

EUROPEAN PARLIAMENT

Working Documents

1979 - 1980

2 May 1979

DOCUMENT 99/79

Report

drawn up on behalf of the Committee on the Environment,
Public Health and Consumer Protection

on environmental carcinogens

Rapporteur: Mr H.E. JAHN

1. 2 2

By letter of 24 November 1977 the Committee on the Environment, Public Health and Consumer Protection requested authorization to draw up a report on environmental carcinogens.

The President of the European Parliament authorized the committee, by letter of 25 January 1978, to draw up a report on this subject.

On 25 January 1978 the Committee on the Environment, Public Health and Consumer Protection appointed Mr Jahn rapporteur.

At its meetings of 21 March and 3 April 1979 the committee considered the draft report and, at the latter meeting, unanimously adopted the motion for a resolution and explanatory statement.

Present: Mrs Krouwel-Vlam, chairman; Mr Jahn, vice-chairman and rapporteur; Mr Ajello, Mr Brégégère, Mr Brown, Mr Didier, Mr Lamberts, Mr W. Müller, Mr Ney, Mrs Squarcialupi, Mr Verhaegen and Mr Wawrzik.

CONTENTS

	<u>Page</u>
A. Motion for a resolution	5
B. Explanatory statement	9
I. Introduction	9
II. General	10
III. Previous initiatives of the European Parliament in the fight against cancer	14
IV. Main findings of the hearing of experts	36
(a) Carcinogenic effects of hydrocarbons	36
(b) Carcinogenic effects of pesticides	39
(c) Possible carcinogenic effects of asbestos dust	40
(d) Possible carcinogenic effects of chemical additives to food	42
(e) Carcinogenic effects of cigarette smoke and international control measures	44
(f) Carcinogenic effects of industrial dusts and smoke on workers and populations of surrounding areas	46
(g) Carcinogenic effects of pharmaceutical products	49
(h) Carcinogenic effects of other harmful substances in the environment and methods of assessing possible carcinogenic effects of newly-marketed substances	51
(i) Epidemiological survey of cancer cases and the surveillance of occupational cancer hazards	54
V. Other comments.....	56

The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following motion for a resolution together with explanatory statement:

MOTION FOR A RESOLUTION

on environmental carcinogens

The European Parliament,

- having regard to

- (a) the European Communities' programme of action on the environment of 22 November 1973¹,
- (b) the Council resolution of 17 May 1977 on the continuation and implementation of a European Community policy and action programme on the environment²,
- (c) the action programme on safety and health at work³,

- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection (Doc. 99/79),

I. General observations and demands

1. Draws attention to the dangers resulting from certain noxious substances in the environment and certain modes of human behaviour which can cause cancer;
2. Recalls that for many years now a number of its Members has tabled written questions drawing attention to the carcinogenic effects of certain substances in the environment and urging the Commission and Council to introduce the necessary Community protective measures;
3. Believes that effective action to combat cancer can no longer be regarded as the sole responsibility of Member States but must also be undertaken by the Community under its programmes on the environment, health protection, safety at work and research;
4. Considers that in performing this task the Community should draw on the most recent advances in specialized research and that, in this context, it should aim at close coordination in order to ensure optimal use of available research resources and prevent unnecessary duplication;
5. Is aware of the difficulty of proving that a particular substance can by itself produce cancer or indicating its precise role in inducing this disease since cancer is often due to the combined effects of various factors, the actual carcinogenic agent being largely unknown;
6. Calls on the Commission to set up a working party of highly qualified experts in the field of cancer research and cancer prevention to advise the Community on all relevant questions and, in particular, to submit practical proposals for Community regulations;

¹ OJ No C 112, 20.12.1973

² OJ No C 139, 13.6.1977

³ OJ No C 165, 11.7.1978

7. Calls on the Commission to step up the implementation of the Community programmes in the field of cancer prevention and to establish necessary priorities, with particular emphasis on preventive measures;
8. Insists that the Community must earmark funds for general cancer research and use them to maximum effect through close cooperation with the cancer research centres and institutes in the Member States and other international institutions;
9. Urges that the number and capacity of testing laboratories with the necessary monitoring apparatus should be increased substantially in the foreseeable future in order to promote the testing of the many products already on the market which are suspected of being carcinogenic or mutagenic; in this context a system should be used which with the aid of short-term tests based on a programmed scheme, enables priorities to be established for long-term testing; also requests the Commission and Council to give the necessary impetus by making adequate financial resources available;
10. Stresses the need to evaluate every newly discovered or developed active substance by carefully weighing benefits against risks;
11. Requests the Commission to propose Community measures to make all newly produced chemicals subject to compulsory registration and authorization along the lines of the US Toxic Substances' Control Act of 1976;
12. Notes that the experts all agree that tobacco smoke is extremely carcinogenic and therefore urges that
 - (a) the tobacco industry make its products as safe as possible by further lowering their tar content and that research to this end be encouraged;
 - (b) further information campaigns be launched on the potential risks of smoking, emphasizing the advantages of low-tar over high-tar tobacco,
 - (c) young people in particular be informed of the dangers of smoking before acquiring the habit by the inclusion of health hygiene courses in school curricula,
 - (d) no-smoking compartments be introduced in trains and aircraft where this has not yet been done;
13. Calls upon the Commission to submit a proposal for a directive on recognized occupational diseases with a view to creating uniform conditions for the protection of workers and, for this purpose, to exploit all the research done in the Member States and, where possible, that done outside the Community too in order to establish specific causal relationships and draw the necessary conclusions for the recognition of cancer as an occupational disease;

Specific recommendations

14. Requests the Commission to consider what measures the Community can adopt in order to organize, coordinate and step up research in the following areas:
 - (a) concentration of epidemiological studies on the carcinogenicity of pesticides on sections of the population involved in their production and use,
 - (b) prevention of the formation of nitrosamines in the human body,
 - (c) preventive medicine;
15. Supports all measures aimed at eliminating the polycyclic hydrocarbons from the human environment by all technical means available or, where this is not feasible, at least reducing them;
16. Awaits with interest the asbestos action programme announced by the Commission and expects its implementation to bring about a reduction in human exposure to asbestos dust, which may be carcinogenic;
17. Recommends that systematic and comparable investigations are carried out in the European asbestos industry using a standardized measurement technique and strategy to determine past and present asbestos dust levels and asks the Commission to propose safety regulations for the asbestos industry on the basis of these findings;
18. Calls on the Commission and Council to ensure that priority is given to the monitoring of toxic substances in industry as proposed in the safety and health programme (determining the sources of chemicals and pooling the information in a central data system);
19. Insists that the Commission propose immediate measures designed to ensure that the effects on workers of styrene are kept to a minimum by the adoption of suitable occupational hygiene measures;
20. Calls upon the Commission to prepare a programme aimed at examining the whole human diet so as to eliminate carcinogenic substances, beginning with food additives which are not technologically necessary and therefore serve no useful purpose;
21. Calls upon the Council to adopt without delay the Commission's proposal for a directive banning the use of pesticides containing certain active substances, including DDT;
22. Requests the Commission to propose suitable measures to warn the consumers of the dangers of aflatoxins and to encourage producers to take effective measures to combat these mould fungi;

23. Considers that
- (a) anti-inflammatory, antithermic, anti-rheumatic and pain-killing drugs should be checked as to their carcinogenic properties by specially qualified study groups,
 - (b) before they are placed on the market, all newly developed drugs should be checked for carcinogenicity, with special reference to their pharmacological properties and the possible toxic effects of intensive use, wherever possible by means of long-term tests,
 - (c) drugs whose therapeutic value is disputed should be neither manufactured nor used,
 - (d) the Commission should take steps to incorporate the relevant provisions in the Community's legislation on drugs;
24. Requests the Commission to propose Community measures designed to bring about a substantial reduction in cold-start emissions from internal combustion engines and emissions from heating installations;
25. Requests the Commission to propose the following measures in the field of cancer epidemiology:
- (a) collection and exploitation of more comprehensive information on working conditions (including correlations) in connection with cancer cases involving employed persons and on smoking among workers,
 - (b) compilation of cancer registers to be kept and stored for a period of at least 30 years, which could be used to monitor the incidence of cancer and offer the additional advantage that each record includes the initial diagnosis and would possibly give more details about the histological type of tumour than are contained in the corresponding mortality records,
 - (c) introduction of comprehensive health monitoring of certain occupational groups, on the Danish model;
26. Is of the opinion that modern methods of treatment with natural remedies can also make a contribution to the fight against cancer and supports, therefore, the various organizations promoting the wider use of naturopathy;

Conclusions

27. Calls on the Commission and Council to give full consideration to the additional suggestions made in the explanatory statement;
28. Instructs its President to forward this resolution and the report of its committee to the Council and Commission of the European Communities and to the national Parliaments and the Ministries of Public Health of the Member States.

EXPLANATORY STATEMENTI. Introduction

1. During a preliminary exchange of views your Committee on the Environment, Public Health and Consumer Protection decided to hold a hearing of experts on the problems of environmental carcinogenesis and use the findings as a basis for further discussion.
2. The hearing was held in Brussels on 22/23 May 1978. The following experts took part:
 - Prof. L. Celli, President of the 'Associazione Mondiale sui problemi del cancro dell'apparato digestivo', Milan
 - Prof. J. Clemmesen, Finsen Institute, Copenhagen
 - Prof. G. Della Porta, 'Istituto Nazionale dei Tumori di Milano', Milan
 - Dr. R. Kroes, Central Institute of Nutrition and Food Research, Zeist (Netherlands)
 - Prof. C. Maltoni, 'Istituto di Oncologia', Bologna
 - Dr. K. Robock, Asbestos Foundation, Neuss
 - Prof. D. Schmähl, Director of the Institute for Toxicology and Chemotherapy at the German Cancer Research Centre, Heidelberg
 - Prof. L. Tomatis, International Agency for Research on Cancer, Lyons
 - Prof. R. Waller, Medical Research Council - Toxicology Unit, St. Bartholomew's Hospital Medical College, London
 - Prof. F. Zajdela, 'Institut de Radium', Orsay (France).
3. Your committee received summaries by experts on the following topics:
 - (a) Carcinogenic effects of hydrocarbons
 - (b) Carcinogenic effects of pesticides
 - (c) Possible carcinogenic effects of asbestos dust
 - (d) Possible carcinogenic effects of chemical additives to food
 - (e) Carcinogenic effects of cigarette smoke and international control measures
 - (f) Carcinogenic effects of industrial dusts and smoke on workers and populations of surrounding areas

- (g) Carcinogenic effects of pharmaceutical products
- (h) Carcinogenic effects of other harmful substances in the environment
- (i) Possibilities for preventive action and means of combatting cancer
- (j) Epidemiological survey of cancer cases
- (k) Surveillance of occupational cancer hazards
- (l) Problems of methods of assessing possible carcinogenic effects of newly-marketed products.

4. The number of experts who spoke on each of these topics ranges from 1 to 6. Following the discussion of the individual topics the experts answered committee members' questions. A verbatim record (PE 54.100) of the hearing was drawn up containing the full text of the speeches made.

Annex I to the verbatim record shows which experts spoke on the various topics. At your committee's request the experts submitted written summaries of their speeches before the hearing; these summaries will be found in Annexes II - IX.

II. General

5. The basis for the drafting of this report is formed by the action programmes of the European Communities on the environment of 1973¹ and 1977² and on safety and health at work of 1978³.

According to the 1973 environment programme one of the most important objectives of a Community environment policy is the prevention, reduction and, where possible, elimination of environmental pollution. One of the general principles of this programme is that 'the best protection of the environment consists in preventing at source the creation of pollution or nuisances, rather than subsequently trying to counteract their effects'. Part II, Chapter 1 contains a list of pollutants chosen on the grounds both of their toxicity and of the current state of knowledge of their significance in the health and ecological fields and for which, if necessary, Community environmental quality standards⁴ will be set.

¹ OJ No. C 112, 20.12.1973

² OJ No. C 139, 13.6.1977

³ OJ No. C 165, 11.7.1978

⁴ Environmental quality standards prescribe, with legal force, the levels of pollution or nuisance not to be exceeded in a given environment, medium, or part thereof.

The 1977 environment programme contains, among other things, a list of research projects (see Title IV, Chapter 4) on, for instance, the establishment of criteria for the compatibility of new industrial products with the environment, epidemiological surveys on the effects of air and water pollution, establishment of criteria (exposure-effect relationships) for pollutants and potentially toxic chemicals, reduction and prevention of pollution and nuisances, including the implementation of 'clean' technologies.

It is an established fact - and one confirmed by the experts - that environmental pollution can lead to cancer. The appropriate measures provided for in the environment programmes should therefore be implemented as a matter of priority.

The action programme on safety and health at work also provides for measures relevant to the fight against cancer. These measures, which are to be implemented between 1978 and the end of 1982, may be summarized as follows:

- preventive and protective action in respect of substances recognized as being carcinogenic, by fixing exposure limits, sampling requirements, measuring methods and satisfactory conditions of hygiene at the workplace and by specifying prohibitions where necessary,
- drafting of information notices on hazards and handbooks on the handling of certain dangerous substances such as pesticides, herbicides, carcinogenic substances, asbestos, arsenic, lead, mercury, cadmium and chlorinated solvents,
- specific Commission action with regard to carcinogens present at workplaces¹ will consist in
 - (a) collecting data on the distribution of carcinogens and their concentration at the workplace,
 - (b) collecting and analysing medical data,
 - (c) perfecting readily applicable methods of detection,
 - (d) fixing the lowest possible levels or, if necessary, prohibiting certain carcinogens present at the workplace.

¹ See OJ No. C 165, 11.7.1978, p. 8

6. It is clear therefore that effective action to combat cancer must not be left to the individual Member States alone but is a matter for the Community and must be carried out under the Community programmes on the environment, health protection, safety at work and research. The Community must make use of the latest developments in specialized research. This will require sound coordination so as to ensure the most rational possible use of available research resources and avoid unnecessary duplication.
7. The objective of this report is to further the implementation of Community programmes in the fight against cancer, to set certain priorities and generally to give impetus to the proposed measures. Your committee believes that the Community should make financial resources available for general cancer research and implement them to optimal effect in close cooperation with the cancer research centres and institutes of the Member States and other international institutions.
8. In this connection your committee draws attention to one of the experts' suggestions, namely that the Commission should set up a working party composed of highly qualified experts in the field of cancer research and cancer prevention to advise the Community on all relevant questions and, in particular, to make practical proposals for Community regulations. Chronological toxicology and, in particular, carcinogenesis represent a special field involving so many difficult problems that it is necessary to set up a special working party in this area. One of the tasks of this group of experts would be to assess the results of the extensive cancer research work currently being carried out in the Community.
9. Your committee realizes that it is extremely difficult to prove that a particular substance constitutes the sole cause of cancer or to indicate its precise role in inducing this disease. In many cases a combination of effects is involved deriving from a variety of causes with the result that the actual cause cannot be identified. Your committee has therefore tried to steer clear of generalizations and dogmatic statements in this report and sought instead to convey the uncertainty which surrounds many of the problems involved, particularly as the experts were themselves in disagreement on many a point. The committee has also come to the conclusion that in many cases it is not possible to adduce conclusive evidence of the carcinogenicity of factors allegedly contributing to cancer.

10. However, the fact that judgments of universal validity cannot be made does not mean that your committee wishes to minimize the problem. On the contrary, this report will clearly indicate the dangers which certain harmful substances in the environment and certain forms of human behaviour present and which can lead to cancer. Particular caution is called for in respect of suspicious factors. Finally, the report attempts to give encouragement to promising Community-wide cancer research and prevention measures.

III. Previous European Parliament initiatives in the fight against cancer

11. In the absence of concrete proposals from the Commission the European Parliament as an institution has not yet become active in the fight against cancer. Several of its members have, however, drawn attention in written questions to the carcinogenic effects of certain substances in the environment and suggested that appropriate measures be taken by the Commission to combat them. Your committee has thought it useful to summarize these written questions and briefly examine each of them. The summary given below does not, however, claim to be exhaustive.

12. In Written Question No. 397/69 on the prohibition of the pesticide DDT in the EEC¹ Mr Boersma and Mr Dröscher referred to paragraph 10 of the resolution of the European Parliament of 1 July 1969² in which it called upon the Commission and Council 'thoroughly to investigate whether, in the light of the suspicions recently voiced by several scientists, DDT can cause cancer, and whether the utilization of this insecticide should be prohibited and accordingly deleted from the list in Annex II of the proposal for a regulation.' The authors of the question then mentioned certain observations made by recognized experts which showed that DDT needed to be banned immediately. The Commission was asked whether it agreed that it was preferable to introduce totally degradable chemical pesticides instead of DDT or, even better, effectively to promote the use of biological techniques for combating pests, in particular

- the cultivation of pest-resistant crops,
- the cultivation of crops suited to local conditions,
- rational crop rotation,
- the cultivation of natural enemies of pests,
- sterilization of male pests.

In its answer of 25 March 1970 the Commission stated that it felt it desirable to use rapidly degradable pesticides instead of pesticides with long-term effects and to promote research on biological pest control methods, integrated pest control and cultivation methods which would lead to the more limited use of chemical pesticides.

¹ OJ No. C 42, 8.4.1970, p. 2

² OJ No. C 97, 28.7.1969, p. 36

The Commission agreed that it might eventually be necessary to ban the use of DDT in the Community; it had already been banned in Denmark and Sweden. It did not, however, deem it necessary to submit to the Council a suitably amended proposal for a regulation on pesticides.

13. The abovementioned resolution of 1 July 1969 prompted Mr Jahn to ask the Commission¹ what was the outcome of the detailed inquiry called for by the European Parliament into the carcinogenic characteristics of DDT and whether it intended to submit a proposal at an early date to prohibit the use of DDT in the Community. In its answer the Commission said that it had proposed, on the general grounds of persistence, bioaccumulation and ecotoxicity, that a general ban should be placed on the use of DDT in the Community. This had been proposed in its proposal for a directive prohibiting the placing on the market and the use of pesticides containing certain active substances². This proposal had been submitted on 5 August 1976 to the Council which was currently examining it.

Mr Jahn put an almost identical question to the Council³. In its answer of 23 November 1977 the latter had to admit that in adopting the directive of 23 November 1976 on the fixing of maximum levels for pesticide residues in and on fruit and vegetables⁴, it had not laid down a maximum tolerance for DDT since at that juncture the Member States had not all reached agreement on that particular point. The Council added that it was currently examining the Commission's proposals for a directive prohibiting the use of pesticides containing certain active substances, which included a ban on DDT.

As the Council has still not completed its deliberations, your committee calls on the Council immediately to adopt the abovementioned proposal for a directive in the wording proposed by the Commission (ban on DDT).

¹ See Written Question No. 515/77, published in OJ No. C 42, 20.2.1978, p. 7

² OJ No. C 200, 26.8.1976, p. 10

³ See Written Question No. 516/77, published in OJ No. C 7, 9.1.1978, p. 11

⁴ OJ No. L 340, 9.12.1976, p. 26

14. In Written Question No. 264/70 on the harmonization of measures in the field of radiation protection¹ Mr Glinne drew the Commission's attention to the fact that according to scientists the risk of cancer as a consequence of atomic radiation was estimated to be three times as high as previously believed. The Commission was therefore asked whether it thought it was necessary to harmonize more systematically and tighten up measures in the field of protection against radiation and the provisions in force at Community level.

In its answer of 29 October 1970, the Commission pointed out that the basic Euratom standards of 2 February 1959, which had been revised in the directives of 5 March 1962 and 27 October 1966, were binding on Member States and constituted a common legal basis for national legislation. Harmonization in the field of radiation protection had been taken as far as possible, as regards measures to monitor radioactivity, the prevention of radiation accidents and the practical organization of radiation protection in all workplaces with a radiation hazard. The nuclear sector was one of the fields in which coordination of Member States' activities had advanced the furthest. Radioactive substances were not released into the natural environment until the Commission had carried out the consultation procedure laid down in Article 31 and Article 37 of the Euratom Treaty and until the exact consequences for human beings had been determined.

15. In Written Question No. 537/70 on carcinogenic substances in diesel exhaust gases² Mr Adams asked the Commission whether it was aware of the fact that diesel exhaust gases contained non-combusted hydrocarbons, carbon monoxide, sulphur dioxide, acids and carcinogenic substances. He also asked the Commission whether it agreed with him that in view of these alarming facts, urgent measures were necessary to prevent pollution of the air by waste gases from diesel engines, as had already been demanded by the European Parliament.

¹ OJ No. C 138, 18.11.1970, p. 16

² OJ No. C 43, 5.5.1971, p. 8

In its answer of 21 April 1971, the Commission promised that it would be immediately submitting to the Council a proposal for a directive on toxic exhaust gases from diesel engines in motor vehicles.

This proposal was submitted to the Council on 30 December 1971¹. On 9 May 1972 the European Parliament delivered a favourable opinion² on this proposal for a directive on the basis of a report by Mr Jahn (Doc. 19/72). On 2 August 1972 the Council adopted the proposal for a directive on measures to be taken against the emission of pollutants from diesel engines for use in vehicles³.

16. In Written Question No. 271/71 on carcinogenic pesticide residues in tobacco⁴ Miss Lulling drew the Commission's attention to the work of the Cancer Research Centre in Heidelberg from which it had emerged that a particular raw tobacco from southern countries contained carcinogenic pesticide residues. The Commission was asked what it intended to do about this and whether it was willing to speed up its work on the harmonization of maximum levels of toxic substances in tobacco.

In its answer of 21 June 1972, the Commission merely gave an assurance that it was trying to find out whether relevant work had been carried out in the Member States.

Your committee would like to know what the Commission has done in this field in the meantime and when a harmonization proposal taking due account of consumer protection considerations is to be expected.

17. In Written Question No. 23/72 on the mould fungus *aspergillus flavus* in food and cattle feed⁵ Mr Vredeling raised the problem of the carcinogenic effects of aflatoxin M. The Commission was asked, in particular, whether there were any preservatives which were safe from the health point of view and could be used for the purposes of protection against this fungus, which secreted aflatoxin M.

¹ OJ No. C 26, 15.3.1972, p. 42

² OJ No. C 56, 2.6.1972, p. 19

³ OJ No. L 190, 20.8.1972, p. 1

⁴ OJ No. C 12, 8.2.1972, p. 1

⁵ OJ No. C 72, 5.7.1972, p. 3

In its answer of 16 June 1972 the Commission confirmed the carcinogenic nature of aflatoxins and indicated that the fungus *aspergillus flavus* affected primarily peanuts, maize and cotton. The best means of combating it consisted of appropriate techniques for harvesting, drying, selection and storage. The formation of mould on food could be suitably prevented by the use of fungicidal preservatives authorized in the Community.

Your committee takes the view that the Commission should propose suitable measures to warn the consumers of the dangers of aflatoxins and to oblige producers to combat mould fungi effectively.

18. Written Question No. 645/73 by Mr Willi Müller and Mr Kater deals with the health risk involved in the manufacture and processing of PVC plastics¹. The Commission was asked whether it was willing to propose Community measures to deal with the hazards to which the workers concerned were exposed.

In its answer of 27 March 1974 the Commission said that it had established contact with the International Agency for Research on Cancer (IARC) in Lyons, which was collecting all available data on the toxicity of vinyl chloride and polyvinyl chloride. The Commission said it would be taking the swiftest possible action on the basis of the latest scientific discoveries.

The authors of this question referred back to this answer six months later² when they drew the Commission's attention to the fact that new discoveries had been made in the meantime which had led the appropriate authorities in the USA, for example, to impose new restrictions on the handling of substances used in manufacturing PVC. In addition, there were now numerous reports from Community countries which bore out the conclusion that PVC products were highly dangerous to health and carcinogenic. The Commission was therefore asked whether it had carried out the follow-up envisaged and what findings it had obtained. It was asked further whether it agreed that, purely as a precaution, measures should be taken at once to deal effectively with the risks involved in the production of PVC.

¹ OJ No. C 53, 9.5.1974, p. 15

² Written Question No. 593/74 by Mr Willi Müller and Mr Kater, published in OJ No. C 56, 8.3.1975, p. 8

In its answer of 7 February 1975 the Commission said that the group of experts which had been set up by the International Agency for Research on Cancer in Lyons had just begun work and that its findings would be announced by the Commission as soon as they were available. In addition, the Commission had organized a scientific conference in Brussels on 17/18 September 1974 on the dangers of vinyl chloride monomer - a basic product used in the manufacture of many plastics - for workers and the environment. The Commission intended to call a meeting of government experts in the near future to examine the feasibility of the Community's defining basic principles for protecting workers and the general public from vinyl chloride monomer poisoning.

19. On the same subject Mr Glinne¹ asked the Commission, in the light of the discovery made in Sweden in 1974 that vinyl chloride was the cause of a particularly rare and malignant form of cancer of the liver, what was the maximum limit permitted by the regulations in each of the Member States, whether the Commission agreed that harmonization was required in this field to improve the protection of workers and whether steps should not be taken to this end.

According to information in the Commission's possession on 11 July 1975 the national regulations on maximum admissible concentrations (MAC) of vinyl chloride monomer at the workplace in the various Community countries specified between 5 ppm (Germany), and 100 ppm (Denmark). The Commission thought it was necessary to afford a sufficient degree of protection for all workers in all the Member States and to propose to this end, to all the enterprises where a risk is present, the same objectives and preventative measures. In a further question² on the same subject Mr Glinne pointed out that the US Occupational Safety and Health Administration had decided that, as from 1 April 1976, workers exposed to doses of vinyl chloride exceeding an average of 1 ppm over 8 hours or 5 ppm over 15 minutes must wear protective masks, since a correlation had been established between the incidence of cancer of the liver (angiosarcoma) and exposure to vinyl chloride. The first symptoms of the disease could occur up to thirty years after exposure to the hazard.

¹ Written Question No. 178/75, published in OJ No. C 192, 22.8.1975, p. 34

² Written Question No. 681/75, published in OJ No. C 82, 7.4.1976, p. 3

The Commission was therefore asked whether it was in the process of updating its minimum safety criteria in conjunction with the interested ministries of the Member States and possibly the Foundation for the Improvement of Living and Working Conditions.

On 3 March 1976 the Commission replied that it was currently reviewing safety criteria applied in Europe and would bear the questioner's comments in mind. It was intending to present a number of proposals in this connection in the near future. It added that on 24 August 1974 it had submitted to the Council a proposal for a directive restricting the marketing of certain dangerous substances and preparations¹ with a view to protecting workers and the general public from risks associated with the use of certain chemicals. It had proposed that this directive should be amended so as to outlaw the use of vinyl chloride monomer as a propellant for aerosols².

On 21 February 1975 the European Parliament delivered a favourable opinion on this proposal in its resolution³ based on a report (Doc. 394/74) drawn up by Mr Walkhoff on behalf of the Committee on Public Health and the Environment. The Council adopted the directive restricting the marketing and use of certain dangerous substances and preparations on 27 July 1976⁴. This directive prohibits the marketing and use of vinyl chloride as a propellant for aerosols for any type of use.

As regards the harmonization of safety criteria promised by the Commission, the latter submitted a proposal for a directive to the Council on 22 November 1976 on the protection of the health of workers occupationally exposed to vinyl chloride monomer⁵. On 13 June 1977 the European Parliament delivered a favourable opinion⁶ on this proposal on the basis of a report (Doc. 122/77) drawn up by Mrs Squarzialupi on behalf of your committee.

¹ OJ No. C 126, 17.10.1974, p. 33

² See Doc. COM(75) 186 final

³ OJ No. C 60, 13.3.1975, p. 49

⁴ OJ No. L 262, 27.9.1976, p. 201

⁵ OJ No. C 291, 10.12.1976, p. 5

⁶ OJ No. C 163, 11.7.1977, p. 11

20. Written Question No. 380/75 by Mrs Dunwoody concerned the packaging of food in polyvinyl chloride plastics¹. In this question she referred to the findings of the United States' Food and Drug Administration, according to which certain kinds of plastics made of PVC may cause cancer because they contain vinyl chloride monomer (VCM). This applied first of all to 'rigid' PVC containers, e.g. salad oil bottles and margarine containers. The Food and Drug Administration intended, therefore, to prohibit the use of 'rigid' containers for food packaging. The Commission was asked whether it was in possession of information to corroborate or rebut these findings, and whether it would submit proposals to prohibit the use of PVC containers for food packaging in the Member States.

In its answer of 3 December 1975 the Commission said that it had consulted the Scientific Committee for Foodstuffs, which had recommended on 28 June 1975 that 'no trace of vinyl chloride should be detectable by the previously agreed method in either foodstuffs or drinking water'. The Commission said it was making every effort to perfect a method of detecting vinyl chloride in foodstuffs. As soon as the findings of the experiments currently being carried out in the Member States were available, the Commission would propose that the Council prohibit the use of any PVC containers which allow vinyl chloride to migrate into foodstuffs. Enforcement of this ban would be monitored by an approved method.

21. Mr Walkhoff asked the Commission² whether, in view of the proven carcinogenic properties of vinyl chloride, the Commission intended to submit a proposal for a directive limiting the amount of vinyl chloride contained in PVC and, if so, when.

In its answer of 14 October 1976, the Commission said that on 6 August 1974 it had submitted to the Council a proposal³ for a directive on materials and objects that come into contact with food³. This proposal embodied an outline arrangement governing this field which was intended to ensure protection for consumers. The Commission had also consulted the Scientific Committee for Foodstuffs concerning the content of vinyl chloride monomers in articles in contact with food. The opinion delivered by the

¹ OJ No. C 1, 5.1.1976, p. 6

² Written Question No. 355/76, published in OJ No. C 276, 22.11.1976, p. 16

³ OJ No. C 121, 11.10.1974, p. 27

Committee was as follows:

- (a) the aim should be to take all possible steps to reduce all forms of exposure to vinyl chloride;
- (b) levels of vinyl chloride in PVC and related polymers should be reduced as far as possible;
- (c) there should be an approved method for establishing that there is no trace of vinyl chloride in food or drinking water.

On the basis of that opinion the Commission was preparing a directive for the implementation of the abovementioned outline directive and would shortly present it to the Council.

On 11 November 1974 the European Parliament delivered a favourable opinion¹ on the Commission's proposal for an outline directive on the basis of a report drawn up by Mrs Orth on behalf of the Committee on Public Health and the Environment (Doc. 321/74). The Council adopted this outline directive on 23 November 1976².

As for the implementing directive, the Commission submitted to the Council on 11 December 1976 a proposal for a directive on materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs³. On 22 April 1977 the European Parliament delivered a favourable opinion⁴ on this proposal on the basis of a report drawn up by Mr Evans on behalf of your committee (Doc. 515/76). The Council adopted the directive on 13 January 1978⁵. According to this directive, the vinyl chloride monomer content of articles in contact with food may not exceed 1 mg/kg in the final product. Materials and articles must not pass on to foodstuffs which are in or have been brought into contact with such materials and articles any vinyl chloride detectable by the method laid down in Annex II (lower detection limit: 0.01 mg/kg).

¹ OJ No. C 155, 9.12.1974, p. 10

² OJ No. L 340, 23.11.1976, p. 19

³ OJ No. C 16, 21.1.1977, p. 8

⁴ OJ No. C 118, 16.5.1977, p. 70

⁵ OJ No. L 44, 15.2.1978, p. 15

22. In Written Question No. 111/77¹ Mrs Squarcialupi and Mr Veronesi drew attention to the fact that the Cancer Research Institute in Bologna had published the results of tests carried out on vinylidene which was clearly shown to have carcinogenic effects. The Commission was asked what measures it intended to take to protect public health in view of the fact that vinylidene was widely used for long-storage food containers.

In its answer of 13 June 1977, the Commission said that the action programme on safety, hygiene and health at work which it had submitted to the Council provided for the investigation of carcinogenic substances including vinylidene chloride. The Commission added that it was currently conducting an enquiry into the use of polyvinylidene chloride - a plastic manufactured from vinylidene chloride monomer - as a substance that comes into contact with foodstuffs. It had also requested the opinion of the Scientific Committee for Foodstuffs regarding the possible toxic effects of vinylidene chloride monomer, which may still be present as a residue in the finished plastic. As soon as it was in possession of all the necessary data, the Commission would propose any measures which may be needed in order to safeguard the health of the consumer. Powers to take any necessary action were already provided by the outline directive of 23 November 1976.²

Your committee would like to know when the Commission intends to take the measures it promised to protect the consumer against the harmful effects of vinylidene chloride monomer.

As no Council decision was forthcoming on the Commission's proposal for a directive on workers exposed to vinyl chloride monomer³, Mrs Squarcialupi asked the Council whether it did not agree that the directive on the protection of the health of workers occupationally exposed to vinyl chloride monomer should be adopted as a matter of urgency since the risk of contracting cancer as a result of frequent handling of this substance was extremely serious.

In its answer of 5 April 1978, the Council said that it had begun to examine the directive and would probably adopt it by June 1978.

¹ OJ No. C 191, 10.8.1977, p. 45

² See penultimate paragraph of point 21 of this explanatory statement

³ See the final paragraph of point 19 of this explanatory statement

The Council adopted the directive on 29 June 1978¹. One of the provisions of this directive was that the maximum admissible concentration of vinyl chloride monomer in the atmosphere of a working area was between 3 ppm and 8 ppm according to average exposure period (reference period).

23. In Written Question No. 653/73 on the health risk from the use of asbestos in brake linings², Mr Willi Müller pointed out that asbestos was used in brake linings and that on application of brakes this asbestos was released into the atmosphere in the form of a very fine dust and was absorbed into the human body either directly through the respiratory organs or indirectly through the natural hydrological cycle. The Commission was asked whether in view of the well-known and uncontroverted carcinogenic properties of asbestos and appreciating the problems caused by its use in motor vehicle brake linings, it would initiate the appropriate research projects and whether such projects would be linked with instructions for the development of technical substitutes which might do away with the need to use asbestos in brake linings.

In its answer of 10 May 1974 the Commission said that it had begun a study of the levels of asbestos in the air and in water and their possible health implications. It also intended to award a number of contracts for research into the effects of asbestos on human health. However, as the Community research programme on the protection of the environment did not include research into technical measures for combating pollution (except in the iron and steel industry), the Commission was unable at the time to initiate research to develop substitute products for asbestos in brake linings.

24. In Written Question No. 625/76 on the hazards caused by the use of asbestos filters for wine³ Mr Lagorce pointed out that the examination of a large number of samples of French table wines had revealed the presence of excessive quantities of asbestos fibres. The presence of these fibres, whose carcinogenic effect was well established, was due to the use of asbestos-based filters which were very attractive commercially. The Commission was asked

¹ OJ No. L 197, 22.7.1978, p. 12

² OJ No. C 65, 7.6.1974, p. 6

³ OJ No. C 35, 11.2.1977, p. 19

if it did not feel that the use of these filters should be prohibited as a matter of urgency and that because of the highly carcinogenic nature of these fibres all suspect wine should be withdrawn from the market.

In its answer of 13 January 1977 the Commission said that although information currently available showed that there was a risk of cancer to the respiratory system if exposed to inhalation, it had not been proved that the risk to human health was increased if asbestos fibres were present in water, beverages and foodstuffs. Consequently, the prohibition of the use of these filters did not seem justified. The Commission therefore considered it inadvisable at that time to withdraw from the market all the suspect wine, which was usually filtered through asbestos-based plates. The Commission admitted, however, that further research was necessary before deciding the position that may be adopted within the Community as to whether to authorize or prohibit the use of asbestos-based filters.

25. In Written Question No. 801/75 on oral contraceptives¹ Mr Glinne said that the United States Food and Drug Administration was considering the introduction, with a month, of measures designed to warn the public against contraceptive pills (called 'sequential' pills) which may lead to blood clots and cancer of the uterus and even the withdrawal of such pills from the market. The Commission was asked what conclusions it had reached as to measures to be applied in the EEC.

In its answer of 31 March 1976 the Commission noted that according to the directives in force, responsibility for authorizing or refusing to authorize the marketing of a proprietary medicinal product rested with the Member States as did responsibility for suspending or withdrawing such authorization. However, when the second directive of 20 May 1975 on proprietary medicinal products² entered into force in October 1976, the Committee for Proprietary Medicinal Products would provide a suitable forum for discussion of the problems raised and, if necessary, for the adoption of conclusions which would apply throughout the Community.

¹ OJ No. C 99, 3.5.1976, p. 35

² OJ No. L 147, 9.6.1975, p. 13

The Commission added that in any case it made a point of keeping abreast of action taken in the United States and of the reasons prompting such action.

26. In Written Question No. 787/75 on the authorization of the use of the red colouring matter amaranth in foodstuffs¹, Mr Jahn drew attention to the carcinogenic nature of this substance. The Commission was asked whether it was prepared, in view of the latest extremely disturbing research results of the North American scientists, to amend its proposal for a directive without delay, so that the use of amaranth in foodstuffs was prohibited forthwith.

The Commission's answer of 29 April 1976 was negative. To justify its position the Commission referred to the opinion of the Scientific Committee for Foodstuffs which in June 1975 laid down a temporary acceptable daily intake (ADI) of 0-0.75 mg/kg body weight for amaranth. After critical and thorough examination of the findings of the North American scientists the Scientific Committee for Foodstuffs had endorsed its opinion of June 1975 on 27 February 1976 and agreed to retain the temporary ADI introduced at that time. Moreover, the use of amaranth in the Community was justified for certain technological reasons since as far as certain foodstuffs were concerned, it would be difficult to find a substitute for amaranth at present.

27. Three Written Questions from Members of the European Parliament - Written Questions No. 62/77 by Mr Martens², No. 70/77 by Mr Seefeld³ and No. 151/77 by Mr Hougardy⁴ - raised the matter of the carcinogenic nature of saccharin. Noting that the USA and Canada had prohibited the use of saccharin as a food sweetener on account of its carcinogenic nature, they asked the Commission to propose that it be prohibited in the EEC too, or to ensure that, until the truth of the matter was finally established, saccharin was sold by chemists only on prescription.

¹ OJ No. C 128, 10.6.1976, p. 9

² OJ No. C 191, 10.8.1977, p. 31

³ Ibidem p. 33

⁴ OJ No. C 223, 19.9.1977, p. 5

In its answers of May and June 1977 the Commission said that it had asked the Scientific Committee for Foodstuffs for its advice on the toxicological acceptability of saccharin in food and would decide if measures were necessary when it had received this advice. In addition, the Commission was in consultation with the Member States which were at present considering the most recent data on saccharin.

Your committee awaits the outcome of these investigations with interest.

28. Written Question No. 1068/77 by Mr Lagorce concerned the risk of cancer from margarine¹. The author of the question referred to the report presented by an American professor at the University of Columbia at a congress of physicians in the Federal Republic of Germany according to which margarine, at least when eaten in large quantities, could cause changes in cellular tissue and encourage cancer. The Commission was asked whether it possessed any reliable comparable statistics, in particular from the World Health Organization, giving a more specific idea of exactly how harmful the effects of eating butter and margarine could be.

In Oral Question No. H-478/77 by Mr Herbert² the Commission was also requested to state its views concerning a possible link between margarine consumption and cancer and what measures it intended to take.

In its answers of March and April 1978 the Commission explained that the action and metabolic effects of the various fats were not yet fully known. The Commission had therefore embarked on research and study programmes in this field with which the Scientific Committee for Foodstuffs had been associated and no steps could be taken until the results of those studies were known.

In the light of these answers Mr Jahn³ asked the Commission which institute or which research workers had been asked to carry out this study.

¹ OJ No. C 137, 12.6.1978, p. 8

² Debates of the European Parliament, No. 228 (March 1978), p. 144

³ Written Question No. 514/78, published in OJ No. C 5, 8.1.1979, p. 13

He also asked the Commission,

- (a) whether any results had been produced so far,
- (b) when these studies were likely to be completed and
- (c) whether the Commission was prepared to notify the relevant European Parliament committee of the research findings as soon as they were available.

In its answer of 7 December 1978 the Commission explained that on the recommendation of the Scientific Committee for Foodstuffs it had arranged for a series of research projects on oils and fats to be carried out by the Rijksinstituut voor de Volksgezondheid in Bilthoven. The Commission had carried out additional studies into the relationship between margarine and butter and had organized a symposium in April 1978 to present the latest scientific data available comparing the properties of various oils and fats. However, the Commission had no knowledge of scientific arguments which would require it to take immediate action. Unjustified criticism of individual oils and fats (including margarine and butter) created unnecessary public concern. The Commission said that it would submit to the Scientific Committee for Foodstuffs all the data made available to it during 1979. The final results of studies and research in the Commission's possession would be included in the next report of the Scientific Committee for Foodstuffs, which would be published as usual. The Commission would be pleased at that time to give any further detailed explanation of the report to the relevant European Parliament committee.

29. Mr Pisoni asked the Commission¹ whether a causal link existed between lung cancer and the death of former miners having contracted silicosis and whether relevant studies had been carried out at Community level.

In its answer of 27 July 1977, the Commission stated that epidemiological studies and surveys carried out at Community level had not established a significant statistical link between lung cancer and the death of former miners suffering from silicosis. The most recent of these surveys had covered 5,000 persons.

¹ Written Question No. 313/77, published in OJ No. C 214, 7.9.1977, p. 16

30. In Written Question No. 69/77 on carcinogenic substances in cosmetic products¹ Mrs Kruchow asked the Commission whether there were any substances which might be carcinogenic among those which under EEC provisions were allowed to be used in cosmetic products and, if so, if it would take steps to prohibit the use of these substances.

In its answer of 3 June 1977, the Commission stated that some substances, although not known to be dangerous had been given only temporary authorization pending the availability of further technical information. The Commission gave an assurance that it would not hesitate to take the appropriate action if new information should show that these or any other substances were dangerous to health.

Written Question No. 1306/77² by Mr Schyns raised the same issue. In particular, his question raised the problem of chloroform authorized for use in toothpaste which, according to a press report published in 1976, was carcinogenic. The Commission was asked whether it was true that chloroform did not serve any technical purpose and why the presence of chloroform did not have to be mentioned on the tube.

In its answer of 17 July 1978, the Commission said that there was so far no evidence of the carcinogenicity of chloroform in man. The question would be placed on the agenda of the Scientific Committee on Cosmetology set up by the Commission on 19 December 1977. Chloroform was used to give toothpaste a certain flavour. The experts consulted when the directive was being drawn up had not considered it necessary for the presence of chloroform to be mentioned on the label.

30a. In Written Question No. 540/78³ on carcinogenic substances in cosmetic products, Mr Brégégère asked the Commission what steps it had taken to prevent the existing stocks of hair dyes, which had caused cancer in laboratory animals and had been withdrawn from the US market, from being sold in the EEC. Secondly, he asked the Commission whether it agreed that this state of affairs was further evidence of the need to provide details of ingredients

¹ OJ No. C 191, 10.8.1977, p. 33

² OJ No. C 199, 21.8.1978, p. 16

³ OJ No. C 282, 27.11.1978, p. 48

on the package in order that suspect products could be rapidly identified.

In its answer of 19 October 1978 the Commission stated that it had asked the Scientific Committee on Cosmetology for an opinion on the six suspect substances contained in hair dyes, and would submit appropriate proposals based on this opinion. The Commission felt that the directive of 27 July 1976 on cosmetic produces¹ should make it possible for all suspect cosmetic products to be rapidly identified.

31. In Written Question No. 386/78 on the importation from the USA of children's pyjamas with carcinogenic effects², Mr Jahn drew attention to the fact that certain children's pyjamas, prohibited in the USA because of their carcinogenic effects, could be freely marketed in the Community. The American Consumer Protection Commission had established that the pyjamas contained 'Tris', a carcinogenic substance which could penetrate the skin and could be absorbed orally if small children sucked the material. The Commission was asked what measures it intended to take or to propose to ensure that

- (a) imports of these pyjamas into the Community were stopped,
- (b) the pyjamas already on the market were withdrawn from sale,
- (c) the public were properly warned of the dangers of these pyjamas.

In its answer of 28 September 1978 the Commission said that according to its information the United States had suspended its exports of children's pyjamas treated with 'Tris'. The Member States had been informed of the problems presented by 'Tris' and had taken the emergency measures they thought necessary. The Commission was taking expert advice on the measures to be taken and was considering how to present appropriate proposals in due course.

32. Mr Glinne drew attention to the fact that the American Environmental Protection Agency had banned the use in the United States of two insecticides, 'heptachlor' and 'chlordane', which were suspected of having a carcinogenic effect in human beings³.

¹ OJ No. L 262, 27.9.1976

² OJ No. C 251, 23.10.1978, p. 17

³ Written Question No. 717/75, published in OJ No. C 82, 7.4.1976, p. 12

In its answer of 1 March 1976 the Commission said that the use of these insecticides, which was authorized in the Community only in a limited number of cases, had been prohibited or discontinued in most Member States. The question of the suspected carcinogenicity to man of heptachlor and chlordane was, however, more controversial.

In reply to Written Question No. 380/77¹ by Mr Guerlin on the risk of cancer arising from the use of styrene, the Commission said that the results of the tests carried out by Professor Maltoni did not at that time offer any conclusive evidence of the carcinogenic effects of styrene. A second set of tests on animals other than the rat were therefore necessary. Once the state of the art was such that dangerous exposure levels at places of work could be determined, the Commission would put to the Council suitable proposals for the protection of workers against styrene as part of its programme of action on safety at work.

Your committee does not find this answer satisfactory. It may take an extremely long time for scientists to determine the exact tolerance level to which workers may be exposed to this allegedly carcinogenic substance before cancer occurs. The Commission is therefore called upon to propose immediate steps with the aim of limiting to a minimum the effects of styrene on workers through appropriate industrial hygiene measures.

In reply to Mr Willi Müller's question² concerning the carcinogenic effects of the chemical acrylonitrile, used in the manufacture of synthetic fibres and plastics, the Commission said that it would propose the necessary measures under the action programme on safety, hygiene and health at work if the investigations in progress confirmed the hazardous nature of acrylonitrile at the production and/or consumption stage.

Your committee awaits with interest the findings of the investigations which have now been in progress for some time.

33. In Written Question No. 653/78 on the general subject of carcinogenic substances³ Mr Schyns drew attention to the fact that the US Occupational Safety and Health Administration had published a

¹ OJ No. C 72, 22.3.1978, p. 3

² Written Question No. 806/77, published in OJ No. C 74, 28.3.1978, p. 4

³ OJ No. C 307, 22.12.1978, p. 28

first list of chemicals which could be carcinogenic and were therefore to be the subject of immediate regulations.

A second list contained 218 chemicals which might be carcinogenic although the exposure level was sufficiently low to prevent them having any effect. A third list included 396 chemicals with slight carcinogenic potential. The Commission was asked whether it felt prompted by these reports to change certain existing directives or propose new directives for adoption by the Council. The Commission was also asked to state what measures it proposed to take to see that the public and occupational bodies were adequately informed so as to limit the risk to workers and consumers.

In its answer of 21 November 1978 the Commission said that it was currently examining the lists compiled by the Occupational Safety and Health Administration. Any follow-up would depend on the outcome of that examination. A specific project in the field of protecting workers against carcinogenic substances and a project for worker enlightenment in regard to this hazard was provided for in the European Communities' action programme on health and safety at work approved by the Council on 29 June 1978.

34. In Written Question No. 798/78 on tobacco advertising¹ Mr Pucci asked the Commission whether it was aware of the resolution by the European Confederation of Tobacco Retailers in which this organization had stated its opposition to any emotive anti-tobacco campaign. In addition, the Commission's attention was drawn to the opinion of 11 April 1978 of the tobacco industry associations (LLAEEE) affiliated to the European Trade Unions, on behalf of over 1 million of their members, stating their opposition to a total ban on the advertising of tobacco products.

In its answer of 22 January 1979 the Commission referred to its view on the question of combating the misuse of tobacco as explained to the European Parliament in January 1978 in answer to Oral Question No. 0-87/77 by Mrs Squarcialupi².

35. Mention should also be made of Written Question No. 7/78³ by Mr Jahn to the Commission on action by the Community against carcinogenic environmental factors.

¹ OJ No. C 45, 19.2.1979, p.27

² See Debates No. 225, January 1978, p.77

³ OJ No. C 175, 24.7.1978, p.33

The Commission was asked

- what measures had been taken at Community level to combat environmental factors causing cancer,
- what proposals the Commission had made on the subject,
- what future steps it intended to take in this area and
- when any steps taken were likely to have an effect.

The Commission's answer may be summarized as follows: Community Directives on the environment already existed; they included provisions which restrict or prohibit the presence of certain carcinogenic substances such as arsenic, hydrocarbons, cadmium and pesticides. The action programme of the European Communities of 29 June 1978 on health and safety at the place of work contained specific measures with regard to carcinogenic substances at places of work¹. The introduction of a ban on a number of carcinogenic substances in the working environment had helped to reduce the levels of carcinogenic substances in the environment in general. The Commission intended to place before the Council in the near future an action programme on asbestos. It was expected that the measures contained in this programme would substantially reduce human exposure to asbestos dust, which may be carcinogenic. The measures proposed by the Commission could not be implemented unless appropriate decisions were taken by the Council.

36. As long ago as 1972 Mr Oele put a Written Question (No. 504/72) to the Commission on the coordination of cancer research in the Community², in which he referred to the relatively unsuccessful attempts by the European Organization for Research on Treatment of Cancer to make a coordinated contribution to the American Cancer Research Programme. The Commission was asked what links existed between the international cancer research organizations located in Europe and the Community institutions and whether it was prepared to investigate what funds were available to help research catch up with technology. The Commission's answer of 30 March 1973 was not very encouraging. Although it confirmed that regular liaison took place between the Commission and European research organizations, the former saw no way of increasing its support for these organizations given the constraints of present programmes and budgetary resources.

¹ Details of this programme will be found in the final paragraph of point 5 of this explanatory statement.

² OJ No. C 67, 17.8.1973, p. 49

37. In Written Question No. 217/74¹ Mr Willi Müller asked the Commission whether, to its knowledge, there were any state-initiated or state-aided programmes for combating cancer or any cancer clinics in the nine Member States. In addition, the Commission was asked whether it considered it necessary and possible to promote such projects in the interests of public health.

In its answer of 31 July 1974 the Commission explained that the nature and extent of the programmes for combating cancer varied from one Member State to another and that all the Member States had special consultancy arrangements and clinics specifically for the treatment of cancer. The Commission said that it had long been in contact with the European Organization for Research on Treatment of Cancer (EORTC), which included the Member States' best specialists, and had given it regular financial support.

38. The specific matter of the financing of the European Organization for Research on Treatment of Cancer was raised by Mr Hougardy in Written Question No. 294/75². In its answer of 21 October 1975 the Commission said that this organization had overall resources totalling 628,000 u.a. (including a Commission contribution of 225,000 u.a.). The Commission's contribution had from the outset been approximately the same amount. The US contribution totalled 127,000 u.a.

Mrs Kruchow asked the Commission about the establishment of a Community retrieval system for literature on cancer research³. She pointed out that various attempts had been made to coordinate information retrieval. The Commission was asked whether it could take steps to achieve a higher level of cooperation in order to increase the efficiency and scope of existing retrieval systems for literature on cancer research and, if possible, to extend this cooperation to other European countries. On 28 July the Commission replied that it could only contemplate a really effective initiative in this field if the Member States could make the necessary resources available for such a common retrieval system. Within the Biomedical

¹ OJ No. C 101, 31.8.1974, p. 30

² OJ No. C 272, 28.11.1975, p. 10

³ Written Question No. 263/76, published in OJ No. C 226, 27.9.1976, p. 25

Information Working Party of the Committee for Scientific and Technical Information and Documentation (CIDST) studies were being pursued with a view to setting up a system for the permanent inventory of current or planned research work with the active cooperation of the nine Community countries; an attempt was being made to incorporate cancer research in this system.

IV. Main findings of the hearing of experts

39. As stated in point 4 details of the hearing will be found in the 'verbatim record' (PE 54.100) and Annexes II to IX thereto. Your committee confines itself here to summarizing the main points made by the experts and, on that basis, recommending a number of concrete measures.

(a) Carcinogenic effects of hydrocarbons

- Experts' observations

40. The experts agreed that higher polycyclic aromatic hydrocarbons of the 3, 4-benzopyrene type cause cancer in both animals and human beings. Because of their low chemical reactivity and resistance to heat they can be eliminated only very slowly. They have been polluting the human biotope since man discovered fire. They are produced whenever there is incomplete combustion of organic material. In this process, known as pyrolysis, the combusted substance breaks down chemically into small hydrocarbon molecules which immediately reunite to form cyclized molecules with a much higher resistance to heat and oxidation. These substances are present in a variety of environmental media, e.g. coal tar, tobacco smoke, the air and smoked foods. They get into the air mainly through heating, factory fumes, and, to a lesser extent, exhaust fumes from motor vehicles. The carcinogenic hydrocarbons are the substances contained in coal tar. They are usually local, carcinogenic substances which cause cancer at the point of contact, on the skin for example, but hardly ever in remote organs. At present carcinogenic hydrocarbons offer the best explanation of lung cancer caused by substances in the environment such as tobacco smoke or polluted air. Several hundreds of these substances have been investigated, and some 50 or 60 are now known to be carcinogenic. To become 'active' they clearly have to be converted by enzymes. This enzymatic conversion is undoubtedly genetically determined, since some people have a higher enzyme level than others so that they metabolize and convert these substances more readily than those with a lower enzyme level. Thus, sensitivity to hydrocarbons varies considerably from one individual to another.

41. There is a long history also, extending back more than one hundred years, of occupational skin cancers associated with contact with mineral oils, and it seems likely that their carcinogenic activity is at least partly attributable to the presence of polycyclic hydrocarbons. The activity varies greatly with the type of oil and between different fractions of refined oils. The most potent are the shale oils. It is possible also that the inhalation of oil mists dispersed in machine shops may pose some lung cancer risks. The risk of cancer does not, however, extend to the lighter fractions of petroleum oil used as motor fuel. These do not contain any appreciable amounts of polycyclic hydrocarbons, and there do not appear to be any carcinogenic risks associated with their handling or use. On the other hand, polycyclic hydrocarbons are liable to be formed in some circumstances on combustion of coal or other hydrocarbon fuel.
42. Cancer of the stomach is extremely common in Iceland and scientists believe that this is attributable to the fact that 70 or 80% of the food consumed in that country consists of smoked fish. However, cancer of the stomach has become less common in many countries in recent decades.

Not all polycyclic hydrocarbons are carcinogenic. Minute chemical differences are often all that distinguish a highly carcinogenic polycyclic hydrocarbon from one which is totally innocuous.

Skin cancer is common in coal mining, owing to the presence of hydrocarbons. However, the most dangerous carcinogenic factor for the skin is undoubtedly ultra-violet radiation from sunlight. It is quite possible that in polluted air areas of the skin contaminated by hydrocarbons which are also exposed to ultra-violet radiation from the sun are subject to the combined effect of the two.

No conclusive evidence has so far been adduced in support of the theory that the oral ingestion of hydrocarbons (chipped potatoes, grilled meat, etc.) can lead to cancer in man.

- Recommendations

43. Measures to combat cancer in this area should be geared to prevention. We should deploy every technical means at our disposal to eliminate or, if that is not possible, at least reduce the polycyclic hydrocarbons in the environment.

In addition, specific research should be carried out into the abovementioned enzyme activities among endangered population groups. The results should be used to determine the degree of risk incurred by individuals according to their level of enzyme activity. In this way genetically high-risk groups could be identified. However, the necessary lymphocyte (type of blood cell) tests have not yet been perfected and cannot therefore be applied on a routine basis.

44. Your committee also calls on the Commission to draw up a proposal for a regulation on recognized occupational diseases so as to provide uniform protection for workers throughout the Community. The recommendation on the recognition of occupational diseases of 1972 is inadequate since (a) it is not binding and (b) it does not cover all occupational diseases. In the new directive the level of assurance should be set lower than before. In particular, it is important to ensure that the burden of proving that his illness is due to his occupation should be removed from the individual worker. In addition, your committee recommends that for the purposes of drawing up these directives all research work carried out by the Member States and, if possible, by third countries, should be assessed in order to establish specific casual relationships and draw the necessary conclusions for the recognition of occupational diseases.
45. In view of the success of measures taken in London where in the last 25 years concentrations of pollutants in the air have been reduced considerably by restrictions on the use of coal and on chimney smoke it might be argued that this example should be followed in other conurbations in the Community.

In this connection attention is drawn to the fact that at the end of January 1979 the first ever large-scale smog alarm was sounded in the Ruhr area and an appeal was made to the whole population to take care to avoid all physical strain, particularly strain of the respiratory organs. This alarm was sounded because of unfavourable atmospheric conditions (inversion) accompanied by intense pollution of the air. It is necessary therefore further to restrict emissions of pollutants, particularly coal dust, from industrial plant by installing filter systems, suction apparatus and other suitable measures.

If these measures are unsuccessful nuclear energy generation capacity must be stepped up in the coming years. According to the experts no polycyclic hydrocarbons are produced during the generation of nuclear energy. Of course, the utilization of nuclear energy involves other safety risks, but these are outside the scope of this report.

46. The carcinogenic hydrocarbon level in the air has fallen in recent years thanks to appropriate preventive measures but more could still be done to improve the situation. The quantity of carcinogenic hydrocarbons emitted by motor vehicles into the air on a cold start is 300 times the amount emitted at a speed of 110 mph. An attempt should therefore be made to achieve a substantial reduction in cold-start emissions - a problem which, given the present state of scientific and technical progress, can undoubtedly be solved. The same applies to emissions from heating installations. The Commission is therefore asked to initiate suitable measures.

(b) Carcinogenic effects of pesticides

- Experts' observations

47. A number of pesticides belong to the group of secondary amines which may react with nitrates to form N-nitroso compounds. These reactions are carcinogenic. Certain pesticides have been proved to be carcinogenic in animals while there is no evidence available that they have produced cancer in humans.

The United Nations World Health Organization and Food and Agricultural Organization have set up committees of experts to investigate the toxicity of pesticides and their presence as residues in food. These committees have established acceptable daily intakes of chemicals in food which have been published. Pesticides which have a known carcinogenic effect are not generally checked for ADI because they are too dangerous.

Many pesticides, particularly halogenous compounds, build up in the organism and persist for long periods. There is no epidemiological evidence of the carcinogenicity of pesticides containing halogens but most of the population is exposed to only very small doses. However, so far there has been no comprehensive or sufficiently wide epidemiological study among the sections of the population concerned so sufficient information is not available.

Arsenic compounds, which are also used as pesticides, have been demonstrated to be carcinogenic in man. Arsenic is one of the few examples of a chemical which has been known to be carcinogenic in humans for many decades and for which, until recently, no evidence of carcinogenicity in experimental animals was available.

48. Generally speaking, it was stressed during the discussion on pesticides that the risk of cancer from carcinogenic substances increases as a function of the dose absorbed. The duration of exposure is also an important factor, however.

Experts do not agree on the definition of a minimal effective dose of a carcinogen. No figures are available monitoring exposure for the compounds produced on an industrial scale which have proved to be carcinogenic in man.

- Recommendations

49. It would seem desirable to concentrate epidemiological studies on the carcinogenicity of pesticides on sections of the population which are heavily exposed, i.e. persons who are involved in the manufacturing and application of these substances.

The Commission is therefore asked to consider what initiatives might be taken by the Community in order to organize, coordinate and intensify research in this area.

(c) Possible carcinogenic effects of asbestos dust

- Experts' observations

50. Carcinogenic properties are attributed to asbestos dust, i.e. inhalable asbestos fibres of specific dimensions which are released during the processing of crude asbestos. The findings of medical investigations point to a dose-effect relationship, in other words a correlation between duration of exposure to asbestos dust and its concentration. Because of the long latency period (over 20 years) before the first symptoms of carcinoma (including mesothelioma) appear, a correlation can

be established between the latter and high dust concentrations in previous decades when no effort was made to combat dust. The highest incidence of death and disease is associated with processing of asbestos insulation materials (spraying), followed by asbestos-based textile production and asbestos mining, the lowest incidence being found in the asbestos cement industry. This is in keeping with the dust levels produced in each of the industries and at their various locations in the past.

51. Detailed investigation has meanwhile shown that an increased risk of carcinoma as a result of exposure to high asbestos concentrations is present only in smokers. This statement by one of the experts was, however, disputed by another who claimed that an increased lung cancer risk existed also for non-smoking asbestos workers. Tobacco is dangerous when asbestos dust is inhaled at the same time (synergism). This applies to lung cancer, but not for the development of another important asbestos tumour, mesothelioma, for which smoke is not an important factor since it occurs in non-smokers as well as in smokers.

52. Short, even very short, exposure can lead to mesothelioma.

For the general population living in cities or in the country, the risk of asbestos-induced cancer is extremely low, because concentrations are not high enough and the duration of exposure is minimal. In the case of asbestos cement the risk is also low as it releases virtually no asbestos.

The carcinogenicity of asbestos is determined by the physical shapes of its fibres rather than by its chemical properties.

- Recommendations

53. Conclusive findings about the carcinogenic effects of asbestos fibres are not yet available. Your committee therefore suggests that systematic and comparable investigations should be carried out within the European asbestos industry. This must be combined with standardized measurement techniques and programmes designed

to determine past and present dust levels and to enable recommendations to be made on threshold levels. Technical measures, with appropriate monitoring facilities must be introduced to ensure that concentrations of two fibres per cm^3 , less if possible, are complied with in the handling of asbestos. This can be achieved in particular by installing suction filters, ventilation and air filtering systems in all asbestos processing works. The risk at the place of work must also be reduced by industrial hygiene measures. Harmonization of such measures at Community level should be proposed by the Commission.

54. Your committee considered the possibility of a smoking ban in asbestos factories but decided against it on the grounds that this was not in itself a solution to the problem.

If, for example, for the purposes of fire resistance, asbestos is incorporated in wood which has to be cut, this should be done under the protection of water in order to prevent dust from arising.

Your committee requests the Commission to propose appropriate Community safety regulations for the asbestos industry.

(d) Possible carcinogenic effects of chemical additives to food

- Experts' observations

55. The substances present in food can be divided into natural and man-made substances. The fact that a particular substance is natural does not necessarily mean that it is safer than a man-made substance. Natural substances can be further divided into food components and their contaminants. There is already adequate legislation in the EEC to eliminate substances which are suspected of having a carcinogenic effect as well as those known to have such an effect.

Certain components of the human diet may react, however, with other substances present in it and form new compounds. For example, nitrites can be formed from nitrates contained in certain varieties of vegetable such as purslane and spinach; these nitrates may then react with other substances forming secondary and tertiary amines and nitrosamines which in many cases have a carcinogenic effect.

Examples of natural contaminants are the equally dangerous mycotoxins and, in particular, the aflatoxins. A great deal of milk contains small, but nonetheless detectable quantities of aflatoxin. In the case of cows the presence of aflatoxin in concentrated feeds may generate conversion products and lead to the formation of aflatoxin M₁, which is in turn secreted with the milk and may thus reach the human organism.

56. The principal group of man-made substances which find their way into foodstuffs in the largest quantities is food additives. In this area too, legislation in Europe is very advanced. Carcinogenic substances are, of course, eliminated. All decisions in this field are based on animal experiments. One food additive, previously authorized but now prohibited, is butter colour. Other man-made contaminants include certain substances which may migrate into food from the packaging, e.g., monomers and vinyl chloride. The residues which reach our food from the pesticides applied to cereals and vegetables are also not unimportant. There is also a risk involved in the use of disinfectants, herbicides, insecticides and growth-promoting substances for cattle. All these substances are present in large quantities in the environment and may reach man through water, plants and soil. An increasing number of authorities are becoming aware of this risk. In the treatment and preserving of a wide range of meats and meat products carcinogenic compounds, albeit in very small quantities, may also be formed.
57. There is absolutely no scientific proof, however, that fat is carcinogenic. It is possible, though by no means certain, that changes in the trace elements caused by a high-fat diet could result in a higher risk of cancer.

The greatest danger is the formation of highly carcinogenic nitrosamines in the stomach following the consumption of food containing additives.

Generally speaking, however, there is a lack of reliable data on the effects of unintentional food additives.

- Recommendations

58. The most useful measure would be to eliminate all food additives which are not technologically necessary, i.e., serve no useful purpose (e.g. preservation).

The Commission is asked to draw up a programme with a view to investigating the whole human diet so as to eliminate carcinogenic substances. For this purpose the Community as a whole should follow the German example of first establishing the innocuousness of a food additive through extensive toxicological experiments before authorizing its use.

In addition, intensified research should be directed towards ways in which the formation of nitrosamines in the human body can be avoided. The Commission is asked to investigate what encouragement the Community can give to such research.

(e) Carcinogenic effects of cigarette smoke and international control measures

- Experts' observations

59. The inhalation of tobacco smoke should be regarded as the main cause of bronchial carcinoma in man. The higher aromatic hydrocarbons it contains are very probably the carcinogenic agents. There are also a number of broncho-toxic substances in tobacco smoke (e.g., acrolein and cyanide), which destroy the self-purifying powers of the bronchus (replacement of the ciliated epithelium by squamous epithelial cells). This change is possibly what paves the way for the carcinogenic effect of hydrocarbons. The vehicle of carcinogenesis is smoke condensate.

There is also a close correlation between smoking and bladder tumours. It is also likely that other forms of cancer (e.g. cancer of the pancreas) are due to smoking.

According to the latest American research over 40 carcinogenic substances of various kinds have been detected in tobacco smoke.

The inhalation of cigar smoke or pipe smoke is equally or even more likely to cause lung cancer. The smoker who does not inhale but merely puffs runs no risk of contracting a bronchial carcinoma.

Smoking damages not only the lungs, the respiratory tract, the heart and vessels, it also damages the digestive tract since every cigarette smoked stimulates the flow of bile, containing phenanthrene - a powerful carcinogen - into the stomach. All cigarettes are dangerous, to a greater or lesser extent.

As an alternative to smoking chewing gum is to be avoided at all costs because every contraction of the jaw muscles releases hydrochloric acid into the stomach which causes stomach ulcers.

- Recommendations

60. International anti-smoking campaigns have so far been relatively unsuccessful. World tobacco consumption is in fact on the increase. The realistic approach, therefore, would be to tackle the incriminated product itself so as to make it 'safer'. Attempts should be made to get smokers to change gradually to low-yield cigarettes, i.e. cigarettes containing less than 8 mg of smoke condensate. The bronchial carcinomas which occur today are attributable to inhalation from cigarettes smoked thirty years ago, which in those days contained an average of 25-30 mg of smoke condensate. The smoke condensate content of today's cigarettes is about 10 mg. Some progress has, therefore, already been made towards the production of lighter cigarettes. This trend must be maintained. Smokers should also be advised not to inhale.

Steps should also be taken to ensure that the tobacco industry provides goods which have been made as safe as possible by reducing their condensate content. Your committee feels that the Community should promote research to this end.

61. It is also necessary - despite doubts about the likelihood of success - to carry out further campaigns to explain the potential risks of smoking.

The important thing is to warn young people about the dangers of smoking early enough, i.e. before they have acquired the habit. Health hygiene should, therefore, be included in schools' curricula. Children must be taught not to smoke as early as the primary school.

It is also necessary in the context of prevention for clear priorities to be established with a view to persuading as many smokers as possible to give up the habit or reduce their consumption.

At a major scientific congress held in the USA in the spring of 1978 it was pointed out that one half of all deaths would soon be attributable to lung cancer if present trends in smoking habits were maintained.

62. Compartments for smokers should be introduced in international trains and aircraft where this is not already the case. Your committee feels, however, that this rule should also apply at national level.
A general ban should be introduced on smoking in aircraft.
63. Restrictions on the advertising of tobacco do not, however, seem to achieve the desired effect. An anti-smoking campaign should therefore be launched to explain the advantages of lighter cigarettes which have a lower tar level over cigarettes and tobacco with high-tar levels.

It is also arguable that in the light of the dangers of passive smoking measures should be taken to protect the non-smoker and, in particular, that there should be a call for a general ban on smoking at work. The committee has not adopted a firm position on this matter.

Smoking in public places should also be prohibited.

64. To try to curb smoking by increasing taxes on cigarettes is extremely dubious from the health point of view. Instead of cigarettes people then buy loose tobacco and roll their own cigarettes, which contain something like four times as much tar as light mass-produced cigarettes.

Your committee therefore rejects any solution along those lines.

(f) Carcinogenic effects of industrial dust and smoke on workers and populations of surrounding areas

- Experts' observations

65. The number and quantity of substances and products used in industry has increased tremendously in recent years. Admittedly only a small number of these substances have been shown to be carcinogenic but this is due to the fact that only a small number of compounds have been studied for their carcinogenic effect.

The number of substances studied is negligible compared to the number of compounds produced and used. Contaminating agents include combustion residues, energy-producing materials, in particular oil and coal, and newly synthesized products, which occur in the form of gas and smoke or in solid form.

In view of the lack of testing laboratories, in particular inhalation chambers, which have to cope with acute and chronic toxicity, carcinogenesis and short-term tests, no more than 50 compounds can be tested per year for carcinogenicity.

A happy medium should be found between being excessively zealous in trying to avoid anything that might have some carcinogenic risk and trying to protect people only from certain well-defined risks.

66. The most widespread, though perhaps not the best defined, problem is that concerned with polycyclic hydrocarbons as components of the smoke from incomplete combustion processes or the tarry fumes produced in some industrial processes such as the carbonization of coal. An increased incidence of lung cancer has been observed among men working in gasworks and in coke ovens.

Generally speaking, smoke from combustion processes in industry does not create any cancer risks, either to workers in the immediate vicinity or to the general public. This is because combustion is usually fairly complete.

67. It is smoke from domestic coal fires that is especially rich in the potentially carcinogenic compound benzo(a)pyrene. In the United Kingdom the Clean Air Act has been particularly effective in reducing concentrations.

There is no clear evidence that occupational exposure to emissions from motor vehicles leads to any increased risk of lung cancer.

An increased incidence of lung cancer has been observed among men in certain other industries associated with specific dusts or fumes, for example the chromate-producing and chromate-using industry.

The production of nickel also entails risks of both lung and nasal cancer, although the exact causative agent has not been identified. Nasal cancer occurs also among furniture makers; this may be attributable to compounds in certain hardwood dusts, or to material produced while working it.

There is no indication that the relatively small amounts of suspect dust dispersed into the air beyond the factories have any detectable effect on the general population.

68. Cancer risks associated with radioactive dusts are confined to plutonium particles in nuclear fuel processing plants. Owing to the extreme precautions taken there is virtually no emission of such material into the air. There are, however, extensive emissions of small amounts of radioactive material of other kinds but mainly from natural sources. The radioactive gas radon escaping from the ground, and from the bricks and stonework of buildings decays into solid radioactive products that attach themselves to other particles in the air. In general, the amounts of radioactive material involved are too small to produce any detectable effect.

There are cancer risks, however, in mines where the ores are rich in uranium. In recent years a particularly high incidence of lung cancer in such mines has been reported.

69. The physical qualities of air pollution play a part in the carcinogenic effect of industrial dust. In some cases the mere existence of dust can tire out the cleaning functions of the organism.

- Recommendations

70. Your committee recommends that the number and capacity of testing laboratories, including the necessary monitoring apparatus, should be substantially increased in the shortest possible time. The investigation of the extremely large number of suspected carcinogenic and mutagenic products in circulation must be vigorously pursued. The Community must give the necessary encouragement in this area by making adequate financial resources available. The Commission is requested to submit appropriate proposals in the near future.
71. A further contribution to solving the problem might be made by allowing medical research staff free access to medical histories and death certificates from which information about cases occurring within the same plant could be obtained. The opportunity should be given to public health

officials to use these documents to draw conclusions about cancer victims. In addition, payrolls should be kept for 30 to 40 years so that it can be established which workmen were previously employed in risky occupations and whether they had cancer. Finally, an attempt should be made to get information on the smoking habits of employees in various plants.

72. In the Frankfurt area, for which data on the causes of air pollution and its variations are available and where environmental conditions have already been investigated with all the parameters of pollution, studies should be extended to include cases of cancer among the population.

All new chemical substances produced should be subject to compulsory registration and authorization along the lines of the US Toxic Substances Control Act introduced in 1976.

In view of the long latency period of cancer (20 to 30 years) steps should now be taken to obtain adequate information for future generations about the present state of environmental pollution by substances suspected of having carcinogenic effects.

(g) Carcinogenic effects of pharmaceutical products

- Experts' observations

73. In an overwhelming majority of cases, before a cell acquires carcinogenic properties it goes through an abnormal biological phase called the pre-cancerous stage. In this phase cancer can be detected early enough, at least in the digestive tract and in particular the stomach, for its progression to be arrested.

The real campaign against cancer, therefore, should be directed against its causes, that is against the substances and circumstances that give rise to the pre-cancerous state. Drugs are among those substances.

74. There are various ways in which drugs can cause stomach cancer, some direct and others indirect. However, all have the effect of breaking down the natural barrier that protects the epithelia from gastric auto-digestion. This is the most dangerous chronic

irritant as far as stomach cancer is concerned. The second is necrosis, followed by allergy. The latter is an abnormal reaction to various substances including certain drugs, and depends on the individual, which explains why the harmful effect of drugs varies from one individual to another. Some people take painkillers with impunity all their lives whilst others suffer serious and sometimes fatal effects from the same drug.

Gastric ulcers, especially in a particular region, are notoriously pre-cancerous.

75. Another effect of some widely used drugs is gastro-intestinal haemorrhage caused by micro-lesions of the tissues which require a reparative process. The reparative processes of the most serious lesions entail the reproduction of a type of tissue with biological pre-cancerous properties.

Few drugs give rise to tumours in man. Some of them have been withdrawn, others are indispensable because they are needed in quite specific situations, e.g. to combat cancer. No specific investigations have been carried out among the general public to establish whether the incidence of tumours is on the increase.

Tests carried out on saccharin have provided no evidence of carcinogenic effects.

- Recommendations

76. A number of widely used drugs such as anti-inflammatory, anti-thermic, anti-rheumatic, painkilling and other therapeutic drugs should be properly controlled by qualified study groups. The control groups should also suggest ways of reducing or eliminating the dangers of such drugs.

Moreover, drugs should be tested for possible carcinogenic action before they are placed on the market, with particular reference to their pharmacological properties and the possible toxic effects of intensive use, if possible on the basis of long-term tests. The risk-benefit ratio and possible acceptable levels of risk will have to be determined by analysing the usefulness of the drug, the possibility of administering a substitute product and the actual degree of exposure to it.

77. It would be desirable to draw the attention of both doctors and students to the possibility of drugs having carcinogenic effects. A risk-use analysis is particularly important in this case, for the use of carcinogenic drugs on human patients is of course justified where dangerous illnesses are involved, especially as carcinogenesis must generally be reckoned to have a latency period of many years or decades, while the acute illness being treated may well be threatening the patient's life.

Drugs whose therapeutic value is doubtful must neither be manufactured nor used. Your committee takes the view that the manufacture and use of such drugs should be banned.

For some drugs which are used very widely and indiscriminately the pharmaceutical industry must be compelled to keep clinical records on given sections of the public which are exposed to the drugs in order to discover any toxic effects over a long period of time.

The Commission is requested to investigate how these demands and recommendations can be incorporated into the Community's legislation on drugs.

(h) Carcinogenic effects of other harmful substances in the environment and methods of assessing possible carcinogenic effects of newly-marketed substances

- Experts' observations

78. Metals, e.g. lead, nickel, cadmium and chromium, are also present in the environment. They are persistent, i.e. they decompose only very slowly, they get into the natural cycle and thus find their way back into man. Environmental and nutritional factors are extremely important in the carcinogenic process.

Substances with carcinogenic effects can be present in the form of atmospheric pollution, water pollution, food contamination or pollution of particular biological systems such as marine plankton. The most serious problem is that of pollution by products and mixtures of products (plastics, detergents and mineral compounds), which form new compounds. Waste disposal, for example, can thus cause contamination of the air.

79. The aromatic amines include a number of substances which can cause cancer in man. The so-called natural products, for example, mycotoxins, are equally harmful.

There is evidence that in some way 80 to 90% of cancers are related to environmental factors of which only some have been identified.

World-wide facilities are limited for testing chemicals. There are in all about 90 institutes distributed in 19 countries carrying out long-term carcinogenistic testing for a total of 900 compounds. The potential for long-term testing of chemicals around the world is of the order of 900, perhaps 950 chemicals a year¹.

Bichloromethyl ether causes lung cancer in humans.

80. The reason for using high-dose levels of suspect substances in experimental animals is to compensate for the relatively low number of animals which it is reasonable to use in an experimental test and to try to maximize the possible effect of the exposure. This view was disputed by another expert who argued that it was necessary to try, as far as possible, to simulate in animals the form of exposure which applies to human beings.

One of the most potent skin carcinogens is sunlight.

81. The International Agency for Research on Cancer (IARC) in Lyons publishes yearly or two-yearly summaries of substances currently being investigated throughout the world; the aim is to prevent duplication.

Research has shown that the content of migrating monomers in drinking water cannot be measured.

Radiation experts have established that a trans-Atlantic flight exposes a person to more radiation than living in the vicinity of a nuclear power station, or even working in a nuclear power station, if the safety provisions are observed.

- Recommendations

82. For every synthetic product an assessment should be made of the risks and benefits involved. If a new substance offers no benefits or only very few benefits it should not be produced at all. Those which truly are beneficial should undergo a series of tests

¹ Another expert claimed that only about 50 substances a year could be tested properly for carcinogenicity (see point 6⁶ of this explanatory statement).

of increasing difficulty and sophistication to choose those which have no toxic or carcinogenic effects. The most important tests here are those to determine chemical affinity with substances already shown to be carcinogenic, tests on biological reactivity, acute and chronic toxicity and short-term tests on micro-organisms and animal cells. The most direct method of determining the carcinogenic effect of a substance is the long-term test on the whole animal.

83. If a substance which offers no particular advantages is found to be doubtful in the first, simplest tests, it should be dropped. However, a substance which is very important from a socio-economic point of view, even if it proves doubtful in the short-term tests, should be tested on animals in the longer term to assess the real risk and if these tests are positive, the substance should be prohibited in all cases except in the very rare cases where this substance is needed to save a patient in immediate danger of death.
84. Very rarely does the competence to assess risks and to assess benefits lie in the same person since they are quite different skills. In testing new substances, therefore, close coordination is necessary between the scientists involved.

Short-term tests are extremely useful for selecting chemicals to be subjected to long-term tests, to identify active fractions in complex mixtures and active metabolites of carcinogens in human body fluids.

The instruments made available to scientists must be suitably expanded.

85. There are about 2 to 3 million known chemical substances in the world and perhaps 3,000 to 5,000 have been adequately tested for their carcinogenic effects. It is therefore necessary to establish a properly programmed scheme with priorities for long-term testing in respect of carcinogenic properties. Thanks to rapid developments in recent years such a scheme and system of priority have now become possible in the case of short-term tests. The Commission is asked to examine what contribution the Community could make in this area.

(i) Epidemiological survey of cancer cases and surveillance of occupational cancer hazards

- Experts' observations

86. The fundamental, and oldest, method used for cancer epidemiology is the collection of case reports. When undertaken on the basis of registration such collection can be carried out without bias and in sufficient numbers for cases of rarer sites of cancer. This is still the most reliable method.

Correlation studies require systematic collection of large numbers of case reports but have, undertaken on the basis of adequate numbers, given important information on the nature and causation of cancers.

87. Case-control studies are usually relatively easy to establish on the basis of a registry and in association with hospitals providing control patients, or on the basis of public registries of a more general character.

Cohort studies covering cases arising within a given period, or among persons exposed to a possible hazard, may be undertaken retrospectively or prospectively.

There is a registration system in Denmark based on hospital cases and death certificates. Data are not, however, available on the current occupation of registered persons.

88. Surveillance through nationally collected mortality data is of considerable value.

Occupational cancer hazards must not be underestimated; smoking is not the only cause of cancer.

A particularly high incidence of pleura tumours has been observed in occupations having contact with asbestos. Some groups of chemical and rubber workers have high death rates for cancer of the bladder.

The rare tumour angiosarcoma of the liver can be produced by vinyl chloride to which workers are heavily exposed in certain jobs in the plastics industry.

- Recommendations

89. Far more information must be collected and assessed concerning working conditions, in connection with cancer cases involving employed persons, and tobacco consumption. Attention should also be given here to the correlation between working conditions and cancerous diseases.

Through European and international cooperation, case figures from small countries must be incorporated into the large data bases in order to facilitate the assessment of risks shown by a small number of cases in one or other industry.

90. Cancer registers should be compiled in all Community countries since in addition to monitoring the incidence of cancer they offer the advantage that each record begins with the initial diagnosis and may contain more information about the histological type of tumour than the corresponding death records. These registers should be kept and stored for a period of at least 30 years.

Building on the foundations provided by the monitoring tests, which are used as a basis for post-retirement pensions payments, a comprehensive health monitoring system should, if possible, be introduced for specific occupational groups, despite the cost involved. In this regard the Danish system provides a useful example.

The Commission is requested to propose the necessary measures.

91. The Community should encourage and promote preventive medicine by financial contributions, as this is a particularly effective means of combating diseases of civilization. In this area too, the Commission must make proposals.

X-ray examinations have shown about 65% uncertainty or even error, and therefore endoscopic and biotic methods, which contribute to better diagnosis and the early detection of cancer, should be encouraged.

92. In its programme on safety and health at work the Commission proposed the introduction of industrial toxicological surveillance. This would mean trying to establish the effects of chemicals and pooling them in some central data system.

Your committee calls on the Commission and Council to ensure that priority is given to implementing this aspect of the programme.

V. Other comments

93. Your committee takes the view that modern methods of treatment by means of natural remedies can also contribute to the fight against cancer. This approach to therapy seeks to enhance the body's own curative powers. A doctor can help the patient by using natural remedies, i.e. the external factors essential to health: air, light, climate and temperature, rest and movement, gymnastics, massage, change of diet, dietetics. Such treatment is not aimed at specific illnesses but seeks to become effective for the patient. Above all, it aims at eliminating any impediment to the body's own healing processes. Modern naturopathy, which has achieved considerable success in classical medicine, in no way rejects outright the use of drugs or surgery. Rather, it seeks to establish as accurately as possible when natural stimuli will be beneficial to the patient, thereby helping to define the sphere of application of all forms of treatment. Naturopathy seeks to avoid the undesirable consequences or side-effects of medical or surgical treatment.

Your committee therefore supports all organizations that have set themselves the goal of promoting naturopathy. In its view, this method of therapy is of especial importance for the prevention of cancer.