

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 25 January 1999

adopting a specific programme for research, technological development and demonstration
on quality of life and management of living resources (1998 to 2002)

(1999/167/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 130i(4) thereof,

Having regard to the proposal from the Commission⁽¹⁾,

Having regard to the opinion of the European Parliament⁽²⁾,

Having regard to the opinion of the Economic and Social Committee⁽³⁾,

(1) Whereas by Decision No 182/1999/EC⁽⁴⁾, the European Parliament and the Council adopted the fifth framework programme of the European Community (hereinafter referred to as the fifth framework programme) for research, technological development and demonstration (hereinafter referred to as RTD) activities for the period 1998 to 2002 setting out the general outlines and scientific and technological objectives of the activities to be carried out in the field of quality of life and management of living resources;

(2) Whereas Article 130i(3) of the Treaty stipulates that the framework programme shall be implemented through specific programmes

developed within each activity under the framework programme, and that each specific programme shall define the detailed rules for implementing it, fix its duration and provide for the means deemed necessary;

(3) Whereas, in accordance with Article 4(2) of Decision No 1110/94/EC of the European Parliament and of the Council of 26 April 1994 concerning the fourth framework programme of the European Community activities in the field of research, technological development and demonstration (1994 to 1998)⁽⁵⁾ and Article 4(2) of the Council Decisions on the specific programmes implementing the fourth framework programme, the Commission has arranged for an external assessment to be conducted which it has transmitted to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions together with its conclusions and comments;

(4) Whereas, in accordance with Article 130j of the Treaty, Council Decision 1999/65/EC of 22 December 1998 concerning the rules for the participation of undertakings, research centres and universities and for the dissemination of research results for the implementation of the fifth framework programme of the European Community (1998 to 2002)⁽⁶⁾ (hereinafter referred to as 'the rules for participation and dissemination') applies to this specific programme; whereas these rules allow the

⁽¹⁾ OJ C 260, 18.8.1998, p. 1.

⁽²⁾ Opinion delivered on 15 December 1998 (not yet published in the Official Journal).

⁽³⁾ OJ C 407, 28.12.1998, p. 123.

⁽⁴⁾ OJ L 26, 1.2.1999, p. 1.

⁽⁵⁾ OJ L 126, 18.5.1994, p. 1. Decision as last amended by Decision No 2535/97/EC (OJ L 347, 18.12.1997, p. 1).

⁽⁶⁾ OJ L 26, 1.2.1999, p. 46.

participation of the Joint Research Centre in the indirect actions covered by this specific programme;

- (5) Whereas, for the purpose of implementing this programme, in addition to cooperation covered by the Agreement on the European Economic Area or by an Association Agreement, it may be appropriate to engage in international cooperation activities, in particular on the basis of Article 130m of the Treaty, with third countries or international organisations;
- (6) Whereas implementation of this programme will also comprise activities and mechanisms aimed at stimulating, disseminating and exploiting RTD results, in particular *vis-à-vis* small and medium-sized enterprises (SMEs), and activities to stimulate the mobility and training of researchers;
- (7) Whereas it is important that the scientific, industrial and user communities should contribute substantially to the definition of activities to be undertaken and should be involved, as appropriate, in the implementation of this programme;
- (8) Whereas research activities under the fifth framework programme should also be geared towards innovation in order to contribute, *inter alia*, to the objectives of the first action plan for innovation;
- (9) Whereas special emphasis should be placed on encouraging the participation of SMEs;
- (10) Whereas the equal opportunities policy of the Community must be taken into account in the implementation of this programme;
- (11) Whereas efficient and transparent management contributes to a more effective and user-friendly programme;
- (12) Whereas administrative expenditure should be included in the Community budget in a transparent fashion;
- (13) Whereas the implementation of this programme should be monitored with a view to adapting it, where appropriate, to scientific and technological developments; whereas in due course there should also be an assessment of progress with the programme by independent experts;
- (14) Whereas the Scientific and Technical Research Committee has been consulted on the scientific and technological content of the specific programmes,

HAS ADOPTED THIS DECISION:

Article 1

In accordance with Article 3(1) of the fifth framework programme, the specific programme on quality of life and management of living resources (hereinafter referred to as the specific programme) is adopted for the period from 25 January 1999 to 31 December 2002.

Article 2

1. In accordance with Annex III to the fifth framework programme, the amount deemed necessary for carrying out the specific programme is EUR 2 413 million, including a maximum of 6,5 % for the Commission's administrative expenditure.

An indicative breakdown of this amount is given in Annex I.

2. Of the amount in paragraph 1

— EUR 553 million is for the period 1998 to 1999,

and

— EUR 1 860 million is for the period 2000 to 2002.

In the case referred to in Article 2(1)(c) of the fifth framework programme, the Council shall adapt the latter figure in accordance with Article 2(1)(c), second indent of the fifth framework programme. Pending a decision by the Council, this specific programme shall not be implemented beyond the provision of the first indent.

3. The budgetary authority shall, in compliance with the scientific and technological objectives and priorities laid down in this Decision, set the appropriations for each financial year taking into account the availability of resources within the multiannual financial perspective.

Article 3

1. The general outlines, the scientific and technological objectives and the priorities for the specific programme are set out in Annex II. They are consistent with the principles and the three categories of selection criteria indicated in Annex I to the fifth framework programme.

2. In accordance with these principles and criteria the selection criteria indicated in Article 10 of the rules for participation and dissemination shall be applied for the selection of the RTD activities to be carried out.

In addition, any participation of industrial entities in industrially-orientated shared-cost actions should, as a general rule, be appropriate to the nature and purpose of the activity.

All these criteria shall be complied with in the implementation of the programme, including the work programme referred to in Article 5(1), although they may be weighted differently.

3. The rules for participation and dissemination shall apply to the specific programme.

4. The detailed rules for financial participation by the Community in the specific programme are those referred to in Article 4 of the fifth framework programme.

The indirect RTD actions under the specific programme are defined in Annexes II and IV to the fifth framework programme.

Specific rules for implementing the programme are set out in Annex III to this Decision.

Article 4

In the light of the criteria referred to in Article 3, and the scientific and technological objectives and priorities set out in Annex II, the Commission:

- (a) shall monitor, with appropriate assistance from independent external experts, the implementation of the specific programme and, where appropriate, submit proposals to Council for adapting it, in accordance with Article 5(1) of the fifth framework programme;
- (b) shall arrange for the external assessment provided for in Article 5(2) of the fifth framework programme to be conducted concerning the activities carried out in the fields covered by the specific programme.

Article 5

1. The Commission shall draw up a work programme specifying:

- (a) in greater detail, the objectives and RTD priorities of Annex II;

- (b) the indicative timetable for the implementation of the specific programme;
- (c) the coordination arrangements set out in Annex III and arrangements to secure the objectives, related to innovation and the participation of SMEs, of the third activity of the fifth framework programme;
- (d) where necessary, the selection criteria and the arrangements for applying them for each type of indirect RTD action.

2. The work programme shall take account of relevant interests, in particular the scientific, industrial and user communities. It shall serve as a basis for implementing the indirect RTD actions according to the procedures set out in the rules for participation and dissemination.

3. The work programme shall be updated where appropriate and be made available by the Commission to all interested parties in a user-friendly form, including in electronic form.

Article 6

1. The Commission shall be responsible for the implementation of this specific programme.

2. The procedure laid down in Article 7 shall apply for the adoption of the following measures:

- the drawing-up and updating of the work programme referred to in Article 5(1), including regarding the content of calls for proposals,
- approval of RTD actions proposed for funding, including participation by entities from third countries, where the estimated amount of the Community contribution under this programme is equal to or more than EUR 0,8 million,
- the drawing-up of the terms of reference for the external assessment provided for in Article 5(2) of the fifth framework programme,
- any adjustment to the indicative breakdown of the amount as set out in Annex I.

Article 7

1. The Commission shall be assisted by a programme committee (hereinafter referred to as 'the

committee') composed of representatives of the Member States and chaired by the representative of the Commission.

2. In the cases referred to in Article 6(2), the representative of the Commission shall submit to the committee a draft of measures to be taken. The committee shall deliver its opinion on the draft measures referred to above within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

3(a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

(b) If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on expiry of a period of nine weeks from the referral of the matter to the Council, the Council

has not acted, the proposed measures shall be adopted by the Commission.

4. The Commission shall regularly inform the committee of the overall progress of the implementation of the specific programme, and shall in particular provide it with information about the progress of all RTD actions funded under this programme.

Article 8

In accordance with Article 5(4) of the fifth framework programme, the Commission shall regularly inform the Council and the European Parliament of the overall progress of the implementation of the programme, including on the participation of SMEs and the simplification of administrative procedures.

Article 9

This Decision is addressed to the Member States.

Done at Brussels, 25 January 1999.

For the Council
The President
J. FISCHER

ANNEX I

INDICATIVE BREAKDOWN OF THE AMOUNT DEEMED NECESSARY

<i>(million EUR)</i>	
Type of activity	Amount
(a) Key actions	
(i) Food, nutrition and health	290
(ii) Control of infectious diseases	300
(iii) The cell factory	400
(iv) Environment and health	160
(v) Sustainable agriculture, fisheries and forestry and integrated development of rural areas including mountain areas	520
(vi) The ageing population and disabilities	190
(b) Research and technological development activities of a generic nature	483
(c) Support for research infrastructures	70
Total	2 413

ANNEX II

THE GENERAL OUTLINES, THE SCIENTIFIC AND TECHNOLOGICAL OBJECTIVES AND THE PRIORITIES

INTRODUCTION

Economic and political developments in Europe have globally resulted in greater prosperity, increased life expectancy and better working conditions. These improvements have, however, been accompanied by challenges such as higher healthcare costs, an ageing population, and environmental degradation and heightened ethical concerns. Increasingly, a gap is becoming evident between natural resources, whether from agriculture and fisheries, mining or the global environment, and human activities. Paradoxically, this has occurred at a time when there is an explosion in the knowledge base concerning the structure and working of all living things, pointing towards new developments in the corresponding sectors, for example healthcare, pharmaceuticals, agriculture, food, etc.

Europe has a strong tradition and an excellent record in research and application of life sciences and technologies. Furthermore, Europe provides a huge single market with a tradition of receptiveness for bio-based products. It has, therefore, the potential to address and solve major challenges such as a varied and safe food supply, affordable healthcare, better medicines, etc. The scientific basis on which living and natural materials are exploited for these ends is undergoing a dramatic change, in which the intimate and interactive workings of living beings are being revealed. With the progress of scientific knowledge in recent decades, one can now expect to probe more deeply the questions surrounding the production of food, the curing of diseases, and the sustainable management and use of biological resources. One can also anticipate clarifying their relationships with human behaviour and needs, industrial practices and consumer demands.

The strategic objective of the programme is to link the ability to discover to the ability to produce, in order to address the needs of society and to meet the requirements of the consumer, leading to future wealth and job creation and improvements in the state of the environment. The strategy of this programme is to focus on specific areas where growing knowledge potentially contains technical answers to some of the pressing questions asked by the citizen which require to be tackled on a European scale. Fundamental ethical values must also be respected.

The novelty of this approach is the willingness to couple the dynamics of massive knowledge production with few areas where there are expected to be desirable spin-offs, while pursuing the renewal of knowledge to reinforce European strengths in fields associated with further growth and quality of life.

The proposed scientific and technological solutions should be seen as part of an integrated system approach, in which human beings are at the core of the issue of the quality of life and of the management of living resources. Six key actions have been identified in which European research should make a contribution, by way of innovative products, processes or services, to problem resolution. These key actions are targeted at socioeconomic needs and the Community's policy objectives, for example in agriculture and fisheries, industry and consumers, and in the fields of health and environment. The gender dimension will be integrated throughout the programme where appropriate.

They are supplemented with research and technological development activities of a generic nature as well as support to research infrastructures aiming at building up, in the longer term, the knowledge base in areas of strategic importance for the future.

Meeting socioeconomic needs. On the demand side, research should be developed which promotes health, reconciles economic developments with environmental requirements, and improves the response to consumer needs. The exploitation of the results of the programme must take account of the socioeconomic dimension. On the supply side, there is huge potential for economic growth and job creation in this field, both in the traditional industries including primary production and in the nascent high technology industries.

Increasing European added-value. The major cross-border issues should be addressed selectively, such as health aspects of diseases (epidemiology, nutrition, food safety, ageing, including age-related disabilities and rare diseases), or transboundary resources management (terrestrial and aquatic living resources). Other areas such as drug abuse, biosafety or bioethics, involve the reinforcement of scientific bases in support of Community policies. Many of the activities to be addressed in the programme (e.g. genome research, neurosciences and technology assessment), due to their size and complexity, are only feasible if they are addressed at the European level.

Improving European competitiveness. The programme will capitalise on specific scientific strengths in knowledge areas and in productive sectors with strong growth potential, such as the biotechnology and food industries. Thus, the heart of this programme, improving the quality of life, promoting life sciences and technologies and decoupling economic growth from environmental degradation, will contribute in the short and in the longer term to European competitiveness and employment. Europe must promote start-ups in particular in the areas of biotechnology and the agro-food industry which have recently shown a consistent growth rate.

Promoting biosafety. The assessment of the behaviour and impact on human and animal health of recombinant organisms (e.g. transgenic plants, microorganisms, vaccines, etc.) and of their fate in the environment, where relevant, is part of every key action.

Respecting an ethical framework. Full respect of human rights and fundamental ethical principles will be ensured throughout all activities in the specific programme in accordance with Article 6 of the European Parliament and Council Decision on the fifth framework programme. These principles include animal welfare requirements in conformity with Community law.

LINKS AND COMPLEMENTARITY WITH THE OTHER PROGRAMMES

Coordination with other thematic programmes is based on promoting synergetic interactions and complementary activities and avoiding unnecessary duplication:

- coordination with the specific programme on a user-friendly information society is based on the following principle: activities concerned with information society technologies as such (which include development, demonstration and take-up actions) will be concentrated in the user-friendly information society programme; activities concerned with the deployment, integration and adaptation of information society technologies in applications relating to the quality of life and the management of living resources will be conducted in this programme,
- coordination with the programmes on competitive and sustainable growth and energy, environment and sustainable development is based on close interaction between the key action 'Food, nutrition and health' of this programme and the key action 'Innovative products, processes and organisation' of the programme on competitive and sustainable growth and the corresponding aspects of the programme on energy, environment and sustainable development. Similar interactions will be established between the key actions 'The cell factory' and 'Sustainable agriculture, fisheries and forestry and integrated development of rural areas, including mountain areas' with the relevant actions of the programmes on competitive and sustainable growth and energy, environment and sustainable development,
- close coordination will be developed with the programme 'Confirming the international role of Community research', in particular where collaboration with international initiatives could bring added-value to European RTD efforts,
- full use will be made of the possibilities offered by COST and Eureka and by cooperation with international organisations to foster synergy between actions and projects in this programme and nationally funded research activities. In the case of cooperation with Eureka, projects corresponding to themes of common interest with the framework programme may be developed in the context of the key actions in conformity with the selection criteria and procedures of the framework programme,

- specific activities aimed at facilitating the involvement of entities in third countries and maintaining links with specialists from third countries trained in Europe will be carried out, which will also contribute to the international dimension of the programme,
- concerning innovation and the participation of SMEs, as new knowledge in the biosciences constantly drives innovation, research partnerships need to be flexible and inclusive. A competitive partnership requires a high level of interaction of biology, engineering, information management, standardisation, capital investment, intellectual property rights, etc., which brings success only on a single-project basis. It will be imperative that measures to stimulate e.g. SMEs and financial partners accompany programme management for each individual action. An 'innovation unit' will focus the promotion activities with a view to the deployment and use of the results of this programme; it will also help to ensure complementarity and an interface with the innovation activities implemented in the context of the programme on 'Innovation and participation of SMEs',
- improving the know-how, skills and qualifications of European researchers and the understanding of the socioeconomic impact of research in the fields covered by this programme is essential to ensure sufficient availability of appropriate expertise and to establish tangible and lasting impacts. Training and socioeconomic research will therefore form an integral part of this programme, complemented by appropriate links with the horizontal programme 'Improving the human research potential and the socioeconomic knowledge base'. Training activities in this programme will include support to fellowships, which will take the form of 'Marie Curie' fellowships following the definitions and rules set out in the horizontal programme.

(a) **KEY ACTIONS**

(i) **Food, nutrition and health**

Objectives and RTD priorities

The aim of this key action is to promote the development of knowledge, technologies and methods, including prenormative aspects, based on multidisciplinary approaches to produce a safe, healthy, balanced and varied food supply for consumers covering the whole food chain thereby promoting consumer protection and contributing to the fight against diseases related to food and the immense costs to health systems arising therefrom. The following scientific and technological objectives will be pursued:

- *development of safe and flexible and new and/or improved manufacturing processes and technologies.*

The aim is to improve the quality and consumer acceptability of food, while ensuring traceability of raw materials and final products.

RTD priorities: improved use of raw materials, production and processing and preservation systems; development of food crops and of functional and safe foods; use of fishery and aquaculture by-products and of poorly exploited species; quality and traceability of raw materials and food products in the food chain; minimal processing and process control; advanced food technologies and packaging systems; improvement of traditional technologies; quality monitoring and quality assurance, including the development of methods for measuring quality,

- *development of tests to detect and processes to eliminate infectious and toxic agents throughout the food chain.*

Research will focus on the hazards of food contaminants, their exact origins and strategies for safer food production.

RTD priorities: improved understanding and control of contamination conditions; rapid detection tests for pathogens, xenobiotics and hormones; new and safer methods of food production; new methodologies for accessing microbial, chemical and allergenic risks,

- *research into the role of food in promoting and sustaining health with respect to diet and nutrition, toxicology, epidemiology, environmental interaction, consumer choice and public health.*

The aim is to reduce diet-related risk factors contributing to chronic disease and to develop new approaches for improved nutrition and more balanced diets.

RTD priorities: the role and impact of food and diet on physiological functions, and physical and mental performance; the particular nutritional needs of defined population groups; links between diet and chronic disease and disorders including genetic factors involved; consumer attitudes and reactions with regard to food products, food-processing methods and labelling.

(ii) Control of infectious diseases

Objectives and RTD priorities

The overall goal of this key action is to combat established, emerging or re-emerging infectious diseases including zoonoses, linked to old, new or mutated agents in humans or animals. This would be achieved primarily by mixing complementary expertise in transdisciplinary projects, by linking these activities to national and international organisations, and by encouraging the interface between academic research, policy-makers, healthcare providers, including the interface between preclinical and clinical research, and the human and animal healthcare industry, pursuing the following scientific and technological objectives:

- *the development of improved or novel mono-component, multi-component and combined vaccines, especially against viral diseases, including the support of multicentre clinical trials.*

RTD priorities: vaccines against emerging and re-emerging infectious diseases and other diseases related to infectious agents (e.g. some cancers) consistent with the relevant Community policy regarding the reduction and eventual replacement of animal testing; vaccines against animal pathogens; development of European networks for clinical and field trials of vaccines and drugs including, where necessary, better understanding of the immune system,

- *new and improved strategies to identify and control infectious diseases, directed at treatment and prevention and based on studies on pathogenesis, emergence of resistance and immunological control.*

RTD priorities: improved understanding of mechanisms of protection against infectious agents, of drug resistance and control of immunological responses; technologies for safer and more efficient vaccines and immunotherapy; specific risk factors, including human behaviour and new technologies such as xenotransplants influencing the spread of infectious diseases and development of new and resistant strains; development and validation of diagnostic tests; research to support the development of an early-warning system and response network for infectious diseases; improved methodologies for early and accurate detection of adverse reactions to drugs and vaccines,

- *aspects connected with public-health, healthcare and care-delivery systems, notably management, prevention and surveillance, behavioural aspects and response to infectious diseases (including modelling of human diseases).*

RTD priorities: organisational and economic aspects of public health and healthcare systems; surveillance, monitoring and assessment methodologies in prevention and cure; methodologies for product safety surveillance in the market place.

(iii) The cell factory

Objectives and RTD priorities

This key action is aimed at helping the Community's enterprises, either established or starting up, to exploit the advances made in life sciences and technology, particularly in the fields of health, environment, agriculture, agro-industries and high value-added products such as chemicals. It is aimed

at the development of multidisciplinary technologies based on the exploitation of the properties of microorganisms, plants and animals, in particular at the tissue, cellular and sub-cellular levels. The objective is to understand the versatile functioning of cells and to develop bio-reactors, bio-molecules and bio-processes with high added-value capable of enhancing the quality of life and health. Being a prerequisite to the functioning of cells as minute factories, sufficient knowledge will have to be secured of their blueprint at the scale at which they operate, through underpinning contributions of structural biology, physiology, nanobiotechnology, genomics and proteomics, with the support of notably physicochemistry, bioinformatics and biochemical engineering. To ensure the safety of new biomolecules or bioprocesses, methods will be made available for monitoring their potential impact on human and animal health, and their contribution to improving standards of environmental care.

This key action should also aim at using RTD to reinforce the prenormative research by making cell cultures available as models for medicine, pharmacology, toxicology and environmental monitoring as a substitute for animal testing. Emphasis would be put on the following scientific and technological objectives:

- *new and innovative health-related processes and products particularly from molecular engineering (for example diagnostics, antibiotics, anti-cancer agents, including plant produced therapeutics)*

Research will focus on bio-products relevant to preventing, detecting and treating human and animal diseases and improving the quality of life.

RTD priorities: improved understanding of the cell, gene functions and gene-delivery methods applicable to the development of new diagnostic and therapeutic substances and strategies; anti-cancer agents, antibiotics, antibodies and therapeutics, vaccines, novel *in-vitro* testing and screening methods as alternatives to animal testing; cells as production units and as diagnostic and detection tools,

- *energy-efficient bio-remediation and waste bio-treatment processes*

The objective is to prevent, detect, monitor, treat and remove pollution as well as to maximise the economic value of waste.

RTD priorities: new bio-processes for preventing industrial pollution, treating, upgrading, and/or recycling bioaccumulable wastes and industrial by-products; bioassays and biosensors; biodegradation of recalcitrant chemicals by microbial catalysts alone or in combination with plant systems and/or chemical catalysts; biodiversity and ecological dynamics of natural and introduced populations,

- *new biological and biotechnological processes and products, new processing technologies using microorganisms, plants or animals for agrifood and agroindustry and high value-added chemical applications*

The focus is on high value biomolecules and bioprocesses leading to enhanced exploitation of renewable resources and to enhanced expression of desirable characteristics for microorganisms, plants and animals. These activities are targeted at sustainable and industrial exploitation prospects and take into account socioeconomic, agronomic, ecological and/or consumer perspectives.

RTD priorities: exploiting the cellular and sub-cellular characteristics of improved microorganisms, plants and animals, including through approaches at genome level; development of methods and strategies for identifying recombinant organisms and their residues in the environment and assessing their potential impact on human and animal health or the environment; new biocatalysts; use of terrestrial and marine organisms as a source of new valuable products; identification and sustainable use of metabolic and genetic diversity.

(iv) Environment and health

Objectives and RTD priorities

The aim of this key action is to achieve a better understanding of the interactions between the genetic, physiological, environmental and social factors involved in sustaining good health and so to help reduce the adverse impact on health of changes in the environment and the workplace and the immense costs to health systems arising therefrom. It covers in particular issues such as prevention and the effects on health of air pollution, heavy metals and toxic substances, noise, climatic changes and electromagnetic radiation, as well as the effects of pollution at the workplace. The following scientific and technological objectives will be pursued:

- *research into diseases and allergies related to or influenced by the environment and research into their treatment and prevention*

The focus is on health impairment caused directly by exposure to the environment and on ways of treatment and prevention, based on sound epidemiological data and an understanding of pathogenesis mechanisms. Research should also be conducted into the impact of environmental pollutants at the workplace.

RTD priorities: analysis and quantification of the impact of environmental factors on human health; assessment of the relative importance of, and the interactions between, factors impinging on health; improved understanding of the interrelations between environmental and public-health indicators for better treatment and prevention; development of an integrated approach to risk assessment taking into account epidemiological, environmental and public-health aspects; bio-markers of environmental exposure and an eventual replacement of animal testing,

- *development of new methods of diagnosis, risk assessment and of processes to reduce causes and harmful environmental health effects*

The objective is to use a multidisciplinary approach for better understanding of the interactions between the social and physical environment, genetic factors and health and to improve the identification of vulnerable groups to environmental exposures and to identify preventive measures in order to reduce causes and environmental factors hazardous to health.

RTD priorities: bio-markers (including bio-indicators) of environmental exposure, effect and/or susceptibility to environmental agents, including mixed exposures and cumulative effects; improvement of predictive toxicity testing and mechanism-based risk assessment consistent with the general objectives of reducing, refining and eventually replacing animal testing; improved methods and technologies for long- and short-term exposure and effects assessment; epidemiological and biomedical studies on possible effects linked to non-ionising irradiation, particularly from cellular phones.

(v) Sustainable agriculture, fisheries and forestry, and integrated development of rural areas including mountain areas

Objectives and RTD priorities

The aim is to develop knowledge and technologies for the production and exploitation of living resources, including forests, covering the whole production chain, taking into account the highly competitive international context and in the light of the need for adaptation to the evolution of the common agricultural and fisheries policies, while also providing the scientific basis for Community regulations and standards, and to promote the multifunctional role of forests and the sustainable management and utilisation of forest resources as an integral factor of rural development. The priority areas are as follows:

- *new and sustainable systems of production, including breeding methods, and exploitation in agriculture, fisheries and aquaculture, taking into account profitability, the sustainable management of resources, product quality and employment as well as animal health and welfare,*

RTD priorities:

- for agriculture: sustainable farm production systems and methods and corresponding *ex-ante* and *ex-post* control and analysis; diversification of production and activities; support to Community policies on plant health (prevention and prediction of, protection against plant diseases and harmful organisms), animal health (prevention, control, eradication of major diseases and zoonoses) and animal welfare; identification and characterisation of the quality of agrofood products and agricultural farm-processed products and farm-processing technologies; definition of parameters, specifications, methods, forms of organisation and technologies for total quality; organic farming systems; plant and animal breeding, including relevant application-oriented genome research, and diversity of genetic resources,
- for fisheries: support to integrated fishery management linking resource conservation, means of capture, interactions with ecosystems, market requirements and socioeconomic considerations; identification and characterisation of the quality of marine products and technologies; development of new concepts for the sustainable use of marine and aquatic living resources,
- for aquaculture: sustainable production systems with the reduction of impact on ecosystems and diversification of cultivated species (both plant and animal); improvement of production techniques; genetic improvement; disease resistance and control,
- *integrated production and exploitation of biological materials for non-food uses*

This will cover integrated production and processing chains with the emphasis on end-use and market requirements.

RTD priorities: industrial products from the green chemical, biopolymers and bioenergy integrated chains,

- *sustainable and multipurpose utilisation of forest resources; the integrated forestry-wood chain*

This encompasses sustainable management and multiple use of European forest resources, in harmony with the political, environmental and social needs, bringing economic growth and employment to rural and coastal areas.

RTD priorities: support to policy issues; multifunctional and sustainable management of forests combining quality production and new and improved technologies with conservation and environmental protection, including protection of forests soils and protection against natural hazards (e.g. forest fires); diversification (non-wood uses including recreational uses, agro-sylvo-pastoral systems). Forests ecosystems biodiversity and genetic improvement. Strategies for sustainable management and multipurpose utilisation of forest resources; the forestry-wood chain; efficient, environment-friendly processes and recycling technologies; high value-added and diversified products accounting for market needs, and consumer requirements,

- *development of methods of control, surveillance and protection, including protection of land and prevention of soil erosion*

The aim is to support the sound implementation of the common agricultural and fisheries policies and related activities. This research may also be useful to the Community in the context of international trade negotiations and of dispute settlements in the framework of WTO, in the area of agriculture.

RTD priorities: reliable, transparent and cost-effective methods of monitoring, assessment and control,

- *pre-legislative research designed to provide a scientific basis for Community legislation*

The aim is to provide support for Community regulations by prenormative research activities.

RTD priorities: prenormative research to provide the scientific basis for regulations in the context of the common agricultural and fisheries policies,

- *new tools and models for the integrated and sustainable development of rural and other relevant areas*

This approach is based on optimisation of the specific potential of each area, including at regional level, the diversification of activities and land use and the involvement of the people concerned.

RTD priorities: analysis of the situation and changes under way, taking into account the relationships between all the sectors involved and the factors influencing technological and socioeconomic changes; multifunctional land use and landscape management as related to important ecosystems and habitats taking also into account aspects relating to cultural heritage; diversification and job opportunities; development of the 'integrated rural and fishery development' concept, with the investigation of potentials and constraints, the elaboration of new models and tools, including for spatial planning and the improvement of the organisational capacity of local actors; support to follow-up and evaluation of rural and coastal development programmes and policies with tools to monitor, assess and forecast socioeconomic and environmental benefit.

(vi) The ageing population and disabilities

Objectives and RTD priorities

This key action aims to help Europe meet the challenge of the growing ageing population through RTD to underpin the development of policies and interventions to extend the quality of life and independence of older people, and to reduce the need for long-term care and its consequential costs. It gives priority to multidisciplinary RTD relating to processes leading to healthy ageing, including demographic, social and economic aspects, and to interventions leading to the postponement and improved management of disability. It aims to generate competitive advantage for a wide range of health-related industries and sectors. Priority areas include:

- *RTD on illnesses, disabilities and health problems with high morbidity, which are age-related and where there is a real prospect of significant prevention, treatment or delay in onset*

RTD priorities: studies on age-related diseases and disorders in the older population (Parkinson's, Alzheimer's diseases, etc.); physiology and pathophysiology of ageing and disability; co-morbidity studies,

- *RTD into biological, psychological, social and economic determinants of healthy ageing and of the mechanisms leading to disability and the postponement of disability*

RTD priorities: cellular and molecular bases of ageing; genetic predisposition; immunology of ageing; basic biological and psychological mechanisms underlying age-related changes (including occupational and genetic effects); model studies and model diseases for specific ageing processes; biomarkers; endocrine, neurocrine and metabolic factors of ageing; psychological implications of ageing,

- *demographic and epidemiological RTD into ageing and disability trends to enable prediction of the size and nature of the ageing population as a basis for policy and planning*

RTD priorities: clinical trials; analysis and quantification of demographic, medical, sociological, lifestyle (including exercise, mobility and nutrition) and environmental factors; prevention; methodology linked to collection of specific data,

- *RTD into new approaches to delaying the onset of disability, to reducing the challenge to older people of their social and physical environment, including the design and development of products*

and services adapted to their needs (e.g. in housing, transport and leisure) and to supporting mental and physical functioning

RTD priorities: methodology relating to quality of life, social integration and coping mechanisms; technologies contributing to less dependency; research on sensory degenerations; psychomotor, sensory and cognitive impairments; rehabilitation and replacement therapies; intervention assessment studies; assessment and quantification of needs and design/development of competitive and adapted products and services,

- *RTD into effective and efficient delivery of health and social care services to older people, including comparative research on the financing of long term care and pensions*

RTD priorities: healthcare outcome research for elderly and disabled, research into specific health services and social care services, as well as into healthcare services organisation; efficiency and quality of healthcare delivery for the elderly; impact of ageing on the evolution and financing of care systems, notably for long term care, and of pensions.

(b) RESEARCH AND TECHNOLOGICAL DEVELOPMENT ACTIVITIES OF A GENERIC NATURE

These activities have a longer-term impact that may even preclude the possibility of satisfying some of the citizens' expressed needs, for as long as fragmentary knowledge is not pooled together to a sufficient degree of completeness. There is, in the related disciplines, a time-dependent need for integration of the science base, which is why industry, services and policy-making in Europe must maintain or reinforce their response capacity in a rapidly changing world.

Efficient interaction between research laboratories and industry will be promoted. Clustering of projects involving core centres and associated laboratories will be encouraged to create a critical mass, to promote interaction between basic and applied research and to ensure maximum transfer of knowledge to and from industry and undertakings. Support ranging from training of young scientists to fellowships for senior researchers will be developed.

- *Chronic and degenerative diseases (in particular cancer and diabetes), cardiovascular diseases and rare diseases*

Major challenges in biomedical research are the elucidation of the aetiology and pathogenesis of multifactorial diseases (e.g. genetic, environmental, lifestyle) of high (e.g. cardiovascular, cancer, diabetes) or low (e.g. rare diseases) morbidity. There is an urgent need to improve diagnosis, treatment, prevention and surveillance through epidemiology and applying advances in modern technology, requiring a multinational approach. The objective is to increase knowledge with regard to the genetic basis, epidemiology, pathogenesis and diagnosis of diseases by integrating basic and clinical research, and to apply modern technology to the treatment and control of major diseases, including rare (e.g., Creutzfeldt-Jakob Disease) and orphan diseases (e.g. illnesses which are prevalent in industrialised or developing countries but are receiving less attention for research in industrialised countries).

RTD priorities: contribution of molecular, genetic, environmental and lifestyle factors and their interactions to the aetiology, pathophysiology, progress and outcome of diseases, leading to new approaches to prevention, diagnosis and treatment, including the development of orphan drugs. Evaluation of novel therapies where multinational, large-scale studies/trials are required, and optimum use of databases, registries, reagents and sample banks,

- *Research into genomes and diseases of genetic origin*

The aim of this activity is to identify the physiological functions of genes and to improve the understanding of the meaning of sequence information. The new knowledge and technologies deriving from this generic action should promote the exploitation of genome information to the

benefit of European health, agriculture, industry and the environment. The organisation of collaboration in this area will underpin the development of expression systems to facilitate the study of genes of industrial and agronomic interest as well as the design of effective molecular and gene-based preventive and therapeutic strategies for human and animal disease. Efforts will be made to ensure that the gap between diagnostic and therapeutic possibilities does not widen.

RTD priorities: this area will address the meaning of genome information and the improvement of the knowledge and understanding of the genetic basis of diseases, including chronic and degenerative diseases. This will require structural studies; comparative analyses of genomes and proteomes; development of novel and user-friendly informatics approaches to enable acquisition of, access to and interpretation of genomic and functional data; development of novel expression systems, model organisms, mutant, transgenic and hybrid organisms with strict regard to ethical principles and the principles of biosafety; development and application of underpinning biochemistry, biophysical, statistical and computational approaches,

— *Neurosciences*

This activity will provide new insights and a better understanding of the mechanisms governing the interrelationship of biological and psychological processes, to promote new diagnostic (e.g. imaging), preventive and therapeutic approaches to neurological and psychiatric disorders and to underpin opportunities for education, innovation in healthcare and computational industries. In this context, synergy and an appropriate flow of information will be strengthened with the human frontier science programme.

RTD priorities: the integration of diverse disciplines, technologies and levels of biological organisation in the following areas: cell communication, mechanisms of learning and memory; mechanisms of brain development, disorder and repair, and their clinical, epidemiological and social implementations. Brain theory, computational neurosciences, and neuroinformatics; human behaviour, cognition and functional mapping of the brain. Integration of theoretical and experimental approaches; integration of basic and clinical research in developing innovative diagnostic, preventive and therapeutic strategies based on novel genetic, cellular, non-invasive, pharmacological and psychological approaches,

— *Public health and health services research*

Improvement of health systems: to improve the health of European citizens and the effectiveness and cost-effectiveness of health-promotion and healthcare technologies and interventions, including evaluation of the effectiveness of non-conventional therapies, enhance health and safety at work, evaluate healthcare models, develop the evidence base for clinical practice and health policy, and study public health variations across Europe.

RTD priorities: improved methodologies in epidemiology; identification of new health determinants (including factors leading to inequalities in health) and aetiological factors of disease through common methodologies and comparative research; socioeconomic and organisational determinants of prevention, care and health services; at the workplace and in the home exposure to biological, chemical and physical agents and to physical and mental stress.

Fighting drug-related problems: to prevent and, where appropriate, control drug-related health problems through establishing the psychological and socioeconomic factors involved in drug-taking and drug abuse, developing better understanding of the long-term health and social consequences of abuse, and developing more effective treatment strategies.

RTD priorities: comparative and analytical research on biological and social causes, risk factors and effects of drug addiction and misuse; psychological and socioeconomic factors of drug abuse; long-term health effects of drug consumption; physical detection aspects, drug profiling and biological monitoring of drugs,

— *Research relating to the disabled*

The aim of this activity is to enhance the quality of life and independence of disabled people.

RTD priorities: research aimed at contributing to improvement of their social and physical environment and the effective and efficient delivery of the health and social care services available to them,

— *Study of problems relating to medical ethics and bioethics in the context of respect for fundamental human values*

The objective is to identify the ethical, legal and social questions raised, not only by medical and biological research alone but also, more broadly, by scientific and technological developments to understand and to promote public discussion of issues of public concern, and to analyse the ethical dimension of legal and regulatory measures.

RTD priorities: ethical aspects of life sciences research and its application to medical practice, food, animals, plants, and the environment⁽¹⁾,

— *Study of the socioeconomic aspects of life sciences and technologies within the perspective of sustainable development (the impact on society, economy and employment)*

Competitiveness and sustainable development will together be the source of the Union's future wealth and employment opportunities, ensuring an enhanced quality of life for Europe's citizens.

Simultaneous pursuit of these objectives is only possible through an adequate recognition of the key interrelations between technologies, environment and society and integration of knowledge into sustainable development policies.

Socioeconomic research is also needed to enhance the quality of the public debate, as illustrated by the interest shown in the applications of modern biotechnologies and its scientific bases and the need for transparent information. The regulatory process in life sciences and technologies and its

⁽¹⁾ Research activities under this programme must comply with the international conventions and codes of conduct, and in particular the Helsinki Declaration of the World Medical Association adopted by the World Medical Assembly.

Account will also be taken of the declaration of the European Council of Amsterdam and the European Parliament's resolution on the banning of human cloning (OJ C 115, 14.4.1997), the European Convention on Human Rights and Biomedicine of the Council of Europe; the opinions of the Group of Advisers on the Ethical Implications of Biotechnology (1991 to 1996) and the opinions of the European Group on Ethics in Science and New Technologies (as from 1998); the Universal Declaration on the Human Genome and Human Rights of UNESCO of 11 November 1997 and the resolutions of the WHO, as well as relevant EC legislation for example, Council Directives of 26 January 1965 and 20 May 1975 on the approximation of the laws, regulations and administrative provisions relating to proprietary medicinal products (65/65/EEC and 75/319/EEC), Council Directive of 24 November 1986 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the protection of animals used for experimental and other scientific purposes (86/609/EEC).

No research activity which modifies or is intended to modify the genetic heritage of human beings by alteration of germ cells or by acting at any other stage in embryonic development and which can make such alteration hereditary will be supported under the present framework programme. In the same way, no research activity understood in the sense of the term 'cloning', with the aim of replacing a germ or embryo cell nucleus with that of the cell of any individual, a cell from an embryo or a cell coming from a later stage of development to the human embryo, will be supported.

Concerning animal experimentation, the principles of replacement by alternative methods, reduction of the number of animals and the refinement of experiments must be applied to the extent possible. Animal suffering must be avoided or kept to a minimum and special attention must be paid to animal experimentation involving species that are the closest to human beings.

Modification of the genetic heritage of animals and animal cloning will be envisaged within this programme only for objectives which are justified on ethical grounds and when carried out under conditions respecting animal welfare and genetic diversity.

Participants in EC research projects must conform to national legislation and applicable codes of conduct and seek the approval of the relevant ethics committee prior to the start of the RTD activities.

impact on citizen's confidence influences public opinion, which in turn has a strong impact on decision-makers.

The objectives are to assist in the construction of strategies and models for sustainable development and to provide a sound scientific basis for the conception, implementation and evaluation of relevant policies, exploiting knowledge and technologies from the life sciences and technologies (including the creation of employment opportunities in the bio-industries), and to develop a better understanding of the links between science and policy; including the ways in which opinions on the benefits and risks of technological progress are formed and are reflected in the regulatory process.

RTD priorities: technology evaluation and assessment, systematic provision of information to the public, education and opinion forming in the field of life sciences and technologies; analysis of social and economic driving forces and of new opportunities in the bioindustries; development of indicators and knowledge bases relevant to decision-making and regulation; analysis of the social and economic aspects of the links between life sciences and technologies and policies in the field of industry, agriculture, fisheries, food, environment, sustainable development, public health, etc.

(c) SUPPORT FOR RESEARCH INFRASTRUCTURES

Objectives

To broaden access, to make optimum use of and to improve the consistency of the existing European research fabric at Community level.

To facilitate and to encourage transnational cooperation in the rational and cost-effective development of RTD facilities in response to emerging needs.

In order to reinforce the European added-value and the optimisation of the required efforts, Community support will be directed towards: transnational coordination, integrated management of, specific aspects of operation of, access to and improvement of existing facilities; coordination and complementation of national or multinational initiatives to develop facilities needed at the European level; networking of communities of researchers and users through research projects and specific training activities centred on appropriate infrastructures, or cooperation of several partners, leading to an integrated service provider; increasing the compatibility of dispersed systems, aiming to provide rapid and effective integration of facilities and resources.

Classes of infrastructures

- Biological data and collections of biological material. Databases, information services and networks of biological expertise; major specialised instrumentation for the study of biological structures; collections of genetic materials, living and non-living specimens; breeding of animals to develop models of human diseases,
 - clinical research facilities, including pre-clinical research, identification of studies and clinical trials that should be done at the European level,
 - facilities for aquaculture and fishery research.
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ANNEX III

SPECIFIC RULES FOR IMPLEMENTING THE PROGRAMME

The specific programme will be implemented through the indirect RTD actions as provided for in Annexes II and IV to the fifth framework programme. In addition, the following rules specific to this programme will apply:

1. Accompanying measures

The accompanying measures will comprise in particular:

- studies in support of the specific programme, including the preparation of future activities,
- the exchange of information, conferences, seminars, workshops and scientific and technical meetings,
- recourse to external expertise, including access to scientific databases, in particular for the purposes of the monitoring of the specific programme provided for in Article 5(1) of the fifth framework programme, the external assessment provided for in Article 5(2) of the fifth framework programme and the evaluation of indirect RTD actions and the monitoring of their implementation,
- dissemination, information and communication activities, including scientific publications, activities for the exploitation of results and the transfer of technologies, encouragement of innovation financing and assistance with the protection of intellectual property,
- training schemes related to RTD activities covered by the specific programme other than Marie Curie fellowships,
- support for schemes to provide information and assistance for research players, including SMEs,
- recourse to external expertise in setting up and providing access to information, assistance and research and innovation promoting services and networks.

2. Coordination arrangements

The Commission will endeavour to ensure complementarity between the indirect RTD actions under the programme, in particular by grouping them around a common objective, and to avoid duplication, while respecting the legitimate interests of proposers of indirect RTD actions.

As far as possible, coordination will also be ensured between actions under the specific programme and those carried out in:

- other specific programmes implementing the fifth framework programme,
- the research and training programmes implementing Council Decision 1999/64/Euratom of 22 December 1998 concerning the fifth framework programme of the European Atomic Energy Community (Euratom) for research and training activities (1998 to 2002)⁽¹⁾,
- other European research frameworks including Eureka and COST,
- other Community research-related instruments.

⁽¹⁾ OJ L 26, 1.2.1999, p. 34.

It will comprise:

- (i) the identification of common themes or priorities, resulting in particular in:
 - the exchange of information,
 - the carrying out of work decided on jointly, entailing in particular the joint initiation of one of the procedures referred to in Article 9 of the rules for participation and dissemination;
 - (ii) the reassignment of proposals for indirect RTD actions between specific programmes or between a specific programme and a research and training programme.
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