

European Communities

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EUROPEAN PARLIAMENT

# Working Documents

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5 December 1979

DOCUMENT 1-552/79

## 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. 88/79) for a decision adopting a fiveyear research and training programme (1980-1984) of the European Atomic Energy community in the field of biology-health protection (radiation protection programme)**

**Rapporteur: Mr A. GHERGO**



By letter of 11 April 1979 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 five-year research and training programme (1980-1984) of the European Atomic Energy Community in the field of biology - health protection (Radiation Protection Programme).

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 Energy, Research and Technology and the Committee on Budgets for their opinions.

On 25 September 1979 the Committee on the Environment, Public Health and Consumer Protection appointed Mr GHERGO rapporteur.

It considered the Commission proposal at its meeting of 2 October 1979 and, at its meeting of 22 November 1979, unanimously adopted the motion for a resolution.

Present: Mr Collins, chairman; Mr Alber, first vice-chairman; Mrs Weber, third vice-chairman; Mr Ghergo, rapporteur; Mr Combe, Mrs Fullet, Miss Hooper, Mrs Krouwel-Vlam, Mrs Maij-Weggen, Mr Mertens, Mr Newton Dunn, Mr Remilly, Mrs Roudy, Mrs Schleicher, Mr Sherlock, Mrs Squarcialupi.

The opinions of the Committee on Energy, Research and Technology and the Committee on Budgets are attached.

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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

embodying the opinion of the European Parliament on the proposal from the Commission of the European Communities to the Council for a Decision adopting a five-year research and training programme (1980-1984) of European Atomic Energy Community in the field of biology - health protection (Radiation Protection Programme)

The European Parliament,

- having regard to the proposal from the Commission of the European Communities to the Council<sup>1</sup>,
  - having been consulted by the Council (Doc. 88/79)
  - having regard to the report of the Committee on Environment, Public Health and Consumer Protection and the opinions of the the Committee on Energy, Research and Technology and the Committee on Budgets (Doc. 1-552/79)
1. Approves the proposal by the Commission for a five-year research and training programme of the European Atomic Energy Community in the field of biology - health protection;
  2. Considers that in view of its length (five years) it is essential that the programme be reviewed after three years;
  3. Assumes that this programme will not duplicate national research, and will lead to the coordination of such research;
  4. Notes that Article 2 of the proposal for a Decision states that the financial resources and staff allocation there mentioned are intended merely as a guide;
  5. Emphasizes that the final financial provision will be decided as part of the budgetary procedure;

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<sup>1</sup> OJ No. C 102, 24.4.1979, p.4

6. Calls on the Commission to make the results of this research available to the widest possible public through an effective information network;
7. Is of the opinion that it is necessary to compile a radiation register for persons professionally exposed to radiation, and calls on the Commission to expedite its preparatory work for such a register;
8. Requests the Commission to incorporate the following amendments in its proposal, pursuant to Article 149, second paragraph, of the EEC Treaty.

Proposal for a decision adopting a five-year research and training programme (1980 to 1984) of the European Atomic Energy Community in the field of biology - health protection (Radiation Protection Programme)

TEXT PROPOSED BY THE COMMISSION  
OF THE EUROPEAN COMMUNITIES<sup>1</sup>

AMENDED TEXT

Recitals and Articles 1 and 2 unchanged

Article 3 (new)

The Commission will continuously monitor the implementation of the programme, both to ascertain if there has been effective coordination and if any change of circumstances or unforeseen results of the research make any adjustments necessary. To this end, it will submit a report to Parliament and the Council at the end of the third year of the programme and will propose any necessary adjustments.

Article 4 (new)

The Commission will, at the end of the programme, take all appropriate steps to see that full use is made of the scientific results obtained, both with the aim of updating Community standards in this area, and of achieving wide dissemination of the information on the risks of exposure to ionizing radiation and the appropriate means of preventing damage therefrom within the Member States and among those segments of the population involved.

Article 3

becomes

Article 5

<sup>1</sup>For complete text, see OJ No. C 102, 24.4.1979, p.4.

EXPLANATORY STATEMENT

I. INTRODUCTION

1. The Commission has forwarded to the Council of the European Communities a proposal for a Council Decision adopting a 'Five-year research and training programme (1980-1984) of the European Atomic Energy Community in the field of biology - health protection (Radiation Protection Programme) '.

The Commission proposal had previously been submitted to the Advisory Committee on Programme Management (ACPM) and to the Scientific and Technical Committee (STC) of the European Communities.

During its meetings of 17 October 1978 and 13-14 November 1978, the Advisory Committee on Programme Management 'Radiation Protection' examined the proposal in detail, and in particular the steps taken to assure coordination between national and Community activities in this field.

The ACPM stated unanimously that it is in the interests of the Community to supplement, broaden and deepen the information necessary for an objective evaluation of the effects of and the hazards arising from ionizing radiations in order to guarantee an adequate protection of man and the environment.

The ACPM agreed unanimously that the scientific content of the proposal was based on a sound assessment of the current and foreseeable research requirements of the Community in radiation protection.

The ACPM proposed unanimously to agree on a renewed multiannual programme as an appropriate way of pursuing research in radiation protection.

For its part, the Scientific and Technical Committee, at the meeting of 19 January 1979, after examining the proposal submitted by the Commission of the European Communities, endorsed the view already expressed by the ACPM and noted that the 'scientific and technical information arising from this programme will assist significantly in updating basic radiation protection standards'.

Further, the STC very strongly supported the proposal of the Commission to implement an overlapping programme for both scientific and organizational reasons and expressed a favourable opinion on the proposed programme.

2. The programme submitted for the opinion of our committee is the fifth in a series of research programmes in the sphere of radiation protection at Community level. The first began in 1959, and the fourth, still in progress, began on 1 January 1976 and will end in 1980.

The programme now proposed would begin on 1 January 1980, overlapping with the programme now in progress, and would end on 31 December 1984.

The main objectives of the proposed programme are:

- to improve scientific and technical knowledge so as to update basic standards for the health protection of the general public and workers against the hazards arising from ionizing radiation;
- to evaluate the biological and ecological consequences of nuclear activities and of the use of nuclear energy and ionizing radiation, in order to ensure adequate protection of man and of the environment whenever unacceptable harm could otherwise be caused to them.

3. In general terms, the present report will examine the following points:

- current problems of radiation protection, particularly as regards the international aspects and the responsibilities deriving therefrom for the European Communities;
- the aims and general characteristics of the research and training programme proposed;
- detailed description of the main sectors of the proposed programme;
- problems relating to the management and evaluation of the programme;
- results achieved by the previous programmes in this series;
- a critical evaluation of the programme and the proposals with regard to the opinion to be delivered by this committee.

## II. CURRENT PROBLEMS IN RADIATION PROTECTION

4. Man and the environment are exposed to an ionizing radiation arising from a multiplicity of natural and artificial sources. Among the former are cosmic radiation, the natural radioactivity of the environment, and radioactive substances, particularly potassium, present in the human body.

The artificial sources are mainly to be found in medical and industrial applications of ionizing radiation, while the use of nuclear technology for military purposes should also be borne in mind, since this could, as a result of an accident, involve the civilian population even in the absence of any war.

5. In recent years, scientific and technical, as well as socio-economic progress has increasingly extended the uses of nuclear energy, and has, as a result, increased the danger of harmful effects of ionizing radiation in the environment and on man. The latter include the risks to which workers employed in activities in which ionizing radiation is used are exposed, and those involving the entire population, who, accidentally or for other reasons (medical applications), may be exposed to radiation.

The harmful action of ionizing radiation on the living organism is not yet fully understood, although scientific research and the catastrophic effects at Hiroshima have demonstrated the principal injuries which directly affect the molecule, causing a profound change in the metabolism of the cell.

A distinction has to be drawn, therefore, between short-term somatic effects, late somatic effects and genetic effects. The first two groups consist of changes, including major ones, in individual organs or physiological systems, or of diseases which affect the whole organism. The genetic effects, on the other hand, are the consequence of changes in the cellular structures responsible for the hereditary transmission of characteristics, which result in hereditary deformation, disease and other defects.

To set up a rational programme of protection against the hazards of ionizing radiation it is first necessary to develop and update the scientific research designed to increase our knowledge of the harmful effects produced, to establish the dangerous dose levels and to adopt effective preventive measures.

Absolute protection from radiation is of course impossible. For this reason, legislation is needed to define the maximum permissible limits of radiation exposure in man. These radiation protection standards exist in all the Community countries. There are also, at Community level, the basic standards for the health protection of the general public and workers against the hazards arising from ionizing radiation, which are binding on all the Member States.

These Community basic standards are currently being updated in the light of recent scientific knowledge, on the basis of a Commission proposal, and following the opinion of the European Parliament.

6. Ionizing radiation hazards do not stop at national boundaries, and the problems to which they give rise are basically similar in every country. Failure to adopt adequate protection measures in one country can give rise to harmful effects in others, and, at the same time, the necessary resources can more easily be found if the efforts of the various countries concerned are united.

For these reasons, and on the basis of Article 7 of the EAEC Treaty, the problem of radiation protection comes within the competence and the responsibility of the European Communities.

### III. GENERAL AIMS AND FEATURES OF THE PROGRAMME

7. The general aims of the proposed radiation protection programme were mentioned in paragraph 2. These are plainly aims which relate directly to certain Community policies of undisputed importance and, in particular, to social, environmental and energy policy.

The proposed Community radiation protection programme represents an attempt to broaden knowledge, by means of a cooperative European effort, in the area of radiation protection, taking into account Europe's particular problems and its existing capabilities.

The programme consists of six main areas of activity, which - arbitrarily but conveniently - serve to show its general structure:

- radiation dosimetry and its interpretation
- behaviour and control of radionuclides in the environment
- short-term somatic effects of ionizing radiation
- late somatic effects of ionizing radiation
- genetic effects of ionizing radiation
- evaluation of radiation risks.

8. Plans for the implementation of the programme provide for wide international cooperation on the basis of shared-cost contracts with the national institutes and universities working on the focal points of this research. Close collaboration and a coordinated division of work are necessary in view of the limited resources available, the large number of different scientific aspects of radiation protection research and of the geographical distribution of the research groups having the necessary specific capabilities. In addition, the work of the Commission's Biology Group at Ispra will continue to be an integral, but small, part of the programme, supplementing and supporting certain research carried out in the contract programmes.

9. The time-scale for the implementation of the proposed programme allows, as has been pointed out, for a partial overlap with the previous programme, because some contracts currently in force will run on into 1980, either to a termination date set at the beginning of the contract, or to one which has become necessary for other reasons.

This arrangement will help to overcome certain problems encountered during past programmes and to ensure continuity and development of the overall research effort.

10. The Commission has evaluated the global needs for the programme at 58.2 million EUA, for the period 1981-1984, to which will be added about 10 million EUA for the year 1980, which are already covered by the budget allocation of 39 million EUA for the period 1976-1980.

This is certainly a substantial increase in absolute figures as compared with the present programme. However, in view of the generally accepted great social relevance of radiation protection, its importance for energy production, and the resulting high requirements in radiobiological research, this amount is estimated necessary to establish a well-balanced programme covering all priority aspects. The content of the programme is based on reorientation and evolution of the present programme, an evolution which accentuates new aspects such as the evaluation of radiation risks and the treatment of acute irradiation, particularly when local.

Expansion will be limited and will affect only the contractual activities which will be allocated more than 81% of the total funds (less than 7% for management and administration of the programme).

The following particular elements have been used as a base for the budget estimate of 58.2 million EUA:

- the expenditure of the year 1980, originally planned as the last year of the current programme (1976-1980) (10 million EUA);
- the need to take account, in some measure, of the increase in costs (+ 6% per year);
- the restoration of the Commission's participation in contract expenditure from the current mean of 33% to its previous level of 40%. This guarantees a significant Commission presence in the combined effort being made in Europe in radiation protection research and in particular allows the mobility of research workers in European laboratories;
- a limited expansion (+ 15% of the contractual activities).

The amount of 10 million EUA for the year 1980 is completely covered by the budget allocation of 39 million EUA for the period 1976-1980. . It corresponds to;

- staff expenditure, recurring administrative expenditure and expenditure relating to the use by the Biology Group of the scientific and technical services of the ISPRA Joint Research Establishment, as requested for the 1980 budget,
- the Community's financial contribution to contracts relating to the year 1980 or as appropriations outstanding from earlier years authorized within the ceiling of 39 million EUA of the 1976-1980 programme.

The amount of 10 million EUA for the year 1980 is the result, not of any real expansion, but of the following factors:

- inflation rate during the period 1976-1980,
- the influence of 'gross salaries' as opposed to 'net salaries' which were previously taken into account.

#### IV - DESCRIPTION OF THE PROGRAMME

11. The programme proposed by the Commission is based on foreseeable requirements of radiation protection in the countries of the Community, in the light of the expected development of nuclear facilities and other sources of ionizing radiation and of their possible effects on man and the environment.

The drafting and application of the Community directives can only be done on a proper basis if the necessary scientific knowledge is acquired and continuously kept up to date.

To this end the proposed programme provides, as already pointed out above, for the studies and research to be oriented towards certain principal activities or sectors.

#### 12. Radiation dosimetry and its interpretation

This is a fundamental sector because it involves adjusting Community standards to scientific advances in methods of measuring the quantity of radiation absorbed, taking account of certain basic parameters (spatial and temporal distribution of radiation energy absorption, transfer to biological tissues, the distribution of energy deposition within various organs and tissues, etc).

Different methods of personal dosimetry are used in different countries, and these must be developed and coordinated at Community level.

Research should be concentrated on the following particular problems in this sector.

- Environmental dosimetry: a more realistic estimate should be made of the dose to the public resulting from natural radio-activity, which will help to make a proper assessment of the risk from man-made radiation sources.
- Exposure in medical diagnosis: this is one of the most important sources of hazard to the population, because of the ever increasing number of diagnostic examinations using ionizing radiation and forms of treatment using radiation energy and radio isotopes. For example, in Italy, under the aegis of INAM, a body which provides health insurance for more than 50% of the whole population, more than 8 million radiological examinations are carried out in one year, with a mean of 28 examinations for every 100 assured persons. A basically similar situation exists in the other countries of the Community.

The basic aim of research in this sector will be to reduce the non-essential dose from this exposure while maintaining the quality of the diagnostic information and the effectiveness of the forms of treatment concerned.

Epidemiological studies of the short-term and late effects of ionizing radiation are very useful here, bearing in mind the need to evaluate the dose absorbed by the individual in the course of repeated examinations, possibly taking place at different health institutions (hospitals, clinics, medico-social services, etc).

It would also be desirable to involve the social security bodies of the various Community countries in the research programme, since these could collaborate by means of surveys on assisted persons who submit themselves to diagnostic examinations or to relevant forms of treatment.

- Biological dosimetry in accidents: cases of this kind are becoming ever more frequent nowadays, but there exist no truly satisfactory systems of checking the dose actually received by a population. Research is needed on the improvement of reliable biological dosimetric methods on the basis of the biological indicators.

### 13. Behaviour and control of radionuclides in the environment

There are today a large number of industrial activities which involve the use of radionuclides, the movement by various channels of radioactive materials and the discharge into the environment of radioactive residues

or waste, for example the extraction and processing of uranium, the reprocessing of irradiated fuels, the introduction of advanced reactors, etc.

The main environmental transfer processes requiring further investigation are:

- resuspension of radionuclides from the sea surface, silts and typical European land surfaces;
- the transfer of radionuclides deposited on the surface of agricultural land to soil, water, plants and animals;
- the migration of radionuclides in a range of rocks and soil types typical of Community countries;
- the transfer of radionuclides released to the aquatic environment, and the uptake by aquatic species;
- atmospheric dispersion and deposition processes in urban areas.

#### 14. Short-term somatic effects of ionizing radiation

Recent technological advances have made it possible to measure and identify the free radicals, and their reaction products, which play an essential role during the early phase of radiological damage, producing among other effects localized radio-lesions and damage to the lympho-hemopoietic system.

This makes it possible to study the prognosis, complications and treatment, not only of radiation injuries to the skin but also to internal surfaces like those of the gastro-intestinal tract, the respiratory tract and many other organs.

#### 15. Late somatic effects of ionizing radiation

One of the most notable late effects of ionizing radiation is the increase in the frequency of malignant tumours in the exposed individuals: these involve the so-called 'stochastic effect', whereby the frequency with which the harmful effect occurs depends typically on the size of radiation dose, but the severity of the effects does not in general depend upon the dose.

Special attention must therefore be given to dosimetry, length of follow-up, comparability of the control series, influence of sex, of age at the time of exposure, mortality resulting from radiation-induced tumours, and the other variables crucial to a proper evaluation of the phenomenon.

There must be an exhaustive follow-up over long periods of individuals exposed to radiation for medical or other reasons, even over decades, with the aim of being able to show up the appearance of malignant tumours in good time. Here surveys on groups of patients who have received repeated or extensive diagnostic radiological investigations will be of great use, making use where possible of data provided by health and social security services.

Another necessary area of research effort is animal studies designed to elucidate the mechanism of cancer induction and the frequency with which malignant changes are likely to be induced.

16. There are other late effects of ionizing radiation, for example the appearance of cataract, reduction of fertility, change in specific organic functions (non-stochastic effects) which need to be investigated more deeply by means of studies on animals and men to achieve a better understanding of the pathogenetic mechanisms and to work out appropriate methods of evaluating the probability of the appearance of effects of these kind in individual subjects and the relationship of this probability to the accumulated dose as a whole.

Here further studies are needed on the hazard involved in radiation exposure during pregnancy, especially as regards teratogenic effects, with a view to determining the existence of any threshold beyond which the recovery or repair of embryonic cells becomes impossible or improbable.

Finally an appropriate research effort, possibly making use of extremely wide epidemiological surveys, should be directed towards determining the cumulative effects of radiation on the life span, as well as of the mechanism by which these effects might act.

#### 17. Genetic effects of ionizing radiation

The harmful genetic effects of radiation have been known and studied for a long time. Nevertheless there is a need to improve knowledge of the incidence of chromosomal aberrations and genetic mutations occurring in exposed subjects, especially with a view to discriminating between the frequency of cases due to radiation from that of cases arising spontaneously in man.

In particular the programme must include:

- epidemiological surveys on the relationship between the dose received and the frequency of harmful genetic effects;
- determination of the in vivo effects on lymphocytes;
- studies on appropriate animal species which provide data that can be extrapolated to man;

- appraisal of the methods and assumptions in risk assessment in extrapolating from animals to man;
- studies on the induction of mutations in germ cells and somatic cells.

#### 18. Evaluation of radiation risks

The results obtained from the research in the various specific sectors listed above will have to be integrated into the establishment of suitable methods for assessing as accurately and objectively as possible, and in a uniform way throughout the different countries of the Community, the consequences of irradiation for man and his environment.

Three groups of problems will be considered:

- assessment of the individual and collective doses resulting from normal discharge and accidental releases of radioactive substances, so as to lead to specific models for evaluation which will take account of all possible pathways of access to man and his environment;
- assessment of the detriment due either to medium and high-level irradiation, as in the event of an accident, or to low doses, to which individuals are exposed for occupational or other reasons;
- assessment of the economic and social consequences of exposure to radiation, for which it should be useful to make use of the data available from social security bodies.

#### V - MANAGEMENT OF THE PROGRAMME

19. Responsibility for the management of the programme will obviously lie with the Commission, who will consult the ACPM and ensure close liaison with the corresponding research and development carried out in the Member States.

Coordination is particularly important because it assists the work of the various individual research groups and avoids duplication and dispersion of resources. It is equally important to maintain and develop working relations with the principal international organizations involved in radiation protection.

It is vital to assure adequate evaluation of the various individual research programmes to be carried out both before, during and at the end of each project. Evaluation during a given project should be carried out once a year by the ACPM and the Commission services with a view to approving the activity carried out and determining any necessary changes, reorientations or new proposals for the individual research groups.

The resources allocated for the implementation of the programme will be largely of a financial nature defined, under the budget heading specified above, by the various research contracts. As regards staff, the Commission has proposed a staffing of 64 officials for the period 1980-1984, as compared with the 97 provided for by the 1973 programme and the 68 (plus 10 local agents for the Biology Group at Ispra) stipulated in the 1976 programme.

#### VI - RESULTS ACHIEVED BY THE PREVIOUS RESEARCH PROGRAMMES

20. In evaluating the Commission proposal, full knowledge of the results achieved by the previous programmes takes on a particular importance, especially their socio-political consequences. However, as regards the last programme (1976-1980), which is still in progress, only some of the results achieved are available.

The Commission, with the means at its disposal, has developed research in the areas of greatest significance and has promoted both the practical application of scientific results (e.g. development of personal dosimeters, diagnosis and treatment of acute radiation injury, execution of inter-comparison programmes) and the rapid translation of scientific knowledge into decisionmaking processes (e.g. establishment of basic safety standards, formulation of criteria for siting decisions).

21. The following is a brief summary of some of the principal results obtained in the 1976-1978 period in the various specific areas of the programme.

#### Radiation dosimetry and its interpretation

Comparative studies have revealed quite a number of imperfections in experimental arrangements, differences in the basic values used to determine the absorbed dose and discrepancies in dosimetry procedures. It was found that differences in results from different laboratories could often be explained by factors of this kind.

Other notable progress was made in the measurement and calculation of underlying parameters, such as those relating to micro-dosimetry in small tissue areas.

The investigation of fundamental mechanisms in radiation physics has indicated interesting possibilities in the use of lyoluminescence in radiation accident dosimetry in some human tissues.

Statistical methods for the assessment of tumour rates in experimental animals as a function of time after irradiation have also been developed.

Finally, other interesting results have been obtained relating to various types of personal dosimetry.

#### Behaviour and control of radionuclides in the environment

Research on radiocontamination of marine, terrestrial and fresh water ecosystems has produced interesting results with regard to the behaviour of the principal radionuclides and has opened the way to applications needed for control of the areas surrounding installations, to knowledge of the mobility and toxicity of radionuclides for living organisms, and possibilities for decontamination of agricultural areas after an accident.

#### Short-term somatic effects of ionizing radiation

In the interests of diagnosis and the treatment of acute radiation injury, considerable progress has been achieved in the elucidation of damage induced in deoxyribonucleic acid (DNA) and there has been in-depth study of the problems relating to the transplant of bone marrow in individuals exposed to high doses of radiation to cure the damage to the hemopoietic system.

#### Late somatic effects of ionizing radiation

Since levels of radiation caused by radiological diagnostic examinations and the use of radioisotopes in treatment constitute one of the principal potential late harmful effects of ionizing radiation, epidemiological studies of irradiated human groups have been carried out, making it possible among other things, to standardize experimental conditions in the laboratories involved, to ascertain by biological measurements in the cerebral cortex the increase in vascularity which precedes gross vascular abnormalities, and to examine the behaviour of certain radionuclides within individual organs and tissues.

Interesting results have also been obtained on the possibility of optimizing image quality in radiographs, at the same time reducing the dose absorbed, as well on the synergistic effects between radiation and other environmental factors (for example, the development of radiation-

induced osteosarcoma seems to be accelerated by application during the latency period of cyclo-phosphamide, a widely used antimetabolic agent).

#### Genetic effects of ionizing radiation

The research carried out in this area was aimed at ascertaining the nature and frequencies of cytogenetic damage in exposed individuals. The results obtained have improved understanding of the very complex ways through which the irradiated cell copes with its lesions and have made it possible to identify the first signs of mutation at the level of the cell, and to calculate, as regards chromosome aberrations, a proportionality between spontaneous and induced mutation rates.

#### Evaluation of radiation risks

This is the most important area of the whole current research programme as regards practical applications, since it helps to determine the optimal conditions for the exploitation of nuclear energy.

Among the results achieved should be noted those concerning parameters to be used for the assessment of the collective dose, by means of a long-distance atmospheric dispersion model (MESOS) which makes it possible to evaluate atmospheric contamination, as well as those relating to attempts to assess the radiological detriment. Here a feasibility study has been initiated on the preparation of a European irradiation register for workers directly assigned to tasks in which they are exposed to irradiation.

Finally, as regards the economic and social consequences of irradiation, the various methods of protection have been catalogued in such a way as to bring out their advantages and disadvantages.

22. In conclusion, this selection of results from the main areas of the research programme shows that there are definite indications as to the practical application of these results. In other cases, however, what have been produced are interim results which call for further intensive research. Finally, for certain problems, provision must be made for research on a long-term basis which can only be expected to provide results in a more distant future.

#### VII - CRITICAL EVALUATION OF THE PROPOSAL FOR A COUNCIL DECISION

23. On the basis of the foregoing, a favourable opinion may be given on the research programme proposed by the Commission. There can be no doubt that the risk of exposure to ionizing radiation has risen significantly in recent years,

and a further upward trend is foreseeable in the near future in all countries of the Community. As a result, it appears more than ever desirable to develop scientific research in this sector in order to obtain the knowledge necessary to achieve increasingly effective radiation protection standards.

These problems directly involve all the Community organs, and above all the European Parliament which, as the direct expression of the popular will of the member countries, cannot remain insensitive to the need to protect individuals and communities against the hazards which can arise from scientific and technological progress and from socio-economic development.

Nevertheless, in examining the proposed programme submitted by the commission, the committee cannot limit itself to delivering a general opinion but must express specific comments, requests and conditions to make the programme more effective, by improving the quality of the research results and helping to make it possible for the community and individual Member States to utilize these results.

24. The document presented by the Commission to amplify the proposal for the five-year programme (1980-1984) lists the results achieved by the preceding 1976-1980 programme and the principal applications of these results in updating basic standards and the Community directives in this area. However, as has already been pointed out in this report, this is a partial and provisional list, given that much of the research is still in progress, and there are absolutely no references, even of the most summary or general kind, to the preceding programmes developed and executed over the period from 1959 to 1976.

It would be very helpful to this committee in drafting its opinion if it could be provided with this information and be given a better indication of how the results of these programmes have been applied in the definition of standards.

25. Another aspect which the committee would wish to bring to the attention of Parliament and of the Council is the need for the research programmes to be oriented towards the opportunity of practical applications in the area of public health and environmental protection policy, as well as of Community energy policy.

It should be recommended to the Commission that within each specific area of activity under the programme (See para. 7 of this report), the following should be the three main target areas for radiation protection:

- acute exposure in high doses from accidental causes, whether affecting individuals or whole communities;
- chronic exposure at medium or low dose from medical applications;
- chronic exposure at medium or low dose of subjects exposed by reason of their work.

As regards this last aspect, particular mention should be made of the hazard to doctors and radiology technicians, for whom the present methods of radiation protection, which have sometimes been shown not to be entirely adequate, must be developed and perfected. The current rules regarding the free circulation of doctors within the EEC increase the urgency of Community action in this area.

26. A point to be stressed is the need for the programme to involve both the major research centres operating in the Community area and public institutions such as the health and social security services, which are in a position to supply important epidemiological, socio-economic and other data.

The recommendation to be made on these lines to the Commission should also point that, when concluding the various individual research contracts, it is desirable to avoid the danger of disharmony and imbalance between the various Member States and to provide for fair alternation between the centres which have participated in previous programmes and

those which are to participate in the new one, now proposed, albeit taking into account the need for continuity in some of the research which has to be carried out over a longer period of time than the lifespan of a single given programme.

27. Another aspect which needs to be brought to the attention of Parliament and of the Council is the need for a continuous and effective check on the implementation of the programme, with periodic consideration of the state of progress of individual contracts, evaluation of interim results and the establishment of the need for any revisions, reorientations or changes.

In this connection, in addition to the annual review provided for in the proposal for the programme (see para. 19 of this report), it must be emphasized that Parliament and the Council should be informed of the results achieved after the first two years of operation of the programme and of any proposals for changes to it. A supplementing amendment on these lines should be put forward to the proposal for a Council decision, in the wording given elsewhere in this report.

28. If the execution of the programme is to be effective, coordination must be assured between the various Community bodies involved in this subject area:

Further, this five-year programme must be linked with the proposal for a Council directive on the protection of workers against hazards arising from harmful exposure to chemical, physical and biological agents at work.

29. To improve the productivity of the research covered by the programme, the Commission is recommended to take every appropriate measure to make as wide use as possible, in the interests of the Community, of the results achieved at the end of the programme (see Doc. 13/79).

Two principal ways of using the results are to be noted:

- updating of the basic standards for radiation protection (Community directives, legislation of individual Member States, administrative arrangements) and of the methods and instruments used to this end (dosimetry, environmental monitoring, biological indicators, etc.);
- publication, within and outside scientific circles, of the principal results achieved, with provision for the dissemination of the relevant information, by the appropriate means and in a suitable form, to the public at large, so as to encourage their active participation in the defence against radiation hazards.

In this connection, attention must be given to the complex problem of excessive use of radiological diagnostic examinations and hence to the need for medical staff and the users of such services to be given proper instruction as a valid and practical instrument of health education.

OPINION OF THE COMMITTEE ON ENERGY AND RESEARCH

Letter from the committee chairman to the chairman of the  
Committee on the Environment, Public Health and Consumer  
Protection

8 October 1979

Dear Mr Chairman,

At its meeting of 4 October 1979<sup>1</sup> the Committee on Energy and  
Research adopted the following opinion:

This programme is the fifth of its kind. The intention is that it  
should carry on from the current fourth programme so that the last year of  
the old programme will coincide with the first year of the new one. The  
Committee on Energy and Research approves this procedure.

In examining the proposal we have assumed, as always, that this pro-  
gramme will not result in the duplication of national research projects  
and we consider that there is a need for an effective information network  
to disseminate the results of the research and also for proper coordination  
of the research work itself.

The principal object of the programme is to investigate and evaluate  
ionizing radiation. We welcome this, from the point of view of both  
energy and research policy. This approval does not constitute the opinion  
of the committee on the use of nuclear power; it is merely a recognition  
of the facts.

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<sup>1</sup>Adopted unanimously.

Present: Mrs WALZ, chairman, Mr IPPOLITO and Mr NORMANTON, vice-chairmen,  
Mr ADAM, Mr CALVEZ (for Mr GALLAND), Mr CROUX, Mrs DEKKER (for Mr CAPANNA),  
Lord DOURO, Mr GRIFFITHS (for Mrs CHARZAT), Mr LINDE, Mr LINKOHR,  
Mr MÜLLER-HERMANN, Mr D'ORMESSON, Mr PAISLEY, Mr PURVIS and Mr SASSANO.

It is regrettable that the Commission's proposal for the Council decision which is intended to set the programme in motion contains no review clause. This would appear to be nothing more than an oversight but we would ask the committee responsible to accept as a draft amendment the following new Article 2a which reproduces verbatim Article 4 of the Council decision of 15 March 1976 (OJ L 74/1976 pp 32-33) on the present programme: 'The Commission shall be responsible for the continuous supervision of the implementation of the programme in order to ensure that real coordination has been achieved and to decide whether developments in the situation or unforeseen research results necessitate changes to the programme. To this end it will report to the Council and to the European Parliament at the end of the second year of the programme and will propose, where appropriate, any amendments necessary'.

We can see no reason why this clause, which is included in so many instances, should be omitted.

We would further request the committee responsible to incorporate the following paragraphs in its motion for a resolution:

- (a) 'Assumes that this programme does not duplicate any national research but rather has the effect of coordinating such work'.
- (b) 'Calls upon the Commission to make the results of the research as widely available as possible through an effective information network'.

Yours faithfully,

Hanna WALZ

OPINION OF THE COMMITTEE ON BUDGETS

Draftsman of the opinion: Mr H. LANGES

On 3/4 October 1979 the Committee on Budgets appointed Mr Langes draftsman of the opinion.

The draft opinion was considered by the committee at its meeting of 10 October 1979 and unanimously adopted.

Present: Mr Lange, chairman; Mr Notenboom and Mr Spinelli, vice-chairmen; Mr Langes, draftsman of the opinion; Mr Adonnino, Mr Barbi, Mrs Boserup, Mrs Hoff, Mr Hord, Mr Dankert, Mr Lega, Mr Ryan and Mr Simonnet.

## I. INTRODUCTION

1. The five-year research and training programme (1980-1984) of the European Atomic Energy Community in the field of biology and health protection - known as the 'radiation protection programme' - has a twofold objective:

- to improve scientific and technical knowledge with a view to updating basic standards for the protection of health against the hazards arising from ionizing radiation;
- to evaluate the biological and ecological consequences of nuclear activities and of the use of nuclear energy, in order to ensure adequate protection of man and of the environment.

2. A Community programme of this type is needed because the problems associated with radiation protection are similar in all the Member States, in which the limited resources available (scientific personnel, finance) contrast with the complexity of the research involved.

The Commission gives a welcome assurance that the programme it is proposing 'does not duplicate national efforts; it stimulates and complements them in topics of common interest'<sup>1</sup>.

## II. THE PREVIOUS RADIATION PROTECTION PROGRAMME 1976-1980

3. A research and training programme for the European Atomic Energy Community in the field of biology - health protection for the years 1976 to 1980 was adopted by the Council on 15 March 1976<sup>2</sup>.

4. On 5 January 1978, a 'Report on the Radiation Protection Programme'<sup>3</sup> was presented pursuant to Article 4 of this decision which laid down that the Commission would report to the Council and to the European Parliament at the end of the programme's second year.

5. In presenting the programme for 1980-1984, the Commission does make some points to help one appraise its previous programme, including:

- The participation of interested parties: 'The majority of the national institutions and many of the university institutes active in this field are to be found among the participants in the Community programme'<sup>4</sup>.

<sup>1</sup> Doc. 88/79, p. 4

<sup>2</sup> OJ No. L 74, 20.3.1976, p. 32

<sup>3</sup> COM(77) 698 final

<sup>4</sup> Doc. 88/79, p. 4

- The volume of publications: More than 600 scientific publications appeared during 1977. Approximately 1,800 articles, monographs, reports etc. have been published during the first three years.
- Contribution to the drafting of international documents: The scientists employed on the Commission's radiation protection programme have contributed to the publications of the United Nation's Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the International Commission on Radiological Protection (ICRP).

### III. TWO PROGRAMMES WHICH OVERLAP

6. As stated in section II, although the previous radiation protection programme expires at the end of 1980, the new programme will cover the period 1980-1984. This means that the two programmes will overlap in 1980.

7. The financial consequences of this overlap are examined below, but your draftsman wishes to point out first of all the reasons which have led the Commission to submit a new programme before the previous one has been completed. These include:

- The desirability of directing research projects in the light of experience gained;
- The amount of time taken to negotiate contracts;
- The need to prevent the break-up of the existing research groups in view of the fact that the number of first-rate scientists in the field of radiation protection is very limited;
- The employment problems of staff under contract.

### IV. THE SECOND RADIATION PROTECTION PROGRAMME (1980-1984)

8. The radiation programme 1980-1984 will cover six major activities:
- (a) Radiation dosimetry and its interpretation with the aim of determining the absorbed dose and assessing the biological effects;
  - (b) Behaviour and control of radionuclides in the environment with the aim of acquiring data on the behaviour of particular radionuclides in various parts of the environment;
  - (c) Short-term somatic effects of ionizing radiation with the aim of increasing knowledge about ionizing radiation and assessing the damage it causes;
  - (d) Late somatic effects of ionizing radiation with the aim of examining the malignant effects of radiation on man, and making studies on animals to elucidate the mechanism of cancer induction;

- (e) Genetic effects of ionizing radiation with the aim of analysing the effects of radiation on genetic material;
- (f) Evaluation of radiation risks with the aim of defining methods of ascertaining the consequences of radiation on man and his environment.

9. The management of the programme will be assured by the Commission in consultation with the ACPM (Advisory Committee on Programme Management).

10. The participants in the research project will come from both national institutes and universities - on the basis of 'cost-shared' contracts to be coordinated by the Commission - and the Biology Group at the Ispra Joint Research Centre, which will be given the task of supplementing and supporting certain studies.

#### V. FINANCIAL ASPECTS

11. The radiation protection programme 1980-1984 is the last in a series which began in 1959 with the Community's first biology programme. Expenditure over these years has been as follows:

1959-1962	3.1 million EUA
1963-1967	17.5 million EUA
1968-1969-1970	temporary expansion of the programme
1971-1975	24.7 million EUA
1976-1980	39.0 million EUA <sup>1</sup>
1980-1984	58.2 million EUA requested by the Commission, plus the 10 million EUA for 1980 entirely covered by the 1976-1980 allocation.

12. The Commission recognizes that the funds requested for 1980-1984 are 'certainly a substantial increase in absolute figures' as compared with the previous programme<sup>2</sup>. It justifies the increased expenditure by (i) stressing its social relevance (the importance of radiation protection for energy production) leading to an expansion (15%) of the contractual activities, and (ii) adducing strictly financial reasons including the increase in costs (+ 6% a year).

<sup>1</sup> In fact the funds requested by the Commission, on which the European Parliament had given a favourable opinion, had been 66.3 million EUA (see COM(75)351 final). The Council, however, made provision for the allocation of 39 million EUA as shown in Article 2 of the decision of 15 March 1976 (OJ No. L 74, 20.3.1976, p. 32).

<sup>2</sup> Doc. 88/79, p. 32.

13. Although the Commission has not provided a detailed breakdown by sector of the overall foreseeable expenditure, there are some points which need to be given consideration:

- Firstly, the actual funds requested for the 1980-1984 programme amount to 58.2 million EUA, in addition to the 10 million EUA for 1980 alone which is totally covered by the appropriations (39 million EUA) allocated to the previous programme.
- The Commission forecasts that 7% of the available appropriations will be taken up by the management and administration of the programme. It will then be possible to earmark the major part of the funds for contractual activities (81%) while 12% of the appropriations will be allocated to the Biology Group at Ispra.
- The number of staff fixed at 68 in the Council Decision of 15 March 1976<sup>1</sup> for the implementation of the 1976-1980 programme has been reduced to 54 (including 41 category A officials). This is another example of the Commission's efforts to reduce expenditure on management as opposed to research activity proper.
- Your draftsman would emphasize that the financial record can be considered sufficiently clear and substantially complete even though some additional details and explanations may be necessary. Taking only the appropriations requested for the new programme 1980-1984 (58.2 million EUA), the breakdown of commitment and payment appropriations under the Commission's proposals is set out below.

Commitment appropriations

Thousands of EUA

Total appropriations	1980	1981	1982	1983	1984	1985
58,200	15,000	20,412	9,675	7,856	5,257	-

Payment appropriations

Thousands of EUA

Total appropriations	1980	1981	1982	1983	1984	1985
58,200	-	11,312	13,825	14,706	15,657	2,700

<sup>1</sup> OJ No. L 74, 20.3.1976, p. 32, Article 2

- The overall cost of the programme for the entire duration of the action is 143,210,000 EUA. Of this, 68,210,000 EUA (58,200,000 + 10,000,000) are chargeable to the Community budget while 75,000,000 EUA will be met from contributions from the national governments.
- If one compares the payment appropriations laid down for 1980 in the financial record of the radiation protection programme 1980-1984 (8,261,000 EUA) with the appropriations entered in the preliminary draft budget for the same year (8,473,000 EUA), one finds there is a difference of 211,000 EUA. This discrepancy is to be ascribed - according to the Commission department questioned on this subject - to a more correct assessment of staff costs carried out for the draft budget. This will not have any effect on the expected payments for later years.

## VI. CONCLUSION

### 14. The Committee on Budgets

- approves the five-year programme;
- notes the text of Article 2 of the proposal for a decision in which the appropriations and staff allocations are merely intended as a guide;
- emphasizes that the final financing will be decided under the budget procedure;
- urges the Committee on the Environment, Public Health and Consumer Protection to expedite the drafting of its report so as to enable the Council to make a start on its deliberation at the meeting on 22 October.

