.8.1990

limits of veterinary medicinal products in foodstuffs of animal origin to be established at Community level.

11. • **Foodstuffs**

Community legislation relating to the *foodstuffs* sector has also consistently identified the promotion and protection of public health as one of its fundamental objectives. A large volume of Community legislation has been produced to ensure the safety of foodstuffs sold in the Community, notably as regards additives, flavours, extraction solvents, contaminants, materials in contact with food, foodstuffs for particular nutritional purposes, quick frozen foodstuffs and food hygiene. Certain Community labelling rules are also inspired by the need to ensure food safety, notably as regards the "use by" date for perishable foodstuffs. Moreover, the Community rules on the official control of foodstuffs require Member States to take active measures to verify the safety of the food supply. Further rules are under consideration by the Council for novel foods and food ingredients, food irradiation and flavours.

12. Virtually all Community food legislation requires that the *Scientific Committee for Food*, is consulted before the adoption of provisions which may have an effect on public health. In order to ensure an adequate coverage of all the disciplines and areas involved, the Scientific Committee for Food has established eight working parties covering food additives, contaminants, flavours, exposure and intake, novel foods and novel food processes, nutrition and dietetic foods, materials and articles in contact with food and microbiology and food hygiene.

13. In 1994, the Commission launched an ambitious programme of scientific cooperation with the Member States for the further investigation of the scientific aspects of food safety, notably in the field of chemical and microbiological contamination of food, and study of dietary intakes. This programme involves the participation of some 80 scientific institutes in the Member States dealing with food safety issues.

14. In the legislative field, the major achievement of 1994 was the final adoption by the Council of the three directives relating to food colours[20], sweeteners[21] and additives[22] other than colours and sweeteners. These directives establish positive lists of food additives, and specify acceptable conditions of use. Their implementation will ensure that food additives are used under safe conditions and do not present a risk for public health. In addition, the Council adopted an amendment to the Directive on extraction solvents, while the Commission presented new proposals in respect of foodstuffs for particular nutritional purposes and for natural mineral waters.

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(20) European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs (OJ No L 237, 10.9.1994, p.13)

(21) European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs (OJ No L 237, 10.9.1994, p. 3)

(22) European Parliament and Council Directive 94/34/EC of 30 June 1994, amending Directive 89/107/EEC on the approximation of the laws of Member States concerning food additives authorised for use in foodstuffs intended for human consumption (OJ No L 237, 10.9.1994, p. 1)

15. • **Medical devices**

Community Legislation relating to Medical Devices is aimed at providing considerable impact on the protection of public health, by establishing a consistent approach to the application of safety requirements in the processes of design, manufacture and marketing of such products.

The legislation is in the form of three Directives covering the wide range of products and technologies experienced in this sector.

The first, Directive 90/385/EEC relating to the high risk products in the field of "Active Implantable Medical Devices", is now fully applicable. Directive 93/42/EEC concerning Medical Devices" deals with a large range of products from rubber catheters and blood bags to Anaesthesia Machines or X Ray/Imaging Devices. This commenced application in January 1995 and will be applied fully by June 1998. The third and last part of the legislative programme dealing with "In Vitro Diagnostic Medical Devices" is being published as a Commission proposal at this time.
The Directives will ensure that only products which have been through suitable processes to ensure that appropriate essential requirements, as specified, have been followed, can be sold for use in the Community. It also means that the different standards which have existed, in terms of safety and useful operation, in different Member States will be replaced by a harmonised process of acceptance which will apply throughout the Community, thus ensuring free movement of effective, safe products.
The Directives indicate in the preamble the intention to "harmonise in order to guarantee the free movement of such devices within the internal market" - "for the safety and health protection of patients, users and, where appropriate, other persons".

### 2.2.1.2 Case law "free movement of goods"

16. Public health protection is explicitly referred to in Article 36 of the EC Treaty as justification for national measures prohibited under Articles 30 and 34. It may also constitute an imperative requirement which Member States may legitimately pursue, in accordance with the case law of the Court of Justice (particularly the "Sandoz", "Van Bennekom" and "German Purity Law" judgments). According to this case law, it is the responsibility of the Member States to determine the level to which they intend to protect public health. However, the Court places two limitations on this right:

- a Member State may lay down requirements for imported products which are stricter than those with which they already comply only if this is justified from the scientific point of view, unless existing uncertainties call for doubt or caution to be exercised;

- national regulations adopted to protect public health must be appropriate and in proportion to the objective.

On 1 June 1994 the Court of Justice delivered a further judgment referring to Article 30 and the protection of public health: Case C-317/92 on the use-by date for medicinal products.

17. Health protection aspects have also been covered by judgments of the Court. Case law relating to Article 36 of the EC Treaty is of interest here. For example:

a) Judgment of 27 April 1993, Commission v. Greece, Case C-375/90: the Court upheld Greece's action under Article 36 justified by the presence of salmonella in frozen chickens: if a *risk* of contamination may present a hazard to human health, it is the responsibility of the Member State, in the absence of harmonisation, to determine the level of protection to be provided, while complying with the requirement to ensure free movement of goods.

b) Judgment of 22 June 1993, Gallagher, Case C-11/92: if a Directive states that public health warnings to be printed on cigarette packets must cover *"at least 4%"* of the surface area, a Member State may require, as far as domestic production is concerned, that the indications should cover *"at least 6%"* since packets which conform to the Directive are ensured free movement. A wording of the type used by the Directive establishes only a minimum level of harmonisation.

c) "Contact lenses" judgement of 25 May 1993, Case C-271/92: a law prohibiting the sale of contact lenses by persons not qualified as opticians is justified on the grounds of protection of public health. The Court refers to the Aragonesa judgment of 25 July 1991 (Cases C-1 and 176/90) according to which Article 36 allows Member States, in the absence of harmonisation, to determine the level of public health protection, while respecting the principle of proportionality.

d) "Van der Veldt" judgment of 14 July 1994, salt content of bread, Case C-17/93:

*"As the Court has consistently held, in the absence of common or harmonised rules on the making and marketing of bread and other bakery products, it is for Member States to regulate all matters relating to the composition, making and marketing of those foodstuffs on their own territory, provided that they do not thereby discriminate against imported products or hinder the importation of products from other Member States* "see judgments of 19 February 1981, Kelderman, 130/80, ECR 527 and 7 February 1984, Jongeneel Kaas et al., 237/82, ECR 483)" (ground No 10).

The extension of national regulations on the maximum salt content of bread and other bakery products to products originating in other Member States which do not have identical manufacturing standards would require those States to vary the method of manufacture according to the place where the bread or bakery product in question was to be sold and thus impede the movement of products lawfully produced and marketed there (ground No 11).

Although the (Belgian) national legislation was adopted with a view to protecting consumer health, the Court holds that this cannot be regarded as justification for the measure concerned (Article 36 of the EC Treaty).

The Belgian authorities were limited *to expressing the opinion that the levels permitted (in other countries) were too high.*

In this connection the Court adds that:

*"General conjecture of that nature does not prove that increasing salt intake by such an amount poses a risk for public health. It is true that, as the Court has already held (see judgment of 6 June 1984, Melkunie, Case 97/83, ECR 2367), the fact that there is a risk to consumers is sufficient to make legislation of the kind at issue compatible with the requirements of Article 36. However, the risk must be measured, not according to the yardstick of general conjecture, but on the basis of relevant scientific research (see, in particular, the judgment of the Court of 12 March 1987, Commission v. Germany, Case 178/84, ECR 1227)"* (ground No 17).

## 2.2.2 Mutual recognition of health profession diplomas

18. Health protection has always been a high priority in the field of mutual recognition of diplomas of the health professions in particular doctors, nurses, midwives, pharmacists, dentists and veterinarians. The Directives concerning these diplomas are based on the free movement articles of the Treaty, 49, 57 and 66 and aim to facilitate the right of free movement of professionals trained in the Community in accordance with comparable standards of training. These standards are co-ordinated, minimum standards.

However, Advisory Committees on the training of these professionals, set up to support the Directives, have the sole task of helping to ensure that the comparable standards are maintained at a high level by reviewing them and making recommendations. The work of these Committees is aimed at national training and therefore helps to ensure highly trained health professionals which in turn contributes to ensuring health protection in the Community.

## 2.2.3 Data protection

19. The common position adopted by the Council (Internal Market) of 20 February 1995 on the amended proposal for a Directive on data protection takes full account of the conclusions of the Council (Health) of May and December 1993 on the implications of this proposal for medical research and for social and health services.

While preserving the Directive's general character, the Council has added to the derogation introduced for the maximum period for storing data for historical, statistical or scientific purposes (Article 6(1)(c)) a number of clarifications, notably in Article 6(1)(b) on the compatibility of processing for such purposes with the processing of data collected for other, specified purposes, or again in Article 11 on the provision of information to individuals. The scope of optional derogation from the right of access to data processed for such purposes has been extended (Article 13(2)). The thirty-fourth recital expressly mentions scientific research and statistics as being fields in which an important public interest might justify derogations from the ban on processing sensitive data on the basis of Article 8(4).

Exceptions to the prohibition on the processing of data revealing racial or ethnic origin, political opinions or religious or philosophical beliefs or of data concerning health or sex life, have been added in order to cover justified needs, essentially in the medical and employment fields, subject to suitable safeguards.

Derogations for reasons of important public interest and derogations from the rules governing the processing of data relating to offenses, criminal convictions or security measures must be notified to the Commission.

## 2.2.4 Trans-European networks

20. As regards the health-related projects in the context of the telematic interchange of data between administrations in the Community (IDA)[23], the Commission proposal for a Council Decision on support for IDA foresees three projects in the field of health, namely CARE (two projects : early warning system and pharmacovigilance) and REITOX (European Information Network on Drugs and Drug Addiction which will be at the disposal of the European Monitoring Centre for Drugs and Drug Addiction). The two care projects retained in IDA are spin-offs of earlier efforts on the European Nervous System (ENS-CARE). ENS-CARE was allocated a budget of 4,248 MECUS over the period 1991 to 1993; its current situation permits the gradual passage from the pilot to exploitation phase, with the general architecture and infrastructure for communicable diseases, statistics, poison control and pharmacovigilance deemed very satisfactory, as is the common technical approach developed for a variety of health applications. Under current IDA plans, CARE-Early warning system (CARE-EWS) work will concentrate over the next two years on development of the pilot system between national administrations, while strictly adhering to the general system architecture foreseen for IDA.

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(23) OJ No C 105, 16.4.1993

## 2.3. Competition policy

21. Generally speaking, Community competition policy does not play a major role in the field of health. This is largely explained by the fact that in the Member States health is considered to be a matter of public welfare and is covered by a regulatory framework; as a result, it is not the subject of anti-trust measures.

This situation differs, for example, from that in the United States, where competition policy plays a very active role in the health sector owing to the different regulatory framework which makes greater provision for private-sector activity. Taking into account the difference in the overall approach to the subject of the model society and social dialogue, this diversity in the field of health is expected to continue.

22. Community competition policy plays an active part in the *pharmaceutical product sector*. Several matters have been addressed by the Commission in this field. The most sensitive aspects are the *financing of research and development*, which is very significant and may give rise to inter-company cooperation or public grants, as well as major price differentials for drugs in the Community as a result of practices in both the private and public sectors.

23. Referring to the first of these aspects, the Commission has recently decided to exempt from the ban on restrictive practices the cooperation agreement under which Merck & Co Inc. and the indirect subsidiarity of Rhône-Poulenc, Pasteur-Mérieux (serums and vaccines) have joined forces to pursue their EC and EFTA activities relating to vaccines for human use through a new joint company. This decision, taken under Article 85 of the EEC Treaty and Article 53 of the EFTA Agreement, is based mainly on the importance of the expected benefits for public health in general and the vaccination of children in particular.
As far as State aids are concerned, Article 92 (3) (c) makes provision for the possibility of a derogation from the principle of incompatibility with the common market for aid to facilitate the development of certain activities. In the field of health, this derogation is applied in particular to research and development aid.

24. As for the problem associated with *medicinal product price differentials*, the Commission has already dealt with or is in the process of dealing with various matters in such a way as to allow parallel imports within the European Union from countries where producers are less expensive.

On one occasion in the past the Commission fined the pharmaceutical concern Sandoz Prodotti Farmaceutici S.p.a. the sum of ECU 800 000 under Article 85, for imposing export bans on its clients. It is currently considering the case of a commonly used medicinal product, the price of which is up to three times higher in some Member States than in others.

## 2.4. Research and technology

25. The overall objectives of Community Research and Technological Development (RTD) policy are defined in a chapter of the Treaty on European Union, and in particular in Article 130f.

This policy is carried out by means of successive Framework Programmes, each made up of Specific RTD Programmes covering different research sectors and which are prepared taking account *inter alia* of the research needs of other Community Policies and of Member States' views, e.g. on matters such as health protection requirements.

26. Health issues are directly and indirectly covered by the 4th Framework RTD Programme adopted in 1994 for a duration of five years with a budget of 12.3 billion ECU. The programmes, research areas and topics most relevant to health include:

- Biomedicine and Health[24] e.g. vaccine development in liaison with the following programme,
- Biotechnology[25];
- Agriculture and Fisheries[26], e.g. aspects of food safety and hygiene ;
- Environment and Climate[27] (complementing the relevant activities in Biomedicine and Health ) ;
- Telematics Applications in the area of health care[28] ;
- Industrial and Materials Technologies (relevant to the working environment) ;

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(24) Council Decision 94/913/EC of 15 December 1994 adopting a specific programme of research and technological development, including demonstration, in the field of biomedicine and health (1994 to 1998), OJ No L 361 of 31/12/94 p.40

(25) Council Decision 94/912/EC of 15 December 1994 adopting a specific programme of research and technological development, including demonstration, in the field of biotechnology (1994 to 1998), OJ No L 361 of 31.12.1994, p.25

(26) Council Decision 94/805/EC of 23 November 1994 adopting a specific programme of research, technological development and demonstration in the field of agriculture and fisheries 'including agro-industry, food technologies, forestry, aquaculture and rural development (1994 to 1998), OJ No L 334 of 22/12/1994, p.73

(27) Council Decision 94/911/EC of 15 December 1994 adopting a specific programme of research and technological development, including demonstration, in the field of environment and climate (1994-1998), OJ No L 361 of 31.12.1994, p.1

(28) see Council Decision 94/801/EC of 23 November 1994, adopting a specific programme of research and technological development, including demonstration in the field of telematics application of common interest, OJ No L 334 of 22 December 1994, p.1

- Standards, Measurement and Testing[29], including standards related to health care and the application of legislation on environmental and worker protection;

- The Targeted Socio-Economic Research Programme[30] will address the socio-economic factors concerning protection of the health and safety of workers, including cross-national cost-benefit analyses of preventive health and safety policies ;

- Scientific and Technical cooperation with Developing countries[31], including research on agriculture, environmental protection and health, the latter covering work on health systems, prevention of predominant diseases and health interventions ;

- Nuclear Fission Safety within the European Atomic Energy Community (EAEC)[32], aims to ensure the safety of all nuclear activities whatever they are, including the integration of radiological protection into a global system for the protection of man and the environment.

- The training and Mobility of Researchers programme[33] will continue to provide support to networks of laboratories, research grants and Euro-conferences on health matters.

27. Biomedical and health research at European Community level started in 1978 and has grown steadily in size and content, from three research networks then, to around 400 in 1994, with more than 6 500 research teams in 17 countries, i.e. the European Union plus Iceland and Norway.

Biomedicine and Health[24] under the 4th Framework Research Programme, with a budget of ECU 336 million covers the following seven target areas:

Area 1: Pharmaceuticals research;
Area 2: Research on biomedical technology and engineering;
Area 3: Brain research;
Area 4: Research on diseases with major socio-economic impact;
Area 5: Human genome research;
Area 6: Public health research, including health services research;

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(29) Council Decision 94/803/EC of 23 November 1994 adopting a specific programme for research and technological development, including demonstration, in the field of standards, measurements and testing (1994 to 1998), OJ No L 334 of 22/12/1994, p. 47

(30) Council Decision 94/915/EC of 15 December 1994 adopting a specific programme of research and technological development, including demonstration, in the field of target socio-economic research (1994 to 1998), OJ No L 361 of 31/12/1994, p. 77

(31) Council Decision 94/807/EC of 23 November 1994 adopting a specific programme of research and technological development, including demonstration in the field of cooperation with third countries and international organizations (1994 to 1998)

(32) Council Decision 94/920/Euratom of 15 December 1994 adopting a specific programme of research and training in the field of nuclear fission safety (reactor safety, waste management and radiation protection) (1994 to 1998)

(33) Council Decision of 15 December 1994 adopting a specific programme of research and technological development, including demonstration, in the field of training and mobility of researchers (1994 to 1998), OJ L 361 of 31.12.1994, p.90

Area 7: Research on biomedical ethics

Close links are being established between the research programmes, in particular in areas 4 and 6, and the Communities action programmes and activities in the field of public health. Under area 4, 22% of the overall budget is devoted to cancer, AIDS, tuberculosis and other infectious diseases as well as to occupational and environmental health. These topics are also public health priorities.
Area 6 (public health research), with 10% of the total budget, will underpin the public health initiatives taken in the context of Article 129 of the Treaty. To that effect, research will be focused initially on the following, among other sub-areas :

- Research into methodologies linked to *health data* on demographic changes, morbidity and mortality in the general population and in specific groups, such as socially deprived groups, in order to identify health needs, using new indicators as appropriate.

- Research into methods of evaluating the *effectiveness of prevention strategies*, including health education, in the Member States.

- Assessment of the socio-economic impact and performance measurement of *health policy initiatives*, including the development of *health information systems*.

## 2.5. Education, vocational training and youth

28. Until the entry into force of the Treaty on European Union, Community action in this field was based primarily on the provisions of the EEC Treaty concerning vocational training, plus where necessary acts adopted by the Education Ministers meeting within the Council. It is now based on Title VIII, Chapter 3, of the EC Treaty, which covers education, vocational training and youth.

The objective of Community programmes is to help sustain the quality of education and training by encouraging cooperation between Member States and the inclusion of a European dimension in teaching. Cooperation takes various forms, including student and teacher mobility, academic recognition of diplomas and exchanges of information on known problems, particularly through voluntarily created networks of establishments.

The Commission does not attempt to exercise a general influence on the sectoral composition of such cooperation schemes. However, health is well represented. For example, the Erasmus programme has supported 13 inter-university cooperation programmes in the fields of public health and health care, the fight against cancer and the prevention of drug addiction, with total funding of ECU 158 million being granted to 111 higher education establishments. The Comett programme, which above all encourages the strengthening of transnational links between universities and businesses in the field of technology, has co-financed the creation of two networks concerned with biomedical engineering and biomagnetism respectively, as well as training modules covering subjects such as computerised planning for dealing with health and environmental questions or training on questions of health and hygiene at the workplace.

29. The Petra and Youth for Europe programmes are more directly involved in health protection. Petra, which is concerned with vocational training for young people and their preparation for adult life, has helped to finance youth initiative programmes managed by young people themselves. 50 such projects, with total financing of the order of ECU 240 000, are directly concerned with prevention, covering subjects such as information and counselling relating to alcoholism, drug addiction and AIDS, etc. Petra has also financed the creation of training modules and training for instructors. Youth for Europe supports cooperation and exchanges between young people outside the school environment, and here as well young people are extensively involved in setting up projects. The result has been more than 40 projects mainly or partly concerned with health themes, particularly drugs, alcohol and sexuality, including AIDS.

## 2.6. Transport

30. In the field of the Common Transport Policy, health protection requirements are addressed primarily through measures to improve transport safety, thereby reducing accidents.

On roads alone, there are 50 000 deaths and some 1.5 million victims of accidents each year. In addition, accidents on the railways, in the air and at sea contribute to an enormous human cost, and a financial cost estimated between 45 and 90 MECU per annum.

31. Under the new Treaty provisions, safety is recognised as an integral part of the Common Transport Policy. The Commission has responded to this significant development with a series of concrete proposals aimed at raising the level of transport safety generally.

32. Particular attention has been paid to maritime safety, both for the sake of passengers and crew, and to minimise the consequences arising from marine pollution. The Commission's Communication on a Common Policy for Safe Seas[34] adopted in early 1993 was followed by a series of proposals for the *improvement of safety at sea.* In particular, the Commission proposed a complementary measure to its earlier ship reporting proposal[35] to address all ships in European waters, not just those calling at EC ports[36]. In March 1994, the Commission adopted a proposal to render more effective throughout the Community port state control of vessels[37]. The Council adopted in November 1994 a Directive[38] on the minimum level of training of seafarers which will improve the level of training of seafarers in recognition of the contribution which human error plays in accidents at sea.

33. Following the Communication for an Action Programme on Road Safety[39] in 1993, the Commission brought forward proposals to harmonise regulations along the lines of the UN-ECE European Agreement concerning the international carriage of dangerous goods

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(34) COM(93)66 of 24.02.1993
(35) Directive 93/75/EEC of 13.09.1993
(36) COM(93) 647 of 17.12.1993
(37) COM(94) 73 of 16.03.1994
(38) Council Directive 94/58/EC of 22.11.1994, OJ No L 319 of 12.12.1994
(39) COM(93) 246 of 09.06.1993

by road (ADR)[40] and to improve and ensure compliance through uniform procedures for checks on the transport of dangerous goods[41]. The Council adopted in November 1994 a Directive[42] on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road and agreed on a common position on the control Directive.

34. At its meeting in November 1993, the Council approved the Commission's Action Programme on Road Safety and also decided to establish a Community database on road traffic accidents[43] that will enable an in depth analysis of the situation for well defined Groups involved in such accidents. In addition the Council decided that *1995* would be the *Year of the Young Driver,* the objective of which would be to address the population group most frequently involved in *road traffic accidents.*

35. In addition to developments in air transport[44] and rail transport[45] in the context of the Transport RTD[46] Programme, the Commission's research effort will address transport safety issues. In particular the air, rail, waterborne and road transport sectors of this programme have sub-areas dedicated to safety issues. Also within the framework of COST (European cooperation in the field of scientific and technical research) safety aspects will continue to be considered. In particular, three programmes currently in force or envisaged concern safety, namely the safety of motorcycle helmets (COST 327), Requirements for road markings (COST 331) and Models for traffic and safety development (COST 329), and the safety aspects of low floor bus operation and design are included in COST 322.

## 2.7. Telecommunications

36. Telematics technologies can contribute to an improvement of *health care and the communication of health-related information* throughout the European Community. The main ways in which they can have an impact are on:

- improvement of health resources management and administration;
- more efficient provision of care by practitioners, through the availability of accurate medical data;
- better matching of recipients and potential donors for organs and tissue transplants;
- seamless medical care across borders thanks to an adequate flow of information between health centres and administrations;
- availability of expertise regardless of the location of patients with the help of telemedicine;
- use of commonly agreed sets of computerised medical records, including patient data cards;

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(40) COM(93) 548 of 24.11.1993
(41) COM(93) 665 of 15.12.1993
(42) Council Directive 94/55/EC of 21.11.1994, OJ No L 319 of 12.12.1994
(43) Decision 93/704/EC of 30.11.1993
(44) COM(93) 406 of 01.09.1993
(45) COM(93) 678 of 15.12.1993
(46) Council Decision 94/914/EC of 15 December 1994 adopting a specific programme for research and technological development, including demonstration in the field of transport (1994 to 1998), OJ L 361 of 31 December 1994, p. 56

- improvement on the education of health care providers, managers, and citizens through the use of advanced learning technologies;
- better geographical coverage of scattered or isolated populations;
- better integration of the disabled and the elderly through technologies including telematics.

The above points are expected to result from the Telematics Applications Programme[28], in its sectors of health care (formely AIM), education and training (formely DELTA), disabled and elderly (formely TIDE), administrations (formely referred to as ENS), urban and rural areas and research networks ; the budget for the period 1994-1998 in the area of health care amounts to ECU 135 million. Other aspects of potentially positive impact on health include: telematics for the environment, telematics for multimodal transport and teleworking (the latter is covered under both the Telematics Applications Programme and the Advanced Communications Technologies and Services Programme).

37. Another important aspect of the Telematics Programme is the *improvement of biomedical research practices* and outcomes owing to better access to information databases and specialised literature sources, as a result of the work in the Libraries Sector of the Telematics Applications Programme, and the IMPACT and VALUE Programmes.

38. With regard to hand-held radiotelephones, the Commission has recently presented a Green Paper on mobile and personal communications in the European Union and a Communication to the European Parliament and the Council on consultation on this Green Paper, together with a proposal for a Council resolution on the further development of such communications[47]. Comments on the Green Paper have confirmed that the public is concerned with the potential hazards to humans on the one hand, and the potential for electromagnetic interference with other electronic equipment such as safety devices, pacemakers and hearing aids on the other.

As regards hazards to workers, the Commission has recently presented a modified proposal for a Council directive, based on Article 118a as mentioned in section 2.10.3 of this report. As regards the general public, the Commission noted that there was broad support for the setting up of action programmes to assess the impact of radio frequency radiation on human health and safety and to accelerate the development of the necessary safety standards.
The Commission accepts that there is a need for further research, surveys and investigations in the area of biological effects of and exposure to electromagnetic fields in the frequency range concerned by mobile and personal communications. In particular, urgent work needs to be undertaken with regard to the so-called "athermal effects" so as to obtain sound data on the role of electromagnetic fields at these frequencies on cancer initiation or tumour promotion. The Commission will support such work, both in the context of action programmes in the field of public health and in the context of COST programmes.

Finally, the Commission is supporting programmes for the establishment of standards in this field aiming at translating into operational quantities and measurement methods and

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(47) COM (94) 145 final of 27.4.1994, and COM (94) 492 final of 23.11.1994

procedures the limits and requirements laid down by Community legislation. The Commission has already forwarded standardisation mandates to CEN/CENELEC concerning the development of standards for thermal effects and of a programme of work on future standards for possible athermal effects.

39. A related area of policy development is work towards the so-called "Information Society" which is intended to consider the indications of the development of new information and telecommunications technology for society and how it can be used to help overcome social problems. In this context the health consequences of these new developments will also be carefully considered.

## 2.8. Consumer policy

### 2.8.1 General product safety

40. Directive 92/59/EEC on general product safety, adopted by the Council on 29 June 1992[48] entered into force on 29 June 1994. This Directive, which applies insofar as other Community product legislation do not lay down safety provisions, obliges producers to place only safe products on the market. Producers shall also provide consumers with the relevant information to enable them to assess the risk inherent in a product and have a system for taking appropriate action in case of risks. Distributors shall act with due care, as professionals, to ensure compliance with the general safety requirement.

The Directive imposes a duty on Member States to adopt the necessary provisions to make producers and distributors comply with their obligations, and to establish authorities to control products on the market. The Directive also lays down a rapid exchange of information procedure for products presenting a serious and immediate risk to the health or safety of consumers.

41. The objectives of the European Home and Leisure Accident Surveillance System (EHLASS) are to organise and coordinate the collecting of data on *home and leisure accidents* with a view to promoting accident prevention, informing and educating consumers so that they make better use of products, and if necessary improving the safety of consumer products.

The system foresees two ways of collecting data. Nine Member States have chosen to collect the data through a network of hospitals while three Member States (Germany, Luxembourg and Spain) use the method of household surveys. For the continuation of this system the Commission in February 1994 adopted a proposal for the period 1994-1997, which was subsequently adopted by the Council and the European Parliament on 7 December 1994[49].

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(48) OJ N° L 228, 11.08.1992, p. 24

(49) Council and European Parliament Decision 3092/94/EC, OJ No L 331, 21.12.1994, p.1.

42. Financial support may be given to information campaigns and studies covering certain aspects, e.g. actions concerning special risk groups such as children and elderly people or products/activities with a high level of risk which require special attention.

## 2.8.2. Safety of cosmetic products

43. The Cosmetics Directive 76/768/EEC[50], as most recently amended by Commission Directive 94/32/EEC[51] of 29 June 1994, is designed to safeguard human health in the context of the establishment and functioning of the internal market.

This Directive lays down, at Community level, the regulations which must be observed as regards the *composition, labelling and packaging* of cosmetic products. It includes various technical annexes containing lists of prohibited substances, substances which cosmetic products must not contain except subject to the restrictions and conditions laid down, and three positive lists relating to colouring agents, preservatives and UV filters. These lists are regularly amended to adapt them to technical progress, on the basis of a procedure involving a *Committee on Adaptation to Technical Progress*, which evaluates the safety of each substance in terms of human health after consulting a *Scientific Committee on Cosmetology*.

44. On 29 June 1994 the Commission adopted the 17th Directive adapting the Cosmetics Directive to technical progress.

1994 also saw the continuation of work relating to implementation of Council Directive 93/35/EEC of 14 June 1993, amending for the sixth time Directive 76/768/EEC, in particular so as to be able to establish, within the required time, a *list of ingredients used* in cosmetic products, conditions and criteria relating to the confidentiality of certain data, and a report on progress in the development, validation and legal acceptance of alternative testing methods to those involving experiments on animals.

## 2.8.3. Safety of toys

45. In this field, the health protection of users, e.g. children, or third parties, is taken into account in the Council Directive 88/378/EEC adopted on 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys[52]. This Directive foresees in particular safety requirements concerning *health hazards linked to chemicals compounds*.

As a general principle, toys must comply with the relevant Community legislation relating to certain categories of products or to the prohibition, restriction of use or labelling of certain dangerous substances and preparations (such as Directives 67/548/EEC on dangerous substances and 88/379/EEC on dangerous preparations). Moreover, the authorised bioavailability of heavy metals (antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium) is listed in Directive 88/378/EEC.

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(50) OJ No L 262, 27.9.1976.
(51) OJ No L 181, 15.7.1994.
(52) OJ No L 187, 16.07.1988.

46. In order to facilitate proof of conformity with the essential requirements for health protection, the Commission has given mandates to the European Committee for Standardisation (CEN) to establish harmonised standards at European level on the migration of certain elements (e.g. the heavy metals listed in the directive on safety of toys), experimental sets for chemistry and related activities, and chemical toys or sets other than experimental sets (such as photographic development sets). Another mandate in this field will be given by the Commission to CEN in the course of 1995 for a new European standard on organic chemical compounds.

## 2.9. Economic and social cohesion

### 2.9.1. European Regional Development Fund (ERDF)

47. Investments in *education and health* in Objective 1 regions (regions lagging in development, with a GDP generally less than 75% that of the Community average) are now included in the scope of the ERDF following the adoption by the Council on 20.07.1993 of the revised Regulations governing the Community's Structural Funds ; the scope of the ERDF remained otherwise broadly the same as before. The Council Declaration accompanying these regulations gave *priority in the field of health to basic health facilities in under-equipped areas.*

48. Member States submitted a total of 17 Objective 1 plans to the Commission which were assessed on the basis of the following specific key criteria : the quality of the plans in relation to the new regulations ; the quality of the proposed strategy and relevance of the measures ; the introduction of innovation. As part of this process an analysis has been undertaken to assess how the Council Declaration relating to health has been interpreted in the Objective 1 plans.

Given the very recent introduction of the possibility of using ERDF in the health field, it might be expected that the number of projects submitted would be relatively limited.

In general terms the use of the extended scope of ERDF in the Objective 1 regions has been primarily confined to *hospital/health centre construction and renovation* in the four Cohesion Fund countries (Ireland, Greece, Portugal and Spain). Other measures also concern the purchase of *medical equipment.* The projects agreed amount to around MECU 2,000 with a total proposed Community contribution of MECU 1,350 representing an average co-financing rate of 65 %. (The total ERDF budget for 5 years is around 100 BECU). The projects are located in Belgium, French Overseas Departments, Greece, Ireland, Portugal and Spain.

49. However, among the projects submitted and financed some were related to improved training facilities and *training of health staff* in areas such as *public health* as well as *prevention* and *health promotion* facilities and actions.

In Portugal the third of the three measures proposed concerns the provision of basic *training for health staff* as well as retraining of existing personnel for the demands of modern medicine. In the French overseas Department of Martinique the economic

insertion project includes measures to facilitate the access of marginalized populations to health services.

In Greece in addition to the modernisation of the infrastructure of health services (including the setting up of a national centre for emergencies and telemedecine services) and of the management of hospitals and the training and retraining of health staff, it is foreseen to establish a national blood transfusion centre contributing significantly to improving blood safety and availability.

A particular project with relevance to *prevention* is to be found in the programme for Hainaut, Belgium. This relates to the prevention of major diseases (cardiovascular diseases, liver cirrhosis, cancer of the uterus and pulmonary tuberculosis). For these conditions the incidence rate is more than twice the national average. The project aims at improving the health situation of the most affected populations and at decreasing, through prevention actions, the economic and social cost of these pathologies. The health structures, professionals and NGOs of five cities will be involved in the 6 year project of 5 MECU with a 50% financing by the ERDF.

## 2.9.2. European Social Fund (ESF)

50. The reform of structural policy has led to far-reaching changes in the tasks and activities of the ESF. In this new situation the ESF takes action to support a policy which aims both at encouraging active measures in the employment market and at improving the general conditions for *making full use of the human factor*. This is a policy which gives much clearer recognition than in the past to the importance of intersectoral links between education/training/employment and other forms of human resources development such as health protection.

51. The ESF's health-related objectives may be identified in the new Community Support Frameworks (CSFs) for 1994-99, which have been established in partnership with the responsible authorities in the Member States. The main aims of the policy adopted in this field may be summarised as follows:

52. *a) To strengthen health system structures*

This aim is specific to the Community's regions which are lagging behind (Objective 1 regions) and consists in reducing the existing disparities between these regions and the most developed ones.

To achieve this, the Structural Funds provide support for national policies designed to modernise health systems by allocating substantial sums either to improve infrastructure and equipment (ERDF) or to develop the human potential employed in the sector (ESF).

More specifically, ESF action is concentrated firstly on initial and continuing training for health professionals, placing emphasis on the promotion of qualifications linked to new medical technologies and new prevention services, and secondly on training for administrative staff in order to facilitate the application of new management methods.

53. *b) To facilitate the social and occupational integration of categories of persons exposed to the phenomena of drug addiction and alcoholism*

This is an integral part of a much broader policy to assist persons exposed to exclusion from the labour market. The aim is twofold: initially to combat the isolation of the groups of persons exposed to drug addiction/alcoholism, and subsequently to create genuine prospects for integration through measures such as information, counselling, training and job creation.

54. *c) To promote health education in schools and training centres*

As part of its support for teaching and initial training, the ESF can contribute significantly to promoting health education. To date, initiatives in this area have been few and far between, which is why the ESF is planning to encourage national authorities to introduce specialisation training for teachers/instructors or specific measures in schools or training centres.

## 2.10. Social dimension

### 2.10.1. Employment

55. In the field of employment and labour market the main involvement with health policy to date has been via the directive[53] on *protection of pregnancy and maternity at work.* Pregnant women and women who are breastfeeding or who have recently given birth are entitled to protection from chemical, physical and biological agents and industrial processes which might put them at risk.

These hazards are listed in two categories. The first category includes those agents and processes which can potentially be hazardous, though the actual risk depends on a specific job description. Examples include physical conditions such as work that involves lifting, noise, tiring movements and postures, exposure to radiation, exposure to biological agents or to chemical agents such as mercury and carbon monoxide. Mental and physical fatigue and other types of stress are also covered.

The second category lists risks considered to be particularly harmful, such as exposure to toxoplasma and rubella virus, to lead and lead derivatives, and underground mining work, or work in pressurised enclosures and underwater diving. These hazards are prohibited.

56. Employers must accordingly adjust the working conditions of exposed workers, or transfer them as appropriate. If this is not possible, workers must be granted paid leave.

Guidelines setting out these hazards in detail are being drawn up by the Commission in consultation with the *Advisory Committee on Safety, Hygiene and Health Protection at Work* and the Member States.

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(53) Council Directive 92/85/EEC, OJ No L 348, 28.11.1992, p.1.

## 2.10.2. Social security and social action

57. . **Social Action**

The White paper on European Social Policy[54] refers to the significant links between public health and social and environmental policy. These include the adverse effects of poverty, unemployment and social exclusion on health and the increasing pressures on health and social protection systems caused by demographic changes, notably the ageing of the population; the role of preventive and rehabilitative health programmes in fostering social integration; the impact of environmental conditions on public health; and the specific health problems and needs arising from increased mobility within the Union and migration into it.

A report on the demographic situation in the Community[55], in accordance with Article 7 of the Social Protocol appended to the Maastricht Treaty, was adopted by the Commission in December 1994. This report analyses phenomena such as population ageing, migration, and the breaking up of family structures, which are at the root of new needs in terms of health, prevention, meeting the cost, and social protection .

58. . **Social Protection**

Council Recommendation 92/442/EEC on the *convergence of social protection objectives and policies* has laid down common objectives as guidelines for Member States' policies. In relation to sickness, the following three objectives are set out:

a) under conditions determined by each Member State, to ensure for all persons legally resident within the territory of the Member State *access to necessary health care* as well as to facilities seeking to prevent illness;

b) to maintain and, where necessary, develop a *high-quality health care system* geared to the evolving needs of the population, and especially those arising from dependence of the elderly, to the development of pathologies and therapies and the need to step up prevention;

c) to organise where necessary the *rehabilitation* of convalescents, particularly following serious illness or an accident, and their subsequent return to work.

59. In April 1994, following on from this Council Recommendation, the Commission adopted the first report on "Social protection in Europe"[56], which sets out to develop the

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(54) COM (94) 333 of 27 July 1994

(55) COM(94) 595 of 13.12.1994.

(56) COM(93) 531 of 26.4.1994.

exchange of information and analysis of Member States' policies. Chapter 7 reviews the measures implemented by Member States in recent years to contain the rise in *health care costs*, a preoccupation common to all Member States. The subjects to be covered by the second report on "Social protection in Europe", due to appear during 1995, include an analysis of the impact of these measures on the quality of the health care system and on equal access to care and prevention for all population groups.

## 2.10.3. Health and safety at work

60. In this field much work has been performed on health and hygiene at work and the prevention of occupational diseases.
The Commission has implemented three action programmes on safety and health at work since 1978, which were all the subject of Council resolutions. The third action programme was an essential complement to the social aspects of the development of the internal market. It was based on three fundamental concepts: 1) the need to push on with improving the safety and health protection of workers on a broad front; 2) the obligation to ensure that workers have adequate protection from the risks of work accidents and occupational diseases ; and, 3) the will to complement the internal market with measures on the safety and health protection of workers. With these three objectives in mind, the Commission decided to devote considerable effort to legislation, although the principles of providing all necessary information to workers enshrined in the earlier programmes was retained.
As concerns legislation, the principles of the legislative programme were to:
- cover a maximum number of risks with a minimum number of directives, in order to avoid fragmented legislation;
- cover the specific requirements of certain high-risk activities or sectors and of certain categories of workers who are particularly vulnerable;
- ensure consistency between Community provisions adopted as part of the completion of the internal market (Article 100a), which lay down the main safety and health requirements to be met in the design, manufacture and marketing products, and directives adopted on the basis of Article 118a, which relate to their use at the workplace.

61. Several directives are of particular relevance to public health. Article 14 of the Council Directive of 12 June 1989 on the introduction of measures to *encourage improvements in the safety and health of workers* at work (89/391/EEC)[57] provides for the health surveillance of workers appropriate to the health and safety risks they incur at work. This requirement is set out in more detail in several individual directives. For example, Council Directives 92/91/EEC[58] and 92/104/EEC[59] on the minimum requirements for improving the safety and health protection of workers in the mineral-extracting industries (drilling operations and surface/underground workings respectively) make provision for health surveillance for all workers before they are assigned to duties related to extraction activities and subsequently at regular intervals (Article 8). Council Directive of 29 May 1990 on the minimum safety and health requirements for work with display screen

(57) OJ No L 183, 29.6.1989, p. 1.
(58) OJ No L 348, 28.11.1992.
(59) OJ No L 404, 31.12.1992, p. 10.

equipment (90/270/EEC)[60] entitles workers to eye and eyesight tests and, if necessary, an ophthalmological examination (Article 9). Finally, Council Directive 92/29/EEC[61] of 31 March 1992 lays down the minimum safety and health requirements for improved medical treatment on board vessels.

62. In 1994 the Commission presented amended proposals for Council Directives on the protection of the health and safety of workers from the risks related to chemical agents at work[62] [63] and on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents[64] [65]. The latter introduces protective measures against the risks resulting from three further physical agents (mechanical vibration, optical radiation, and electro-magnetic fields and waves) and amends certain provisions on protection against noise.

On 18 July 1994 the Council adopted a Regulation[66] 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.
As announced in its Communication on the medium term social action programme[67] the Commission will present a communication, including a draft decision, on the Fourth Programme concerning Safety, Hygiene and Health Protection at Work (1995-2000) setting out the measures necessary in this area, and including a proposal for a specific programme SAFE to promote better awareness of health and safety legislation in small and medium-size enterprises. These measures will be complemented by actions undertaken under the proposed Community action programme on health promotion (1995-1999)[68].

## 2.11.Health protection and the environment

63. The physical environment has a major direct influence on human health not only through contaminated air, water and soil but also through the impact of the biological environment on food supply and on disease transmission mechanisms.

DG XI policy in implementing the "European Community Programme of Policy and Action in relation to the Environment and Sustainable Development" (Fifth Programme)[69] aims to develop a strategy which integrates environmental considerations in other policy areas and broadens the range of instruments that can be

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(60) OJ No L 156, 21.6.1990, p. 14.
(61) OJ N° L 113, 30.4.1992, p. 19
(62) COM(93) 155 final
(63) COM(94) 230 final
(64) OJ No C 77, 18.3.1993
(65) OJ No C 230, 19.9.1994
(66) Council Regulation No 2062/94, OJ No L 216, 20.8.1994, p. 1
(67) COM (95) 134 final of 12.4.1995
(68) COM (94) 202 - 94/0130 (COD)
(69) OJ C 138 of 17.05.1993, p. 1

used to achieve increased and more effective environmental protection and to ensure sustainable economic growth and more employment.

Environmental factors that could impair human health include:
- climatic change and global warming
- stratospheric ozone depletion
- atmospheric ozone concentration
- high concentration of sulphur and nitrogen oxides and of airborne particulates
- acidification of soils
- pollution of soils and of groundwater
- exposure to man-made noxious chemical agents and substances.

64. The Community is playing a major role in the wider international area and has taken an active part in the United Nations Conference on Environment and Development (UNCED) and participates in the Commission on Sustainable Development (CSD) set up at UNCED. The European Commission actively participated in the Second European Conference on Environment and Health in Helsinki on 20-22 June 1994 and is represented in the European Environment and Health Committee (EEHC), which has been established to take forward work on the follow-up to the Helsinki conference.

## 2.12. Energy policy

65. The production and use of energy can have either a direct or indirect effect on health conditions. This is why - although there is still not a common energy policy at Community level - the European Commission, together with the parties concerned, has since 1986 been working on the components of a Community energy policy which have contributed, among other things, to an improvement in living standards.

66. One of the aims of the strategy is to promote the well-being of citizens through the efficient and *rational production and use of energy*, thus having a positive impact in the area of public health.

The energy sector provides for direct measures to protect public health in its different areas of concern, for example through the Safety and Health Commission for the Mining and Other Extractive Industries, which establishes specific rules and obligations relating to worker protection that are considered to be among the most demanding in the world. The Euratom Treaty, moreover, dedicates its third chapter to health protection.

67. Since the production and consumption of energy may have a negative impact on the environment and adversely affect living conditions for the general population, over the years more efficient and sophisticated measures to protect the environment in the hydrocarbons, coal and nuclear sectors have been developed. These measures, although not directly aimed at public health, certainly have a positive effect on it.

Programmes such as THERMIE, ALTENER, SAVE, etc. have also been developed with a view to improving technology, using energy rationallly and efficiently, and using renewable resources. The aim is to achieve better living conditions in general and thus to help improve public health.

## 2.13. Agricultural policy

### 2.13.1. General objectives

68. The Commission is involved in the harmonisation of essential health requirements in relation to animals, products of animal origin and products of plant origin. Such actions are necessary in order to avoid the placing on the market of products which would present a hazard to human and animal health, and to ensure free movement of such products.

### 2.13.2. Legal context

69. Harmonisation of health rules for animals, products of animal origin and products of plant origin has been established *to protect the consumer and the livestock population* of the Community and to ensure free movement throughout the Community. This objective falls within the terms of Article 39 of the Treaty for the agricultural products mentioned in Annex II of the Treaty.

As the Court has held in its judgements[70], Article 43 of the Treaty is the appropriate legal basis for any legislation concerning the production and marketing of agricultural products listed in Annex II to the Treaty which contribute to the achievement of one or more of the objectives of the Common Agricultural Policy set out in Article 39 of the Treaty.

### 2.13.3. Strategy

70. *a) Veterinary control strategy is based on the following principles :*

- protection of human health and production of wholesome food in the hygienic processing, storage and distribution of raw animal products. A prerequisite is for food-producing animals to be in good health. In addition, a high "environmental health" level, i.e. a hygienic state in the environment around these animals and in agricultural inputs, is equally important,

- health checks on animals and animal products at the internal borders of the Community have been replaced by controls and checks carried out at the places of origin. Spot checks should be also carried out at the place of destination or elsewhere when there is reason to suspect that a problem exists,

- cooperation and coordination of measures,

- a scientific basis for the legislation and implementation decisions underpinned by the Community's own independent scientific committees and liaison laboratories,

- cooperation between the various services involved through exchanges of national officials, training courses, seminars, etc...

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(70) 23 February 1988 in cases 68/86 and 131/86

- information technology, ADNS, ANIMO and SHIFT systems,

- provision of a safeguard clause to enable rapid action to prevent a serious animal health or public health incident,

- financial assistance through a Community contribution to programmes for disease eradication and control, to the work of liaison and reference laboratories and to seminars and training courses,

- ensuring that the conditions for the placing on the market of animals and products originating from third countries are equivalent to those applied by the Community.

71. *b) Strategy in the field of plant products:*

- to ensure that plant protection products are, when properly used, safe to human and animal health and the environment,

- to ensure that levels of contaminants arising from agricultural production are safe for consumers,

- to facilitate cooperation and coordination of measures,

- to provide a science basis for legislation using independent scientific committees as necessary.

*c) Legislative action*

72. This entails the utilisation of a variety of different legal mechanisms covering the three major segments of the production cycle : upstream (pre-harvest), on-farm (production-harvest) and downstream (post-harvest processing).

73. The UPSTREAM elements cover regulation of agricultural inputs (e.g. pesticides, feedingstuffs), use of veterinary medicines, additives in feedingstuffs, production aids such as BST, wastes and contaminants.

74. The ON-FARM elements include the regulation of animal and plant health, conditions of production, including aquaculture animals, for public health purposes. Important zoonoses such as rabies, TB, brucellosis and salmonella are subject to Community-supported programmes of eradication or control. The objective is clear - a high standard of health on the farm and at primary production level. This approach continues to require common strategies and implementation, e.g. on disease control.

75. The POST-HARVEST elements cover the regulation of the movement conditions for animals and animal products, including food hygiene until it reaches the consumer. This has required legislation on food production hygiene, with specific provisions for the different product sectors such as meat, fish and dairy, tailored to the particular risks each

product poses, and requirements on the examination, monitoring and surveillance of and testing for the presence of microbiological and chemical contaminants.

## 2.13.4. Application

76. *a) Organisation of controls and inspections*

Throughout health legislation, the principal is maintained that the *prime responsibility* for checking compliance with Community requirements lies with the *manufacturer and producer*. They must ensure that the products of animal and plant origin they produce do not present hazards by carrying out the necessary checks on products and by applying the HACCP principles (Hazard Analysis Critical Control Points). The role of the *competent authorities of the Member States* is to ensure that the Community requirements are properly applied by control of Community health programmes, farming units and their inputs, food production establishments, production processes and subsequent movement of the product concerned. In certain cases, a special role must be attributed to officials of the competent authority which have to carry out specific inspection and certification tasks .

*b) Special actions and campaigns*

77. • **Tobacco sector**

The new Common Organisation of the Market (COM) in raw tobacco (Council Regulation (EEC) No 2075/92) takes extensive account of the health factor:

- The Community Fund for tobacco research and information has been set up under this new system. Its objective is to finance *measures to discourage and provide information on smoking* as well as scientific *research* with a view to steering tobacco production towards the *least harmful varieties*.
The Fund is financed by tobacco planters through a deduction from the premiums paid to them.
The rules for its application are set out in Commission Regulation (EEC) No 2427/93 of 1 September 1993[71].

- Article 14 of the Council Regulation makes provision for a *three-year programme for the conversion of plantations* of Mavra, Tsebelia, Forcheimer, Havana IIc and hydrids of Geudertheimer tobacco to varieties more in line with market requirements or to other agricultural crops. This programme was launched beginning with the 1993 harvest.

- Finally, the new COM is based on a *quota system* limiting Community production.

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[71] OJ No L 223, 2.9.1993

78. • **Wine and spirits sector**

Common wine and spirits policy is primarily a quality policy. The measures taken at Community level are designed to *safeguard product quality* by adopting descriptions relating to the production of these products. It is not just a question of preserving the intrinsic quality of wines and spirits, but also of fixing maxmimum contents of certain substances which affect consumers' health (volatile acidity, $SO_2$, etc.). Other specific provisions have been adopted solely to *protect consumers' health*, e.g. the ban on the use of lead in sealing capsules.

79. On a different note, there is clearly a rather delicate link between alcoholic beverages such as wines and spirits and health. *Excessive consumption* of such products is obviously *harmful to health*. Wine consumption in the European Community is *steadily falling* (by approx. 2% per year), and consumption of spirits is generally declining. The COM measures for wine are aimed at stabilising the market by adapting supply to this change in demand (grubbing, yield limitation, distilling of surplus production, etc.). Most distilled products are not used in the spirits sector, but find their way into other sectors (cosmetics, pharmaceuticals, paints, etc.) and even into the fuel industry, in order to avoid distortions of competition or interference with traditional markets. In view of the rather precarious situation of a large number of wine growers in the Community, it would seem advisable, while continuing to pursue a policy of health protection, not to adopt extreme measures which would be likely to aggravate the market imbalance without giving producers enough time to adapt to this situation.

80. • **Quality milk and beef and veal promotion programmes**

These programmes each contain a nutrition component, which is more advanced in the case of milk than meat. The promotion programmes for milk (Regulations (EEC) Nos 585/93 and 3582/93) include chapters on *nutrition* focusing on the benefits of foodstuffs containing milk (calcium and osteoporosis, growth in young children, nutrition for pregnant women). Since 1990 (Regulations Nos 1000/90 and 465/92) the Community has also financed the setting up of scientific databases covering the nutritional qualities of milk with regard to certain public health problems (growth, osteoporosis, cardiovascular disease) as well as data dissemination.

81. • **Olive oil promotion programmes**

These programmes include a section on the dissemination of scientific knowledge on the nutritional value of the product to the medical and paramedical professions and to the general public[72].

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(72) Communication from the Commission on the 6th action programme (end 1994-end 1996) to promote the consumption of olive oil, COM(94) 86 final of 22.03.1994.

## 2.14 Fisheries

82. There are currently a number of different activities relating to the protection of human health under the Common Fisheries Policy .

During the period 1991-1994 the Commission distributed a total budget of more than ECU 230 million among the Member States for the improvement of fishery product marketing and processing conditions. One of the priorities of this investment was to bring marketing and processing establishments *into line with health standards*. These guidelines remain in force under the reformed Structural Funds and are coordinated with and incorporated into other Community policies.

83. In 1993 the Commission also provided funding to the amount of ECU 0.2 million for measures in certain Member States to *promote the consumption of fishery products* on the basis of an epidemiological medical study illustrating the *positive impact* of an increase in the consumption of such products *on health in general* and in particular on the risk of cardio-vascular disease resulting from eating habits.

84. Several projects relating to hygiene and fishery products were also financed under the AIR research programme between 1991 and April 1994 (total funding ECU 3.8 million), and additional studies are planned. Furthermore, in view of the importance of the consumption of fishery products for health, special emphasis will be placed on this aspect in the measures designed to promote the consumption of fishery and aquaculture products.

## 2.15. A people's Europe

### 2.15.1. Taxation

85. As regards tax rates on manufactured tobacco products and alcoholic beverages, the Commission is required by Article 4 of Directive 92/79/EEC, Article 4 of Directive 92/80/EEC and Article 10 of Directive 92/82/EEC to carry out a review of rates every two years, taking account of the proper functioning of the internal market and the wider objectives of the Treaty. The first report[73] is being prepared and is expected to be transmitted by the Commission to the Council and European Parliament in the near future.

### 2.15.2. Public health

86. On the basis of Article 129 of the Union Treaty, the Commission has presented a Communication on the framework for action in the field of public health[74]. In this connection four priority action areas necessitating specific programmes were identified in 1994:

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(73) COM(94) 484

(74) COM(93) 559 final of 24 November 1993.

a) the fight against cancer, for which the Commission adopted a proposal for a European Parliament and Council Decision[75] adopting an action plan 1995-1999 to combat cancer[76].

b) the prevention of AIDS and other communicable diseases, for which the Commission, on 5 October 1994, adopted a proposal for a European Parliament and Council Decision[77] adopting a Community action programme on the prevention of AIDS and certain other communicable diseases[78].

c) prevention of drug dependence, for which the Commission, on 21 June 1994, adopted a proposal for a European Parliament and Council Decision[79] adopting a programme of Community action on the prevention of drug dependence (1995-2000)[80].

d) health promotion, information, education and training, for which the Commission adopted a proposal for a European Parliament and Council Decision[81] adopting a programme of Community action (1995-2000) - [82].

87. As required by the Council, the Commission presented a report in November 1994 on the implementation of the 1993 action plan of the "Europe against AIDS" programme 1991-1993,[83] as well as a report on the execution of the "Europe against Cancer programme" in 1993[84] and a Communication on blood safety and self-sufficiency in the European Community[85].
Moreover, the Commission's Action Programme on transport for people with reduced mobility[86] includes a medium-term measure for the enlarged scope of regulations banning/reducing smoking in all areas of transport (including as a workplace) in accordance with Council Resolution No. 89/C 189/01 of 18.7.1989 on banning smoking in places open to the public.

## 2.15.3. Solidarity

88. *a) Measures to help the disabled*

A Council Decision of 25 February 1993 established a third Community action programme to promote equal opportunities and the integration of disabled people, HELIOS II, from 1 January 1993 to 31 December 1996. The programme emphasises the

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(75) OJ No C 139, 21.5.1994, p.2.
(76) COM(94) 83 final - 94/0/105 (COD).
(77) OJ No C 333, 29.11.1994, p.34.
(78) COM(94) 413 final - 94/0222 (COD).
(79) OJ No C 257, 14.9.1994, p.4.
(80) COM(94) 223 final - 94/0135 (COD)
(81) OJ No C 252, 9.9.1994, p.3.
(82) COM(94) 202 final - 94/0130 (COD)
(83) COM(94) 525 final of 25.11.1994
(84) COM(94) 550 final of 5.12.1994
(85) COM (94) 652 final of 21.12.1994.
(86) COM(93) 433 final of 26.11.1993

development of exchange and information activities, and the cooperation of non-governmental organisations.

89. The Commission has also introduced a framework initiative on "Employment" which aims to contribute to the development of human resources, improve the workings of the labour market and promote social solidarity in the European Union. There are three strands within the initiative, one of which, HORIZON, gives priority to improving the employment prospects of disabled people.

90. *b) Measures to help older people*

Several measures relating to the health of older people were funded under the European Year of Older People and Solidarity Between Generations (1993). In 1994 the Commission financed the Community's "Healthy Ageing" operation organised by Eurolink Age.

## 2.15.4. Human rights and fundamental freedoms

91. **. Ethical aspects of biotechnology**

In November 1991, in the context of the policy to promote the competitiveness of the biotechnology industries (*Communication SEC (91) 629 final, White Paper on Growth, Competitiveness and Employment*), the Commission set up a *group of advisers on ethical implications in biotechnology*. The mandate of this independent group is to give its opinion to the Commission on the ethical questions arising in the various applications of biotechnology, i.e. health, agriculture, agrifood industry and the environment. In the medical field, biotechnology offers considerable hopes in respect of treatment or diagnosis of genetic or acquired diseases. New methods of treatment, which are often only at the experimental stage, involve risks and raise questions, particularly in terms of ethics. The group of advisers devotes special attention to such matters. In March 1993 it adopted an opinion on *products derived from blood or human plasma*, and in December 1994 it delivered an opinion to the Commission on the ethical implications of *gene therapy*.

## 2.15.5. Information and culture

92. In the context of the EUROBAROMETER surveys carried out for the Commission, special surveys were designed to reveal Europeans' attitudes, opinions and levels of knowledge concerning drugs, cancer and AIDS.

93. In cooperation with the Council of Europe, the Commission has this year been working on two information campaigns where *sport and health* have been important elements. On the basis of the code of ethics in sport drawn up by the Council of Europe, a *fair-play campaign* was established in 1993. The code of ethics underlines, among other things, the need to combat drugs, doping, the use of alcohol and violence and to emphasise sport's role in fostering social relations and well-being. It also stresses the responsibility on sportsmen and women, and on those in their immediate circle (clubs, coaches, parents). The campaign's target groups are athletes and especially youngsters.

T-shirts, stickers and posters have been distributed through sport organisations, the Commission Offices, at different sport events, sports conferences, etc. throughout 1994.

94. *Europack - information on doping* : the second information campaign in cooperation with the Council of Europe is an educational product, which has the objective of supplying national and/or international (sports) organisations responsible for health care, or more specifically, for education on anti-doping, with materials on education in this area.

## III. HEALTH PROTECTION ASPECTS IN EXTERNAL RELATIONS

### 3.1. Relations with third countries

95. In the relations between the European Community and third countries, health protection is included in both bilateral and regional programmes.

For example, drug demand reduction is a key element of the Commission's multidisciplinary international drug programmes. These programmes encompass :

- Measures covering primary and secondary prevention, epidemiology and training in priority countries and regions such as the Mediterranean Basin, the Middle East and Central and Eastern Europe.

- In the framework of North/South cooperation on Drugs, part of the 10 MECU budget in 1994 is devoted to prevention and health aspects: a joint Commission/UNESCO activity is currently establishing a world-wide network of NGOs active in the field, including those active in intra-Community programmes;

- In the PHARE Regional Programme on Drugs covering 11 PHARE countries (12 MECU for two years), a significant part is devoted to health prevention aspects, including education and training; links have been established between the actions under this programme and the ones carried out within the Community, such as the 1994 European Drug Prevention Week.

Moreover, clauses on the fight against drugs are included in the agreements the Community makes with third countries.

The fight against drugs also makes use of the new opportunities offered by the Common Foreign and Security Policy.

96. More generally, a number of health projects in both Central and Eastern European Countries (CEEC) and in the New Independent States (NIS) are covered by the PHARE[87] and TACIS programmes.

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(87) Phare Health: Progress and strategy paper (1994)

PHARE activities within the health sector are concerned with the *reforms and restructuring* necessary in the CEEC to render their respective health systems *viable within a market economy context, financially sustainable and socially acceptable.*

In the light of analysis of the CEEC's problems in the health sector, key reforms and restructuring needs covered under the PHARE programme are:

- reform of the financing system including budget programming and allocation, cost containment measures, payment of care-providers, health insurances issues, etc.;
- reorganisation of health services, in particular to make care increasingly less hospital and more community based, including privatisation issues;
- pharmaceutical policy (legislation, pricing policy, supply and distribution system);
- human resources management while meeting the training and retraining needs arising from the new health-service environment;
- development of disease prevention and health promotion activities with a special focus on areas where EC directives and practices have been developed (health and safety at work for instance)

Excluding humanitarian aid, over ECU 100 million has been made available for health sector reform in the period 1990-1993 in ten Central and Eastern European Countries, Bulgaria, Hungary, Poland and Romania being the major beneficiaries.

97. In the framework of TACIS, one project has so far been established in Russia for 4.5 MECU. The TACIS approach to activities in the health sector is similar to that of PHARE.

## 3.2. General development cooperation

## Cooperation with ACP countries in the health field and on AIDS

98. EC-ACP cooperation in the health field under Lomé IV includes a major retargeting of assistance and a significant increase in allocated funding. After focusing for a long time on the construction of health infrastructure and the supply of equipment and being implemented through specific projects, assistance in the health field now responds to a more long-term vision and a more global sectoral approach. It is designed to *facilitate* the definition and implementation of essential measures to *reform health care systems.*

99. A mid-term assessment shows that in terms of commitments the total volume of aid has progressed very rapidly during the initial years of the seventh EDF. It now exceeds ECU 0.5 billion, representing more than twice the sum under the sixth EDF. On the basis of the data currently available, it may be estimated that cooperation in the health field will absorb more than 7% of resources under the seventh EDF. The resources released under the "structural adjustment facility" account for half this total. In this way it will be possible to maintain or even increase the public resources allocated to the health sector, particularly those earmarked for helping to fund operation of health services. Assistance is also being made available to help reform budget procedures and structures with a view to improving coherence between budgets and health policies.

100. The number and size of projects and programmes have also increased significantly in recent years. Half of the resources allocated are earmarked for the primary and secondary sectors, reflecting the emphasis placed on reinforcing basic services. A considerable effort is also being made to help countries *improve their medicinal product supply systems*, and make pharmaceutical products more accessible to their populations. The strengthening of institutional capacities and training also represent very important aspects of cooperation.

101. Since 1987 assistance has been given to the fight against the HIV and AIDS epidemic, focusing on support for regional and national prevention strategies, particularly those designed to *improve services concerned with combating sexually transmissible diseases*, promote information and awareness campaigns specifically aimed at risk groups, and *improve blood transfusion safety*.

As far as HIV/AIDS is concerned, the EC's total financial contribution over the period 1987-1994 amounted to around ECU 87 million and was allocated to measures covering 85 developing countries in Africa, Asia and Latin America.

102. Substantial assistance has also been given to health measures under "*rehabilitation*" programmes in countries experiencing serious crises. Finally, a significant proportion of co-financing granted to European NGOs has been earmarked for improving the health of the populations of developing countries.

103. At the end of 1993 and in the course of 1994 the Commission launched and supported a process geared to improving *coordination between European partners*. This was achieved mainly through meetings of European experts and the development of exchanges of information.

One of the most important results of this process was the adoption, on 6 May 1994, by the Council of:

- a Resolution (COM(94) 77) setting out the general framework for a policy of cooperation for the Community and Member States in the field of health and emphasising the need for parallel action to create an environment which is more conducive to health and facilitate the reform of health care systems;
- a Resolution referring more specifically to HIV/AIDS and setting out policy principles and action priorities, with the emphasis on the need to:
  * control the spreading of the epidemic,
  * strengthen the health sector to enable it to face up to the additional burden represented by HIV/AIDS,
  * give more consideration to the economic and social consequences of the epidemic
  * improve scientific knowledge in this field.

## 3.3. Humanitarian aid

104. ECHO, the European Community Humanitarian Office, which has been operational since April 1992, was set up against the background of an explosion in the demand for humanitarian aid throughout the world as a result of the major crises which the international community has had to face up to in recent years. Aiming to achieve

efficiency and speed up reactions, ECHO prepares, implements, finances, monitors and assesses operations and decisions relating to humanitarian aid, including food aid and help for refugees and displaced persons.

105. ECHO's operational activities in the health field include integration of health protection aspects into humanitarian aid operations through several types of action to help the victims of disasters:
   - *Medicinal products*: the most important aspect of the Office's work relating to health.
   - *Vaccination campaigns*.
   - *Supply of medical equipment* (minor surgery, general surgery, operating theatres, etc.), as well as specific equipment for the disabled (protheses) or health equipment (hygiene kits), etc.
   - *Food*: health aspects are systematically taken into account in deciding the composition of food aid, both in terms of assessment of the nutritional needs of the food aid recipients and in controlling food distribution, in accordance with standards laid down by WHO.
   - *Re-education*: functional rehabilitation for the disabled, as well as psychological support (e.g. Bosnian rape victims).
   - Environment: *infrastructure operations to improve the general level of health and hygiene* (wells, health units), health and hygiene measures including the supply of detergents, water treatment or even the supply of quality-controlled seeds.

   Very often, part of the funds allocated to these activities is earmarked for the *training of local medical staff*.

106. Although operational activities represent the main aspect of ECHO's work, prevention activities have become significantly more important over the past year. "Disaster preparedness" measures have been developed primarily for dealing with natural disasters. At the World Conference on the prevention of natural disasters held in Yokohama in May 1994, which took stock of the outcome of the International Decade for Natural Disaster Reduction, ECHO launched its programme of action on *disaster preparedness and prevention*. This includes, in the health field, training for disaster victims (public health, health education, etc.).

107. The "training" aspect is also involved in measures to boost the skills of the staff of ECHO partners. A *university diploma in humanitarian aid* has been created by ECHO in conjunction with DG XXII and has been developed in several universities in the Member States. This multidisciplinary diploma, a European conception of the "Erasmus" type, covers five major disciplines relevant to the humanitarian field, particularly medicine-epidemiology. Teaching started in September 1994.

## 3.4. International organisations and conferences

108. On 21 June 1994, in the context of its cooperation with the *Council of Europe*, the Community deposited the instruments of ratification for the Convention on the Elaboration of a European Pharmacopoeia. The Commission departments regularly follow the work of the Council of Europe and particularly of its committees, which draw up conventions which the Community may also sign.

The Commission subsidised and organised in collaboration with the Pompidou Group, Athens, March 1994, an international conference on the management of drug addicts in prison. The participants were professionals working in the drug field, administrators form the Ministries of Health and Justice and researchers to allow exchanges from different approaches. Conclusions setting guidelines on the management of drug addicts in prison have been adopted by the majority of participants.

109. The Commission subsidised and participated actively in the Xth International Conference on AIDS, Yokohama, 7-12 August 1994. Press information notices as well as a Blue Book : "*The World with HIV/AIDS : the European Community response - 1994*" summarising the AIDS-related activities of the Commission, were widely distributed. A European Community stand presenting activities in the fields of development, public health and research was visited by several thousand participants. Moreover, a European Commission Pre-Conference was organised focusing on both AIDS public health issues in Europe and aid development programmes.

## IV. HEALTH PROTECTION ASPECTS OF COOPERATION IN THE FIELD OF JUSTICE AND HOME AFFAIRS

### Drugs

110. When the Treaty on European Union came into force on 1 November 1993, it opened up the possibility of integrated action by the Union in the fight against drugs, using its competences in public health (Article 129), in the Common Foreign and Security Policy (Title V), and in Justice and Home Affairs (Title VI). In June 1994 the Commission was therefore able to present a draft multiannual Global Action Plan for the Union for the period 1995-1999 [88], which further emphasises prevention measures in the context of an integral and coordinated response to the drugs phenomenon, together with a specific Community programme to fight against drug dependence based on its new competence for public health (see point 2.15.2 of this report). So far the Global Action Plan has received a warm welcome from the Member States, the European Parliament and ECOSOC. The Essen European Council asked the Council to ensure that discussions on the Global Action Plan were completed in time for the conclusions to be put before the Cannes European Council in June 1995.

111. The European Monitoring Centre for Drugs and Drug Addiction, the EMCDDA, was set up by Council Regulation (EEC) No 302/93[89] and came into force on 30 October 1993 following the decision by the European Council on the seats of the decentralised agencies. It has a mandate to provide the Community and its Member States with objective, reliable and comparable information at European level on drugs and the consequences of drug addiction.

The Centre will collect and analyse currently available data on the global drugs problem and in particular data relating to reducing demand for drugs. It will seek to improve

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(88) COM(94) 234 final

(89) Council Regulation of 8 February 1993, OJ L 36 of 12.02.1993

data comparison methods through the Union and will cooperate actively with the Pompidou Group of the Council of Europe, UNDCP and WHO in the field of information on drugs.

# V. CONCLUSIONS

1. Through the introduction of explicit provisions on health (Articles 3(o) and 129) in the EC Treaty, the important **role that health protection** requirements play in Community policies has been **recognised.**
   This report on health protection requirements in Community policies, the first to be produced by the Commission pursuant to Articles 3(o) and 129 of the E.C. Treaty concerning health protection and public health, presents a survey of the way health-related issues have been dealt with in existing Community policies.
   The many and varied measures and policies that are relevant to health and the interactions between them have made it difficult to provide an overview that is at once reasonably comprehensive, fully coherent, clearly focused and not of inordinate length. In this, the first such report the ideal balance between these aims may not have been struck. Improvements will therefore be sought in the preparation of future reports.

2. **This report illustrates that the provisions on health protection are already applied in many Community policies**. It gives an overview of the interface of health with other policies and in particular of the impact of Community measures on the health of the European citizen. Moreover, it demonstrates that the action of striving to improve the health of the citizens of the European Union in itself constitutes an important added value in implementing the objectives of the European Union.
   This report deals not only with health protection, but also with all matters which can have a significant impact on public health. For example, the modernisation and increased efficiency of infrastructures for transport, energy and environment will greatly benefit the health of citizens and improve the quality of their lives. Many items covered under the 4th RTD Framework Programme will also contribute to health protection, in particular the part of the new Biomedicine and Health[24] programme concerning public health research. Similarly, the new Community education and training programmes SOCRATES[90] and LEONARDO[91] as well as the third phase of the "Youth for Europe" programme[92] will create better opportunities for the citizens of the Community to take decisions about their own behaviour and health.

3. **It responds to the Treaty obligation** and demands from the Council, the European Parliament and the Economic Social Committee and will help to improve the transparency and coherence of Community policies, and inter-sectoral coordination on health protection related issues.

4. **Other Community policies may need to be complemented by public health measures**. Notably, in the agriculture sector more consideration should be given to enhancing intersectoral cooperation in relation to the development of promotion campaigns aiming to improve nutritional balance and putting emphasis on increasing

(90) OJ L 87 of 20.04.1995, p. 10
(91) OJ No L 340 of 29.12.1994, p.8
(92) OJ L 87 of 20.04.1995, p. 1

the consumption of those foods which are beneficial to health, such as fish and fruit and vegetables. In the context of action on social and economic development, and in the fight against unemployment, consideration should be given to creating more health sector jobs to address new health needs. However any such action must be balanced against the need to control health care costs. But the issues of *controlling health care costs* and *safeguarding social protection principles* also have to be addressed.

5. **Public health policies need to be complementary to other policies**. The health protection requirement, as a component of Community policy, should be applied in such a way as not to conflict with the basic cornerstones of the Union's policy. In any Community action health interests have to be carefully balanced with other interests such as economic and social factors. Excessive measures aimed at health protection in the field of consumer protection and agriculture can, for example, have adverse effects on employment and the economic situation and thus ultimately produce a negative impact on the health of the workers of the sectors involved.
   In order to achieve balanced and coherent policies in relation to health protection measures in areas such as industry, agriculture and consumer protection, the Commission will seek closer cooperation with the research, health, social and other sectors involved.
   Article 129 gives the Community a clear mandate for promoting research in the field of disease causation and transmission. In the field of drugs, for example, the Commission will ensure coherence between the drug dependence programme, the work carried out by the EMCDDA and the Community's specific programmes under the 4th Framework Programme for research, particularly regarding research on biomedicine and health, including research on causes and toxic effects of drug dependence but also taking into consideration results from the new Targeted Socio-economic Research programme, in particular those arising from "Research into social integration and social exclusion in Europe", as well as from the COST Social Sciences research collaboration action A6.

6. This report, by outlining the interrelationships between different policy areas, aims to reinforce the intersectoral coordination of health protection aspects in Community policy. Such coordination can increase synergy and avoid duplication of effort and thus improve the efficiency and effectiveness of the operations undertaken to the benefit of all Community citizens.

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