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Report

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

on the proposal from the Commission of the European Communities to the Council (Doc. 1-470/83 - COM(83) 301 final) for a Decision adopting a multiannual research and training programme for the European Atomic Energy Community in the field of radiation protection (1985-1989)

Rapporteur: Sir Peter VANNECK

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By letter of 20 June 1983, the President of the Council of the European Communities requested the European Parliament to deliver an opinion on the proposal from the Commission of the European Communities to the Council for a Decision adopting a multiannual research and training programme for the European Atomic Energy Community in the field of radiation protection (1985–1989).

On 4 July 1983, the President of the European Parliament referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Budgets and the Committee on Energy, Research and Technology for an opinion.

At its meeting of 22 June 1983, the Committee on the Environment, Public Health and Consumer Protection appointed Sir Peter Vanneck rapporteur.

The committee considered the draft report at its meeting of 23 November 1983 and adopted it unanimously.

The following took part in the vote: Mr COLLINS, chairman; Mrs WEBER, vice-chairman; Sir Peter VANNECK, rapporteur; Mr ALBER, Mr BOMBARD, Mr DEL DUCA, Mr JOHNSON, Mrs KROUWEL-VLAM, Mrs LENTZ-CORNETTE, Mr MERTENS (deputizing for Mr RYAN), Mr PETERSEN (deputizing for Mr MUNTINGH), Mr PROVAN (deputizing for Miss HOOPER), Mrs PRUVOT (deputizing for Mrs SCRIVENER), Mrs SPAAK, Mrs SQUARCIALUPI and Mr VAN HEMELDONCK.

The opinion of the Committee on Energy, Research and Technology is attached.

The opinion of the Committee on Budgets will be published separately.

The report was tabled on 29 November 1983.

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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

closing the procedure for consultation of the European Parliament on the proposal from the Commission of the European Communities to the Council, for a Decision adopting a multiannual research and training programme for the European Atomic Energy Community in the field of radiation protection (1985-1989)

The European Parliament,

- \sim having regard to the proposal from the Commission to the Council (COM (83) 301 final)¹,
- having been consulted by the Council (Doc. 1-470/83),
- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinions of the Committee on Energy, Research and Technology and the Committee on Budgets (Doc. 1-1128/83),
- having regard to the result of the vote on the Commission's proposal,
- having regard to the fact that the effects of low doses concern the entire population, and an intensive effort is therefore required to understand and assess the effects of such doses, as important issues of political decision-making depend on the outcome of such studies,
- Approves the proposal by the Commission for a five-year research and training programme of the European Atomic Energy Community in the field of radiation protection;
- Considers that in view of its length (five years) it is essential that the programme be reviewed after three years;

¹ OJ No. C 179, 6.7.1983, p.3

- Calls on the Commission to make the results of this research available to the widest possible public through an effective information network;
- 4. Is of the opinion that mobility and exchange of scientists are vital for an effective execution of the research programme on radiation protection;
- 5. Emphasizes the importance of providing means for a certain flexibility in order that the programme can respond to urgent needs in radiation protection research which may newly arise during its execution;
- 6. Notes that several of the subjects to which the Radiation Protection Programme addresses itself have valuable implications for other fields of medicine and environmental science (e.g. for the treatment of leukemia, for the transport of pollutants) and it is desirable that these results be fully utilized for the benefit of human health and for the preservation of the environment;
- 7. Entreats the Council to follow his commitment "to decide by the end of the fourth year of the present programme upon a new programme to come into effect on 1 January 1985" to ensure continuity of its activities (Doc. 5323/80 ATO 28, Annex I).
- 8. Instructs its President to forward to the Council and Commission, as Parliament's opinion, the Commission's proposal as voted by Parliament and the corresponding resolution.

EXPLANATORY STATEMENT

I. The context of the Radiation Brotection Programme

1. The Commission has forwarded to the Council of the European Communities a proposal for a Council decision adopting a multiannual research and training programme for the European Atomic Energy Community in the field of radiation protection (1985-1989).

The Commission's proposal has been previously submitted to the Advisory Committee on Programme Management (ACPM) Biology-Health Protection and to the Scientific and Technical Committee (STC) of the European Communities. Both committees strongly supported the proposal. The ACPM pointed out that the financial estimation for the programme represents the minimum level necessary for its proper execution, and the STC advised that the programme should proceed on the general lines and at the level of the expenditure proposed.

2. The Radiation Protection Programme deals with the objective evaluation of the effects and hazards to man and his environment arising from natural and man-made ionizing radiation. This Community research programme is proposed pursuant to the Euratom Treaty, which charges the Commission with "the study of the harmful effects of radiation in living organisms".

The Radiation Protection Programme is based on the general research strategy of the Commission as developed in the Framework Programme and, in particular, is in line with its objective "Improving living and working conditions". The Commission has created the Research Action Programme "Health and Safety" as a principal vehicle for the implementation of this objective. The Radiation Protection Programme forms an integral part of this Research Action Programme.

- 3. The principal goals of the Radiation Protection Programme are:
- to screen and assess problems related to the protection of man and his environment against ionizing radiation, and to suggest action before such problems become a threat to man,
- to improve the methods necessary to protect workers and the population by updating the scientific basis for appropriate standards and by further developing techniques to prevent and counteract harmful effects of radiation, and to cope with the consequences of radiation accidents,
- to assess radiation risks and set them in perspective to other risks arising in modern society,
- to provide pertinent and up-to-date information for decision making.

 In this way, the programme contributes to the scientific basis for the
 "Basic Safety Standards for the Health Protection of the General Public and
 Workers against the Dangers of Ionizing Radiation".

II. Need for radiation protection

- 4. Man and his environment have been exposed to ionizing radiation from cosmic rays and natural radioactivity since the beginning of their existence. This natural radiation has contributed and continues to contribute to the amount of cancer and genetic damage arising in man and other organisms. The discovery of X-rays and artificial radioactivity almost 90 years ago has added to this a variety of other sources from medical and industrial applications. The contribution of man-made radiation, largely due to medical diagnostics, to the exposure of the population is still below that from natural radiation.
- 5. The effects of ionizing radiation on man may be classified into two groups: those which can arise with full severity regardless of dose (stochastic effects) and those which develop only if a certain dose is exceeded (non-stochastic effects). The former effects are cancer and genetic (heritable) changes. Cancer constitutes the principal hazard of low doses

to the individual and can appear after long latent periods following irradiation. Genetic changes may occur in the progeny and in future generations derived from exposed persons. The most important threshold effects are: the acute radiation syndromes, the chronic radiation damage (e.g. "radiation burns") and the harm to the developing organism. The threshold doses required to cause these effects in the adult are relatively high so that they are attained only when excess exposure has occurred accidentally or has been planned for medical reasons. Considerably lower doses can, however, result in damage in utero; pregnant women therefore require special attention in radiation protection.

- 6. Exposure of the population derives to a large extent from natural sources, but even this is, to a certain extent, subject to human intervention. For example, the indoor concentration of radon which emanates from the ground and from the building itself depends on local geological conditions, the type of construction material used and on the rate of ventilation. Energy conservation which reduces ventilation therefore brings about an increased exposure to radiation. A similar dilemma between two conflicting goals is encountered in medical application, the second principal contributor to population exposure, where the need to obtain indispensable diagnostic information must be reconciled with the demand for the lowest possible radiation dose. Thus, one must not only search for ways to keep doses from natural and man-made sources as low as reasonably achievable but one must probe the alternative risk incurred by such a reduction and develop appropriate criteria for decision making.
- 7. Radioactive substances find their way to man through various pathways in his environment as do other toxic agents. Moreover, industrial development has greatly affected the natural environment to an extent that small additional interventions may tip the ecological equilibrium in an irreversible way. A more complete understanding of the mechanisms of transport of radionuclides in the environment and their behaviour in the biosphere is indispensable for the safety of man and his environment.

III. The role of the Community in Radiation Protection

- 8. The Community occupies a strategic and unique place in research on radiation protection. The multiannual research programmes of the Commission were able to establish stable relations with all important European research institutions in this field. This allowed research to be coordinated in such a way that a given problem can be tackled by different approaches in those institutions best suited due to their scientific man-power, know-how and equipment. The cooperative groups of European scientists, initiated and supported by the Commission, have made it possible to define and attack important problems of radiation protection jointly in a most efficient way. Moreover, the long-term commitment of contracts by the Commission has given the consistent base of support required to carry out projects of long duration, for example on late effects of radiation, radioecology or epidemiology. All these factors have helped to create a truly European climate of research in radiation protection and have resulted in considerable savings for the Member States.
- 9. The programme is divided into six sectors, namely:
- Radiation dosimetry and its interpretation;
- Behaviour and control of radionuclides;
- Non-stochastic effects of ionizing radiation;
- Radiation carcinogenesis;
- Genetic effects of ionizing radiation;
- Evaluation of radiation risk and optimization of protection.

These sectors represent a reasonable, although somewhat arbitrary, classification of the problems with which radiation protection research is confronted. Several areas of priorities transcend these sectors, and much of the success of the programme depends upon how well the different sectors will jointly contribute to such common goals as:

- the effects of low doses;
- radioactive pollution and its consequences;
- treatment of radiation accidents;
- radiation carcinogenesis in man and its mechanisms;
- effects on the developing organism;

- genetic effects and their repair;
- epidemiological studies in human populations;
- risk assessment and optimization of protection;
- evaluation of accident consequences;
- reduction of patient exposure from medical diagnostic procedures.
- 10. A brief summary of the work proposed in the different sectors illustrates how these priorities areapproached in various ways.

The sector "Dosimetry" concentrates on problems arising from the determination of body and organ doses, the correct interpretation and application of radiation protection standards and on basic research related to the understanding of radiation effects, particularly with respect to low doses and to radiations of different quality. In this way, this sector provides the substructure on which all other work rests.

The sector "Behaviour and control of radionuclides in the environment" aims to provide information on transfer and effects of radionuclides from their source to man. Particular exphasis is given to situations where the natural radiation background is enhanced, to the long-term behaviour of radionuclides and to the safety of disposal of radioactive wastes. Thereby, the relative importance of different radionuclides is taken into account, priority being given to long-lived radionuclides such as actinides, technetium and carbon-14 and to nuclides which may become important in connection with new technologies as tritium from fusion.

The sector "Non-stochastic effects of ionizing radiation" studies and threshold and the pathogenesis of effects arising only above a certain dose. Diagnosis and treatment of the consequences of radiation accidents are to be improved. Special attention is devoted to the effects on the developing organism since they may arise following much lower doses than needed to affect the adult.

The sector "Radiation carcinogenesis" strives to elucidate the mechanisms by which radiation induces cancer and to determine the risk of such cancer in man. Studies on molecular and cellular mechanisms as well as other experiments provide a basis for extrapolations to man, which must be confirmed by observations on available irradiated human populations. The special case of carcinogenesis from radionuclides incorporated in the body receives particular attention.

The sector "Genetic effects of ionizing ratiation" deals with the mechanisms and the risks of heritable changes which will affect future generations. Studies on repair of genetic damage are stressed because this is a crucial factor in the expression of genetic damage. Investigations are designed to determine the natural incidence of genetic damage and the contribution radiation can make to it. Wherever possible, experimental systems relevant for man are analyzed.

The sector "Evaluation of radiation risks and optimization of protection" aims to integrate the results obtained in the other sectors to evaluate both benefits and risks, from ionizing radiation and to set the risks in perspective with other risks society encounters. The risks from exposure to natural radioactivity are evaluated, ways are sought to reduce patient exposure from medical diagnostic procedures without impairing their clinical value and to optimize radiological protection. Analysis of the consequences of accidents and the assessment of the economic and social implications of the use of ionizing radiation complement the work in this sector.

IV. Management and means of the programme

11. The Commission estimates the means necessary for the programme which is to cover the period 1985-1989 at 94 million ECU. This amount allows for compensation of inflation, so that the programme is continued at about the same level in manpower and monetary commitment as the present programme, plus some limited funds (about 7% of the total amount) to encourage mobility and exchange of scientists between participating laboratories and to respond to urgent new needs not yet foreseeable at the time of the decision of the proposal.

The programme is executed by means of cost-sharing contracts with national institutions, universities or cooperative groups of scientists to which the Commission contributes a certain percentage (between 25 and 40%) of the cost of research. A minor part of the programme is executed by the Commission's own group at the Joint Research Centre at Ispra. Dissemination of knowledge is assured by regular study group meetings, seminars and symposia as well as by reports and monographs issued by the Commission. Contacts are maintained with international organizations as well as with countries outside the Community such as the U.S.A., Canada and Japan.

An Advisory Committee on Programme Management helps the Commission in selecting, guiding and evaluating the research carried out in this programme. This committee also assures the efficient interphasing of the programme with corresponding programmes of the Member States.

The Commission will report to Parliament and Council at the end of the third year of the programme and propose any amendments considered necessary at this time.

V. <u>Evaluation</u>

12. The Commission of the European Communities had appointed a panel of seven highly qualified independent outside experts to examine in depth the scientific work of the 1976-1980 programme and of the main features of the current 1980-1984 programme. From this report, to be published in 1983 as EUR 8648, the following remarks are cited:

"The programme ... is well balanced, productive, and reasonably comprehensive in scope. Most of the major laboratories active in radiation studies ... participate in the programme.

The programme was productive contributing about 40% of the research funds to the work of 700 European Community scientists and resulting in 600 publications per year ...

The efficiency of the programme is due in large part to the successful development of five year blocks of financial support. This leads to great stability in accomplishing especially the longer-term work.

The achievements of the programme in the 1976-1980 period have demonstrated the power of the Commission of the European Communities in successfully developing specific subject areas".

Several detailed recommendations with respect to scientific content made by the evaluation committee have been incorporated in the present programme proposal.

VI. Conclusions

- 13. The Radiation Protection Programme accords with the needs to protect man and his environment from the hazards of ionizing radiation. The increasing use of ionizing radiation in industry and medicine and the valid public concern about the dangers of ionizing radiation make it mandatory that relevant and up-to-date scientific information is obtained.
- 14. The problems to which the programme addresses itself are of concern for the entire Community, and many of them can be solved only by a concerted approach in which the scientific and manpower resources of the Member States are pooled. The success of the past programmes attests to the effectiveness of such a Community-wide approach.
- 15. It is noted that by means of cost-sharing contracts and efforts to coordinate and disseminate knowledge, the Commission maintains scientific relations with all important research institutions and many universities working in the field of radiation protection.

VII. Recommendations

1.6. Examining the proposal in detail, it is recommended to the Commission to emphasize certain aspects which, while mentioned in the proposal, require the particular attention of the Radiation Protection Programme:

The effects of low doses concern the entire population, and an intensive effort is therefore required to understand and assess the effects of such doses. Important issues of political decision—making depend on the outcome of such studies.

Radioactive pollution, as any other form of pollution, must be subject to careful control. Thus, the long-term behaviour of long-lived radionuclides in the environment and their action on man must continue to be investigated in detail.

The period during which the organism develops constitutes the most sensitive phase in human life. The consequences of radiation exposure and their threshold doses for exposure during that period require detailed study.

Medical applications of ionizing radiation tend to increase with improved health facilities. Care must be taken that no damage to health ensues from such use. Medical radiation diagnostics, particularly routine tests for large groups of the population, must be optimized to keep population exposure to a minimum.

The increased use of ionizing radiation in industry requires that provisions be maintained and extended to treat accidents, including those involving local or partial body irradiation. European cooperation is indispensable to provide the best possible treatment of such accidents.

Observations on man are the final proofstone for evaluating the risks of ionizing radiation. Exposed human populations likely to yield information on risks of ionizing radiation should be carefully studied.

Wide-ranging policy decisions demand a clear understanding of the risks and benefits of alternative options. Exposure to radiation being today a particularly controversial issue must be carefully evaluated with respect to its risks and benefits in relation to other procedures. This demands extensive studies on an experimental and theoretical level.

- 17. New problems continue to crop up in radiation protection. The programme must be sufficiently flexible so that it can respond to such urgent needs which may newly arise during its execution. Means are to be provided for such flexibility.
- 18. Optimal execution of research requires regular exchange of information, know-how and experimental facilities. Mobility and exchange of scientists are vital for the radiation protection programme and will moreover promote a European climate of research.
- 19. Continuous interaction with national programmes of the Member States remains an essential task for the programme. In order to avoid duplications of research and to direct available funds to those laboratories best suited for a given task, a competent advisory committee is indispensable.
- 20. The efforts made to establish closer scientific ties with countries outside the Community such as the U.S., Canada and Japan should be intensified since international cooperation is essential for progress in radiation protection.
- 21. Management of the programme as a whole has been successful in the past. It is, however, desirable that the programme be evaluated by outside reviewers at regular intervals.
- 22. Former recommendations stressed the point that the results of the programme should be made available as widely as possible. An additional effort should be made to provide information on a more comprehensible level to the public at large.

- 23. Several of the subjects to which the Radiation Protection Programme addresses itself have implications for other fields of medicine and environmental science (e.g. for the treatment of leukemia, for the transport of pollutants). It is desirable that these results be fully utilized for the benefit of human health and for the preservation of the environment. It is noted that, in creating a Research Action Programme "Health and Safety", the Commission has made a first step in this direction.
- 24. Contracts by the Commission enable many laboratories to continue their long-range research and to keep highly qualified scientists engaged. Irreparable damage to radiation protection research could result if funding were temporarily interrupted by a decision on the programme taken too late to maintain existing research groups. It is imperative therefore that the Council follows its commitment "to decide by the end of the fourth year of the present programme upon a new programme to come into effect on 1 January 1985" to ensure continuity of its activities (Doc. 5323/80 ATO 28, Annex I).

OPINION OF THE COMMITTEE ON ENERGY, RESEARCH AND TECHNOLOGY

(Rule 101 of the Rules of Procedure)

Draftsman: Mrs A. PHLIX

On 12 July 1983, the Committee on Energy, Research and Technology appointed Mrs PHLIX draftsman of the opinion.

The committee considered the Commission's proposal and the draft opinion at its meetings of 12 July and 3 November 1983 and adopted the conclusions unanimously on 23 November 1983.

The following took part in the vote: Mrs Walz, chairman; Mr Seligman and Mr Ippolito, vice-chairmen; Mrs Phlix, draftsman; Mr Bernard, Mr Flanagan, Mr Herman, Mr Moreland, Mr Pedini, Mr Phlimlin, Mr Pintat, Mr Purvis, Mr Rinsche, Mr Rogalla, Mr Sassano, Mr Sälzer, Sir Peter Vanneck and Mr Veronesi.

1. Under the Euratom Treaty (Annex I. VI) the Commission is responsible for the 'study of the detection and measurement of harmful radiations'. Under this provision, various research programmes in the area of radiation protection have been undertaken.

These successive programmes have made a significant contribution to an objective evaluation of the effects of and the hazards arising from ionizing radiation and their usefulness is demonstrated by the importance attached to the results.

- 2. The proposed radiation protection research programme is not only in line with the Commission strategy set out in the framework programme 1984 1987 (Proposals for a European scientific and technical strategy (COM(82) 865 final)), but also forms part of the Research Action Programme (RAP) 'Health and Safety'.
- 3. The present proposal under the research and training programme for the European Atomic Energy Community in the field of radiation protection adopted by the Council on 18 March 1980 (OJ No. L 78, 25 March 1980, p. 19) covers the period 1985 1989.
- 4. The research programme proposed by the Commission forms an integrated and coherent whole, subdivided into six sectors:
 - 1. radiation dosimetry and its interpretation,
 - 2. behaviour and control of radio nuclides in the environment,
 - 3. non-stochastic effects of ionizing radiation,
 - 4. radiation carcinogenesis,
 - 5. genetic effects of ionizing radiation,
 - 6. evaluation of radiation risks and optimization of protection.

Research priorities are established for each of these six sectors.

5. Based on results achieved, the present state of the art, and the recognized needs of radiological protection, certain problem areas affecting the six sectors have been defined and emphasized in the present programme. These problem areas are:

- man-made radioactive pollution and, more specifically, obtaining more detailed information on the consequences for man and the environment of normal discharges and the storage of waste;
- analysis, prediction and treatment of accident consequences for man and the environment,
- the development of improved models of the movement, metabolism and action of radionuclides in man;
- research into the evaluation of the effects of low-dose exposure to both natural and man-made ionizing radiation in order to outline the best strategies towards other carcinogenic agents;
- studies to identify which molecular and structural changes produce a cancerous cell after irradiation and which factors influence such changes and promote the eventual emergence of a malignant tumour;
- determination of the relationship between low doses of radiation and genetic effects and of the processes involved in the repair of genetic damage and the hereditary factors associated with an increased sensitivity to radiation;
- coordinated epidemiological studies involving a sufficient number of individuals to detect the effects of low doses;
- limiting the medical exposure of the population to ionizing radiation by systematic determination of the doses delivered by different procedures;
- development of risk evaluation techniques and the optimization of protection as well as placing radiation risks in their correct perspective as compared to other risks.
- 6. The programme will be implemented through contracts with highly specialized institutions and universities selected after consultation of the competent advisory committee.
- 7. The Commission estimates the appropriations required to implement the programme, including expenditure for a staff of 60 officials, at 93.4 million ECU for the period 1985 1989; this estimate takes into account the probable rise in costs during the research period.

CONCLUSIONS

8. The RAP 'Health and Safety' comprises 4 sub-programmes ('Radiation Protection', 'Medical and Public Health Research', 'Safety and Hygiene at the Work Place' and 'Non-ionizing Radiation'; the first two are under way and the latter two in preparation).

The coordination of these sub-programmes is justified by the common goals and links between the various aspects of health and safety.

The Committee on Energy, Research and Technology welcomes the fact that special attention has been paid here to the importance of coordination and underlines the need to prevent overlapping or gaps.

9. The Committee on Energy, Research and Technology considers that the Commission's proposal will make an important contribution towards achieving one of the main goals of the framework programme, 'improving living and working conditions' and the RAP 'Health and Safety' programme.

It is also interesting to note that approximately 30% of all research in the area of radiation protection is carried out under the auspices of the Commission and that some 80% of all research efforts in the Community are linked with the radiation protection programme in some way (for example through cooperative groups, meetings of experts and direct relations with institutions that have entered into contracts with the Commission).

- 10. The Committee on Energy, Research and Technology takes the view that implementation of the programmes through contacts with national institutions and universities results in the most efficient and economically sound use of the scientific potential and facilities of the Member States.
- 11. The Committee on Energy and Research also wishes to emphasize that the research findings relating to the risks of radiation are relevant to two important fields, firstly the future development of energy sources and their use, and secondly the optimum use of ionizing radiation in medicine, which is currently the greatest source of man-made population exposure. This will obviously influence the economic and social structures of society and will have repercussions on such areas as employment.

- 12. Moreover, it has already been proved that research into the effects of radiation also has repercussions on other sectors of public health and helps to advance knowledge in such areas as: bone marrow transplantations, genetic structures, biotechnology, treatment of heavy metal intoxications, the role of viruses and oncogenes, neutron therapy, alternative clinical diagnostic procedures, risk-assessment in other industrial sectors, etc.
- 13. The Committee on Energy, Research and Technology calls for continuity in the current research programme to safeguard the back-up facilities for research.
- 14. The committee also underlines the need to encourage fruitful cooperation between educational and research establishments partly by providing funds for international exchanges of research scientists.
- 15. In the opinion of the Committee on Energy, Research and Technology, efforts should be made to inform the public of the activities of the Commission in this field and the results achieved.
- 16. The Committee on Energy, Research and Technology asks to be kept up to date on the development and results of the research at regular intervals to permit an ongoing assessment of its social relevance and the establishing of a dialogue between Parliaemnt and the Commission.
- 17. The Committee on Energy, Research and Technology is in favour of implementation of the proposed research programme and considers that the resources and staff requested are commensurate with the importance of the research.