

COMMISSION OF THE EUROPEAN COMMUNITIES

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ACTION AGAINST CANCER

(Communication from the Commission to the Council)

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DIRECTORATE-GENERAL
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AN OVERVIEW OF

EXISTING COMMUNITY ACTIONS AGAINST CANCER

(Working Document from Commission Services)

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Introductory Statement

1. The European Council in Milan (28-29 June 1985) expressed interest in a French memorandum calling for, and emphasizing the value of, a coordinated European action against cancer, making full use of existing structures.

A letter was subsequently sent on the same subject by the President of the Council of Ministers of Italy to the Heads of States and Governments and to the President of the Commission of the European Communities.

The European Council in Luxembourg (2-3 December 1985) took note of a French-Italian communication on this subject and asked that the Ministers of Foreign Affairs should examine at their next meeting the best way of giving a rapid and effective follow-up to this initiative.

The Commission welcomes these initiatives and fully shares the views expressed in the above-mentioned documents.

Community Actions

2. The Commission has so far undertaken a series of actions which, in various ways, contribute to the fight against cancer.¹
3. As regards prevention, Directives have been adopted by Council which have a direct bearing on cancer induction by physical and chemical agents. The "Basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation" and the "Protection of workers from risks relating to exposure to

¹ An "Overview" of these actions is attached in annex.

chemical, physical and biological agents" including protection from asbestos and vinyl chloride, are examples of such Directives.

4. In the light of the conclusions of the European Council in Milan, the Commission has submitted to the Council a Proposal for a Resolution on a Programme of Action of the European Communities on Cancer Prevention. This programme aims at improving the health and quality of life of the citizens within the Community and at providing a setting in which existing actions and future initiatives in the field of prevention can be made more coherent. The objectives of the programme are to halt the increase of cancer, to establish health strategies for those factors to which cancer is attributed, to facilitate development of population screening and treatment, to improve the monitoring of the health and specific groups of the population in order to identify risk factors for cancer, and to collaborate with international and national organization to these ends and to the application of the results of cancer research.

Prevention and therapy of cancer must undoubtedly contain an important element of public and professional information and education. The draft Resolution therefore proposes that due attention be given to these. The Commission will seek to act jointly with national authorities.

This proposal is currently under discussion in Council.

5. In the field of research, a series of actions in the areas of cancerogenesis and cancer therapy have been supported in Community research programmes, mainly the Environmental Protection, Radiation Protection and Medical Research programmes of the EEC and the ECSC. In this context, the

Coordinating and Data Center of the European Organization for Research on Treatment of Cancer (EORTC) has been given financial support.

6. The Commission has announced to Council that "a coordination action on cancer, in agreement with the conclusions of the Milan Summit"¹ will be embodied into the proposal for a renewal of its Medical Research Programme, to be presented to Council in early 1986. This clearly identifies a "Cancer" action which will focus on three areas: early detection and diagnosis, multi-modality treatment (including the development and improvement of clinical trials in organ-oriented projects), and transfer of research results. In conducting this programme, the Commission will seek to make an optimal use of existing structures.

Conclusions

7. Important national and international efforts are underway at present. Community actions have been described above. New initiatives have been proposed at the recent European Councils. Given the desirability, therefore, of appropriate consultation and coordination between all the parties concerned, it appears that the Community framework offers a possibility for the development of a coherent "Europe against Cancer" action which would optimize the benefits of the various efforts already being undertaken, without interfering in their efficient functioning or duplicating existing work.

As a first step, the Commission intends to host an ad-hoc expert committee, composed of high-level scientists and cancer specialists, in order to make recommendations on the ways and means of implementing a European action against cancer.

¹ COM(85) 530 final.

The Council is therefore requested:

- to decide on the launching of an action to be known as "Europe Against Cancer", aimed at ensuring the optimum coordination of all initiatives currently being taken in Europe as well as the study of new initiatives in the fields of prevention and research (including therapy);
- to take note of the Commission's intention to convene the above-mentioned ad-hoc expert committee and to report back to Council with specific proposals based on the recommendations of the Committee within a period of 3 months;
- to undertake to examine as a matter of priority the existing Commission proposals on prevention as well as the forthcoming proposals on research with a view to their rapid adoption.

1.0. The need to protect workers and the public against the long-term effects, in particular cancer, of dangerous chemical, biological and physical agents has been the objective of many actions at Community level. These have been contained in a number of different sectorial activities, namely radiation protection, occupational health and safety, internal market, agriculture and environment. Research programmes and epidemiological and statistical studies have been undertaken in support these actions. References and additional information are given in the annexes.

2.0. RADIATION PROTECTION

2.1. The Treaty establishing the European Atomic Energy Community prescribes that basic standards for the protection of the health of the general public and workers against the dangers of ionising radiation - principally cancer - shall be laid down. To this end in 1959 the Council adopted the first Directive laying down such basic standards and this was last updated in Directives of 1980 and 1984. In addition, in 1984 a Directive laid down basic measures for the protection of patients undergoing medical examination or treatment with X-rays. Ongoing work is concerned with protection from naturally occurring radiation, radioactive discharge and waste management and transport. This work is assisted by a group of experts as prescribed in the Treaty.

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3.0. OCCUPATIONAL HEALTH AND SAFETY

- 3.1. The first programme of action on safety and health at work, adopted in 1978, required the development of a preventive and protective action for substances recognized as being carcinogenic and this was reemphasised in the second programme for the years 1984-88. Council has adopted Directives on the protection of workers from risks relating to exposure to chemical, physical and biological agents and in particular to protection from asbestos and vinyl chloride. Council is currently considering the proscription of four carcinogenic substances and subsequent measures will address benzene, acrylonitrile, arsenic and nickel compounds. The scientific and technical bases for such actions have been determined in a series of studies. This work is assisted by an Advisory Committee established by Council in 1974.

4.0. INTERNAL MARKET

- 4.1. Community rules relating to medicinal products safeguard public health whilst ensuring that the development of the pharmaceutical industry and trade in medicinal products will not be hindered. Since 1975 Directives have laid down carcinogenicity and mutagenicity testing of human and veterinary drugs. This work is assisted by a Committee for Proprietary Medicinal Products.

- 4.2. Food additives are subject to stringent testing and regulation. The Scientific Committee for Food has established guidelines for the safety assessment of food additives which include provisions for testing of chronic toxicity and carcinogenicity.

5.0. AGRICULTURE

- 5.1. Since 1970, Council Directives have controlled by means of positive lists the use of additives, contaminants and compounds resulting from developments in the biotechnology of feedingstuffs. The use of compounds involving potential carcinogenic risks is discarded. The assessment of the safety of animals, human beings and environment is done by committees of experts of the Member States working in close collaboration with Commission services. The Commission is assisted in this task by the Scientific Committee for Animal Nutrition.
- 5.2. At a Community level measures have existed since 1976 controlling levels of pesticide residues in and on fruit and vegetables, and measures were adopted in 1979 to prohibit the marketing and use of certain plant protection products. Proposals are at present under examination in the Council to extend the scope of the foodstuffs covered.
- 5.3. The Commission before making proposals to the Council consults its Scientific Committee for Pesticides and national experts on the possible toxicological effects of the substances including carcinogenicity, and acts accordingly.

6.0. ENVIRONMENT

- 6.1. A number of carcinogenic, mutagenic and teratogenic substances are being studied within the framework of the Directives relating to the classification and labelling of dangerous chemicals. The classification of these substances is discussed in a working group of governmental experts and, in the case of divergent opinions amongst the Member States, by a group of highly qualified "specialized experts".
- 6.2. For the purpose of classification and labelling, carcinogenic substances are divided into three categories. The label is then decided according to which category the substance is placed in, taking into account other dangerous properties. Substances in categories 1 and 2 are ascribed the risk phrase "May cause cancer" and the symbol "toxic" (skull and crossbones); substances in category 3 are ascribed the risk phrase "Possible risk of irreversible effects" and the symbol "harmful" (St. Andrew's cross).
- 6.3. After the approval of the Technical Progress Committee, the labelling requirement is published as a Commission Directive. This Committee has just approved the labelling of 27 substances of categories 1 or 2. A further 15 suspected carcinogenic substances are under discussion. Some Member States have announced that they will submit to the working group other suspected carcinogens for classification and labelling.

7.0. TOXICOLOGY

- 7.1. The Scientific Advisory Committee to examine the toxicity and ecotoxicity of chemical compounds has presented advice on the grouping of carcinogenic, teratogenic and mutagenic substances for the purposes of identification and product handling. The Committee has expressed an opinion on 17 such substances or classes of compounds and this work is ongoing.

- 7.2. The proposal for a Council Resolution on an action programme on toxicology for health protection makes reference to the development of new methods for determining the long-term effects of chemical substances including their carcinogenic and mutagenic potential and quantitative risk estimations. It stresses the health importance of immunotoxic effects and the relationship between immune depression and cancer.

8.0. PUBLIC HEALTH

- 8.1. A number of pilot projects have been undertaken relating to tobacco and alcohol consumption and an ongoing programme of workshops and conferences has dealt with technical problems in health education and monitoring the health of the population.

9.0. STATISTICS

- 9.1. The Statistical Office collates data from the Member States on mortality from cancer. In collaboration with Commission Services and the International Agency for Research on Cancer, a cancer atlas of the European Community is under preparation.
- 9.2. The principles and practice of protection of personal data in a research-dependent environment was the subject of a report on "The Confidentiality of Medical Records" presented in 1984.

10.0. RESEARCH

- 10.1. In the third sectorial research and development programme of the European Economic Community in the field of medical and public health research for the period 1982-86, projects have concerned the development of new medical technologies for early detection and diagnosis, eg. positron emission tomography, identification and characterisation of biological tissues by NMR, automated cytology. These techniques are applicable to various cancers. In addition, financial support has been given to the Coordinating and Data Center of EORTC.
- 10.2. In the fourth ECSC occupational medicine research programme special reference is made to cancer and the identification of increased risk through research into the carcinogenicity of atmospheric pollutants. Work has focussed on the risk of lung cancer from welding fumes and this has involved bioassays of pollutants with in vitro and in vivo testing, clinical and epidemiological studies. This work will be extended in the fifth programme 1987-91.
- 10.3. In the field of radiation protection, past programmes have addressed fundamental cytological and biochemical effects of ionising radiation. The current five-year programme, 1985-1989, denotes an important part of its resources to radiation carcinogenesis. It is concerned with the possible carcinogenic and mutagenic effects of low dose exposures and effects of naturally occurring radon and other sources. Research areas are : molecular alterations, cellular transformation, experimental carcinogenesis, biological effects of incorporated radionuclides and human observations.
- 10.4. In the third environmental protection programme (1981-1985) research relating to cancer is concerned with the assessment of the mutagenic and carcinogenic potential of environmental chemicals and with the carcinogenicity of chemicals and fibrous materials.
- 10.5. Each research programme has a committee for management and coordination to assist the Commission in the implementation of the Council's Decisions.

ANNEX OF REFERENCES

Community instruments

1. Directive 1959 laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation - O.J. No 11, 20.2.1959
2. Directive 62/1.633/Euratom - 5.3.1962 -
3. Directive 66/45/Euratom - 27.10.1966
4. Directive 76/579/Euratom - 1.6.1976
5. Directive 80/836/Euratom - 15.7.1980 - O.J. L.246 - 17.9.1980
6. Directive 84/467/Euratom - 3.9.1984, amending Directive 80/836/Euratom as regards the basic standards for the health protection of the general public and workers against the dangers of ionizing radiation - O.J. L.265 - 5.10.1984.
- ~~7. Directive 84/466/Euratom - 3.9.1984, laying down basic measures for the radiation protection of persons undergoing medical examination or treatment - O.J. L.265 - 5.10.1984.~~

ARTICLE 31, EURATOM TREATY, states :

The basic standards shall be worked out by the Commission after it has obtained the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts, and in particular public health experts, in the Member States.

OCCUPATIONAL HEALTH AND SAFETYCommunity instruments

1. Resolution of 29.6.1978 on an action programme of the European Communities on safety and health at work - O.J. C.165 - 11.7.1978.
2. Resolution of 27.2.1984 on a second programme of action of the European Communities on safety and health at work - O.J. C.67 - 8.3.1984.
3. Directive 78/610/EEC on the approximation of the laws, regulations and administrative provisions of the Member States on the protection of the health of workers exposed to vinyl chloride monomer - O.J. L.197 - 22.7.1978.
4. Directive 80/1107/EEC of 27.11.80 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work - O.J. L.327 - 3.12.1980.
5. Directive 83/477/EEC of 19. 9.1983 on the protection of workers from the risks related to exposure to asbestos at work - O.J. L.263 - 24.9.1983.
6. Proposal for a Directive on the protection of workers by the proscription of specified agents and/or work activities - O.J. C.270 - 10.10.1984.
7. Proposal for a Directive on the protection of workers from the risks related to exposure to benzene at work.
8. Council Decision 74/325/EEC of 27.5.1974 setting up an Advisory Committee on safety, hygiene and health protection at work - O.J. L.185 - 9.7.1974.

INTERNAL MARKETCommunity instruments

1. Directive 75/318/EEC of 20.5.1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products. O.J. L.147 - 9.6.1975, as modified by Directive 83/570/EEC - O.J. L.332 - 28.11.1983.
2. Recommendation 83/571/EEC of 26.10.1983 concerning tests relating to the placing on the market of proprietary medicinal products.
3. Directive 81/852/EEC of 28.9.1981 on the approximation of the Laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products - O.J. L.317 - 6.11.1981.
4. Proposals for Directives amending Directives 75/318/EEC and 81/852/EEC - O.J. C.293 - 5.11.1984.
5. Recommendation 80/1089/EEC of 11.11.1980 concerning tests relating to the safety evaluation of food additives. O.J. L.320 - 27.11.1980.
6. Committee for Proprietary Medicinal Products. Directives 75/318/EEC and 83/570/EEC.
7. Committee for Proprietary Veterinary Products. Directive 81/851/EEC.

Publications

1. The rules governing medicaments in the European Community, July 1984, ISBN 92/825/4529-034.
2. Guidelines for the safety assessment of food-additives. Report of the Scientific Committee for Food - 22.2.1980.
3. Studies on anti-neoplastic agents (in preparation).

AGRICULTURECommunity instruments

1. Council Directive 70/524/EEC of 14.12.1970 concerning the use of additives in feedingstuffs.
2. Council Directive 74/63/EEC of 17.12.1973, concerning maximum levels of undesirable substances and products in feedingstuffs.
3. Council Directive 82/471/EEC of 30.06.1982, concerning certain products used in feedingstuffs.
4. Council Directive 76/895/EEC of 9.12.1976, relating to the fixing of maximum levels of pesticides in and on fruit and vegetables.
5. Council Directive 79/117/EEC of 8.2.1979 concerning the prohibition of the placing on the market and use of plant protection products concerning certain active substances.

ENVIRONMENTCommunity instruments

1. Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.
O.J. 196 of 16.8.1967.
2. Council Directive 79/831/EEC of 18 September 1979 amending for the sixth time Directive 67/548/EEC.
O.J. L 259 of 15.10.1979.
3. Commission Directive 83/467/EEC of 29.7.1983 adapting to technical progress for the fifth time Council Directive 67/548/EEC.
O.J. L 257 of 16.9.1983.
4. Commission Directive 84/449/EEC of 25.4.1984 adapting to technical progress for the sixth time Council Directive 67/548/EEC.
O.J. L 251 of 19.9.1984.
5. Proposal for a Council Directive on the approximation of the laws, regulations and administrative provisions of the member States relating to the classification, packaging and labelling of dangerous preparations.
O.J. C 211 of 22.8.1985.
6. Resolution of 19.5.1981 on a second programme of the European Economic Community for a consumer protection and information policy.
O.J. C 133 of 3.6.1981.
7. Resolution of 7.2.1983 on the continuation and implementation of a European Community policy and action programme on the environment.
O.J. C 46 of 17.2.1983.

Opinions of government experts and "specialized experts" on labelling of suspected carcinogenic substances.

STATISTICSCommunity Instrument

"The Confidentiality of Medical Records" - The principles and practice
of protection in a research-dependent environment
EUR.9471 - 1984.

RESEARCHCommunity instruments

1. Decision, 17.8.82, adopting a sectorial research and development programme of the European Economic Community in the field of medical and public health research - concerted action (1982-1986) - O.J. L.248 - 24.8.1982.
2. Decision, 3.2.1981, adopting a fourth ECSC medical research programme on the effects on the health of workers of physical and other environmental factors at the workplace - O.J. C.307 - 27.11.1981.
3. Decision, 18.3.1980, adopting a multi-annual research and training programme for the European Atomic Energy Community in the field of radiation protection (1980-1984) - O.J. L.78 - 25.3.1980.
4. Decision, 12.3.1985, adopting a multi-annual research and training programme for the European Atomic Energy Community in the field of radiation protection (1985-1989) - O.J. L.83 - 25.3.1985.
5. Decision, 3.3.1981, adopting a sectorial R. & D. programme in the field of environment (1981-1985) - O.J. L.101 - 11.4.1981.