European Commission

THE SIXTH FRAMEWORK PROGRAMME

The Sixth Framework Programme covers Community activities in the field of research, technological development and demonstration (RTD) for the period 2002 to 2006

Work Programme

for the specific programme for research, technological development and demonstration:

"Integrating and strengthening the European Research Area"

PRIORITY 1: Life Sciences, Genomics and Biotechnology for Health

Update July 2003

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0. GENERAL INTRODUCTION

1. General

Following the adoption of the specific programme for research, technological development and demonstration: "Integrating and strengthening the European Research Area"[1] and the rules of participation and dissemination[2] under the EC Treaty, the Commission has adopted, with the assistance of the programme committee, this work programme which sets out in greater detail the objectives and technological priorities and the timetable for implementation of the specific programme, in particular for the first year of operation.

As regards the **Priority Thematic Areas of Research**, the new instruments (integrated projects and networks of excellence) are recognised as being an overall priority means to attain the objectives of critical mass, integration of the research capacities, management simplification and European added value.

The new instruments referred to will be used from the start in each theme and, where deemed appropriate, as a priority means, while maintaining the use of specific targeted projects and co-ordination actions. In particular, a smooth transition with previous programmes will be ensured.

In terms of participation of the Community in programmes undertaken by several Member States (Article 169 of the Treaty), this is only foreseen, at this stage, in the priority thematic area of research addressing 'life sciences, genomics and biotechnology for health'.

More information on the provisions for implementing the new instruments is available on Cordis (*http://www.cordis.lu/fp6/instruments.htm).*

Regarding research activities in areas involving **Specific Activities Covering a Wider Field of Research**, these will be implemented, at this stage, using specific targeted research projects, co-ordination actions, and specific research projects for small and medium sized enterprises (SMEs).

Concerning **Strengthening the Foundations of the European Research Area**, the implementation will mostly take the form of specific targeted research projects and co-ordination actions.

Specific support actions, including calls for tender, and co-ordination actions may be applied throughout the programme

In drawing up this work programme, the Commission has relied on advice from advisory groups and, for the Priority Thematic Areas of Research, on the results of a call for expressions of interest, which was launched in early 2002. More information on this, including the list of members of the advisory groups and the results of the call for expressions of interest, is available on Cordis.

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[1] OJ L 294, 29.10.2002, p. y.
[2] OJ L 355, 30.12.2002, p. 23.

2. Scope of Work Programme

The scope of this work programme corresponds to that defined in the specific programme. The calls for proposals planned within this work programme are those foreseen to close in 2003 along with, in many cases, an indication of those calls intended to close in 2004. Annex A gives an overview of these calls. Some topics in the specific programme have been left until a later stage and these will be addressed in future revisions of the work programme.

3. Cross Cutting Issues

There are several issues that are important to all parts of the work programme. These are addressed here and, as appropriate, elaborated in the various parts. Please note that the work related to statistics in this work programme will be implemented in close co-operation with EUROSTAT, in particular the parts relating to the priority thematic areas "Information Society technologies" and "Citizens and governance in a knowledge-based society", as well as the part addressing policy-oriented research under the heading "Specific activities covering a wider field of research".

a) This work programme places special emphasis on the needs of small and medium-sized enterprises (SMEs). In particular, at least 15% of the funding allocated to the Priority Thematic Areas of Research is foreseen for SMEs. In order to reach this objective, special actions are foreseen such as SME specific calls for proposals in the context of the new instruments, reinforcement of National Contact Points, and specific training and take-up measures. In addition, the involvement of SMEs is taken into account in the evaluation criteria particularly for the new instruments. Also the fact that enterprise groupings which represent large communities of SMEs may play an active role in the new instruments will contribute to reaching the above-mentioned objective.

b) Proposers based in Associated States may take part in this programme on the same footing and with the same rights and obligations as those based in Member States. In addition, this work programme underlines the importance of involving associated candidate countries in the Community's research policy and in the European Research Area. Specific support actions will also be implemented to stimulate, encourage and facilitate the participation of organisations from the candidate countries in the activities of the priority thematic areas. These will comprise information, awareness and training activities, promotion of candidate country competencies, support to researchers from these countries to participate in conferences and to prepare proposals, establishment and reinforcement of networks or centres of excellence between Member States and candidate countries, and between centres of excellence of candidate countries and within candidate countries, measures in support of SMEs in candidate countries to better participate, evaluation of RTD systems and policies in a particular field, the screening of research establishments active in a particular field, and

prospective studies aimed at defining research policies and organisation of research systems in a particular field. See Annex D for details of the specific support actions to be implemented for associated candidate countries.

c) International co-operation represents an important dimension of the Sixth Framework Programme. As a contribution to a European Research Area open to the world, it will be implemented in the Sixth Framework Programme through three major routes:
   - The opening of "Focusing and Integrating Community Research" to third country organisations with substantial funding,
   - Specific measures in support of international co-operation, and
   - International activities under the heading of Human Resources in the specific programme for research, technological development and demonstration "structuring the European Research Area".

   The first two, as part of the specific programme "Integrating and strengthening the European Research Area", are covered by the present work programme. They also correspond to the second activity referred to in Article 164 of the Treaty, which covers co-operation with third countries and international organisations.

   - *Opening of "Focusing and Integrating Community Research" to third country organisations*

   Funding is available for the participation of researchers, teams and institutions from third countries in projects within the seven Priority Thematic Areas of Research, as well as under "Specific activities covering a wider field of research". Under this heading, the activities in question have the following overall objectives:

   - To help European researchers, businesses and research organisations in the European Union and in the countries associated with the Framework programme to have access to knowledge and expertise existing elsewhere in the world, and
   - To help ensure Europe's strong and coherent participation in the research initiatives conducted at international level in order to push back the boundaries of knowledge or help to resolve the major global issues.

   Any particular issue concerning the international dimension of the seven Priority Thematic Areas of Research and of the Specific activities concerning a wider field of research is set out in the relevant chapter of this work programme.

Participants from all third countries[3] and from international organisations may take part in all activities under this heading in addition to the minimum number of participants required.

Participants from developing countries, Mediterranean partner countries, Western Balkan countries, as well as Russia and the new independent states (see the list of countries in Annex C) can be funded in all activities under this heading[4].Other third country participants can also be funded in those areas where the relevant part of this work programme makes reference to this possibility or if it is essential for carrying out the research activity.

- *Specific measures in support of international co-operation*

315 million Euro will fund "Specific measures in support of international co-operation". In support of the external relations, including the development policy, of the Community, these measures target the following groups of third countries: Developing countries, Mediterranean partner countries, Western Balkan countries, and Russia and the new independent states. The activities and calls for proposals under this heading, which are complementary to the opening of the Priority Thematic Areas of Research, are presented in Chapter 10 of this work programme. Requirements for consortium composition are set out in this part.

- *Participation and funding for third country entities under the heading "Strengthening the European Research Area"*

International co-operation with third country partners and international organisations will be actively fostered on all topics which will benefit from such co-operation. Furthermore, third country entities and international organisations can benefit from Community financial contribution. To this end, topics for international co-operation will be specified, where appropriate, in calls. This applies particularly to those third countries with whom co-operation agreements have been concluded.

d) Research activities carried out under this work programme must respect fundamental ethical principles and the requirements as stipulated in the decision on the specific programme for research, technological development and demonstration: "Integrating and strengthening the European Research Area". More information on the review procedure is foreseen in the "Guidelines on Proposal Evaluation and Project Selection Procedures" (*http://www.cordis.lu/fp6/eval-guidelines*). Annex B to this work programme also details the issues to be covered in any ethical review.

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[3] There is currently no co-operation with Afghanistan, Iraq, Iran, Libya, Myanmar, or North Korea. This situation is subject to review, in line with the Community's external policies. Please check on Cordis for updates.

[4] 285 million euro has in fact been allocated for participation from the targeted third countries (see Annex C) within the Priority Thematic Areas of Research and specific activities covering a wider field of research.

e) As much as possible and in association with the specific programme for research, technological development and demonstration "Structuring the European Research Area", the mobility of researchers will be promoted, particularly with a view to the successful creation of the European Research Area.

f) This work programme attempts, where possible, to reinforce and increase the place and role of women in science and research both from the perspective of equal opportunities and gender relevance of the topics covered.

g) A particular effort will be carried out to take into consideration the ethical, social, legal, regulatory and wider cultural aspects of the research including socio-economic research, and innovation, resulting from the possible deployment, use and effects of the newly developed technologies or processes and scenarios covered by each of the thematic priorities. This effort will be complemented by socio-economic research carried out within the priority addressing 'Citizens and governance in a knowledge-based society'.

h) In the context of the regular report to be submitted to the European Parliament and the Council, the Commission will report in detail on progress in implementing the specific programme, and, in particular, progress towards achieving its objectives and meeting its priorities.

i) The promotion of innovation is a cross-cutting issue, relevant to the whole European Community RTD Framework Programme. This issue aims to meet the Treaty objective of strengthening the scientific and technological bases of Community industry *and encouraging it to become more competitive at international level*[5].

In this context, an important goal is to promote exploitation of the results of those projects which include R&D components[6]. To this end, consortia should pay sufficient attention to the management of knowledge and pursuit of innovation in their projects. These issues should be addressed in the proposals, and will be taken into account during their evaluation[7].

In particular, the participants should include in their projects "innovation-related activities", that may be supported by EC funding. Examples of such activities include the protection and management of knowledge and intellectual property, the analysis of socio-economic factors affecting the exploitation of the project's results, and feasibility studies for the creation of spin-offs.

During a project, the participants will be requested to report periodically on these issues, in particular by developing and updating throughout the

[5] EC Treaty, Art. 163.1

[6] As confirmed in the Council decision of 30.9.2002 relating to the specific RTD programme for "Integrating and strengthening the European Research Area" (Annex, section 1.1 – OJ L 294/7)

[7] As stated in Art. 10.1.e of the rules of participation (OJ L 355/28)

project a *plan for using and disseminating the knowledge*. This plan should describe the innovation-related activities already implemented and those being planned, as well as their actual or expected impact.

Besides these central project-level activities, specific mechanisms will ensure that there is exchange of information and experience between the activities of the different work programmes as regards their innovation dimension, and that the innovation-related achievements be properly analysed and evaluated[8].

4. Submitting a Proposal

Proposals should be submitted under the terms of a call for proposals[9]. In order to submit a proposal, a proposer should consult the following:

- This work programme,
- The relevant call for proposals as it is published in the *Official Journal of the European Union*, and
- The relevant Guide for Proposers.

These and a number of other useful texts, including the rules for participation and details on the contracts, are available on Cordis (as referred to above).

5. Cross Cutting Proposals

Proposals are invited to be submitted on the basis of calls for proposals, which are, in the case of the Priority Thematic Areas of Research organised thematically. Proposals that address more than one thematic area will be accommodated by the Commission, provided the proposal addresses areas covered by this work programme.

The specific programme is focused on a number of thematic priorities. They encompass a wide range of disciplines and proposals that cut across the boundaries of themes are to be expected. The criterion of relevance to the objectives of the specific programme is a *sine qua non* for the further consideration of such proposals. Furthermore, proposals will not be accepted if they do not fall within the scope of the work programme.

Cross-cutting proposals may be categorised as follows:

- **Proposals with a clear "centre of gravity".** Given the nature of research carried out today, a large proportion of proposals contain some degree of multi-disciplinarity. These are handled by normal submission and evaluation procedures. For proposals which contain a significant

[8] cf. OJ L 294/50, section 2.f of the Annex

[9] Proposals for specific support actions, which do not fall within the scope of a call for proposals, may be submitted to the Commission only when it is provided for in this work programme.

technological or thematic element from a different part of the programme, the procedure involves the proposal being treated by the thematic area represented by the greatest proportion of the proposal (ie, its "centre of gravity"). For proposals where the centre of gravity is not immediately obvious, the Commission will examine the proposal content and decide in which thematic area the proposal is best handled. If a proposal is transferred to a thematic area other than the one to which it was submitted, it will be handled in the framework of the new thematic area. However, if the new centre of gravity does not have an open call at the time of transfer, the proposal will be held over, with the agreement of the proposers, until a suitable call is open, but only if such a call is explicitly foreseen by the work programme. If successful, the proposal will be handled and funded by the thematic centre of gravity.

- **Joint calls for proposals**. In certain fields, it is clear that proposals will always contain a high proportion of interest for different thematic areas. In this instance, the Commission uses calls for proposals issued jointly by two or more programme/thematic areas, with a pooling of budget. This procedure only occurs for well-defined areas where the cross cutting nature of the proposals to be received can be clearly identified in advance.

- **Proposals with horizontal interest**. These relate to proposals which are of general interest to all parts of the specific programme but of no specific interest to an individual part. If such proposals are truly innovative and ground breaking, there is the possibility of referring them to the work programme part that addresses "anticipating scientific and technological needs", once this part is open for the receipt of such proposals. Proposals with a horizontal interest which do not meet this criterion may, if applicable, be handled like proposals with a centre of gravity (see first bullet point).

6. Evaluation Criteria and Related Issues

The "Guidelines on Proposal Evaluation and Project Selection Procedures" describes the basic procedures to be followed by all programmes under the Sixth Framework Programme of the European Community.

The set of criteria applicable to this work programme is given in Annex B. Any complementary criteria are clearly stated in the relevant part of this work programme. Evaluation thresholds for each set of criteria are given in Annex B and apply unless otherwise clearly stated. In addition, Annex B outlines how the following will be addressed: gender issues, ethical and/or safety aspects, and the education dimension.

All proposals before they are selected for funding and which deal with ethical issues and any proposal for which ethical concerns have been identified during the scientific evaluation may be reviewed by a separate ethical review panel. The "Guidelines on Proposal Evaluation and Project Selection Procedures" gives more details on the evaluation procedure as a whole as well as details of the ethical review procedure.

Furthermore, the work programmes, and consequently their calls for proposals, may specify and restrict the participation of legal entities in an indirect action according to their activity and type, according to the instrument deployed and to take into account specific objectives of the Framework Programme.

Calls for proposals may involve a two-stage evaluation procedure. When such a procedure is employed, this is stated clearly in the call for proposals. More information on this process is given in the "Guidelines on Proposal Evaluation and Project Selection Procedures".

Finally, when evaluating proposals received in response to a call, the Commission may opt to send the proposals to external experts or make proposals available by electronic means, so that the experts can carry out their examination at their home or place of work.

7. Specific Support Actions

Support activities are more limited in scope than the accompanying measures of the previous Framework Programmes. These projects aim to **contribute actively** to the implementation of activities of the work programme, the analysis and dissemination of results or the preparation of future activities, with a view to enabling the Community to achieve or define its RTD strategic objectives. Therefore, a significant emphasis has been placed on Support Actions:

- to promote and facilitate the dissemination, transfer, exploitation, assessment and/or broad take-up of past and present programme results (over and above the standard diffusion and exploitation activities of individual projects);
- to contribute to strategic objectives, notably regarding the European research area (e.g. pilot initiatives on benchmarking, mapping, networking, etc.);
- to prepare future community RTD activities, (e.g. via prospective studies, exploratory measures. pilot actions etc.);

as opposed to awareness and information exchange activities, e.g. annual Workshops and Conferences, that would take place anyway without Commission support. The latter activities will not be welcome if they do not **serve** the programme's strategic objectives, (in the sense of the European Research Area, improved co-ordination, public awareness, preparation of future Community initiatives, etc.).

A limited number of specific support actions may be funded, where such a request does not fall within the scope of a call for proposals, when they have particular characteristics and value to the objectives and the scientific and technological content of the specific programme. Such requests for grants must be for actions of European significance and could, for example, provide support for major policy-related workshops in the context of activities of the

rotating Presidency of the Union. They should be submitted at least five months in advance of the event for which support is requested. The evaluation criteria will be those applicable to specific support actions as laid down in this work programme.

I. FOCUSING AND INTEGRATING COMMUNITY RESEARCH

THEMATIC PRIORITY AREA 1
Life sciences, genomics and biotechnology for health

1.1 INTRODUCTION

The sequencing of the human genome and many other genomes heralds a new age in human biology, offering unprecedented opportunities to improve human health and to stimulate industrial and economic activity. In making its contribution to realising these benefits, this theme will focus on integrating post-genomic research, including research on related molecular mechanisms, into the more established biomedical and biotechnological approaches, and will facilitate the integration of research capacities (both public and private) across Europe to increase coherence and achieve critical mass. Integrated multidisciplinary research, which enables a strong interaction between technology and biology, is vital in this theme for translating genome data into practical applications. In addition, an essential element will be to involve key stakeholders, for example**,** as appropriate industry, healthcare providers and physicians, policy makers, regulatory authorities, patient associations, and experts on ethical matters, etc in implementing the theme. Furthermore, attention will be paid to childhood diseases and related treatments whenever appropriate, and gender aspects in the research will be taken into account[10].

This thematic priority will stimulate and sustain multidisciplinary basic research to exploit the full potential of genome information to underpin applications to human health. In the field of applications, the emphasis will be put on research aimed at bringing basic knowledge through to the application stage ("translational" approach), to enable real and consistent and coordinated progress at European level in medicine and improve the quality of life. This research may also have implications for research on areas such as agriculture and environment, which are addressed under other thematic priorities; such implications should be duly taken into account in the course of the implementation of the thematic priorities concerned.

The updated work programme describes the research areas in which project proposals can be presented for the second call.

1.2 OBJECTIVES, STRUCTURE, AND OVERALL APPROACH

The content of this updated work programme and the research topics selected for the second call has been influenced by various inputs including analysis of Expressions of Interest, 2002. In addition the work programme also takes into account the budget limitations, the urgency of the scientific actions and the possible overlaps between research topics.

[10] Causes, clinical manifestation, consequences and treatment of disease and disorders often differ between women, men and children. Therefore, all activities funded within this thematic priority must take the possibility of such differences into account in their research protocols, methodologies and analysis of results.

In preparing proposals, applicants should consider the horizontal issues mentioned in the general introduction[11] and the following issues which are specifically relevant to this theme:

Gender aspects in research

Gender aspects in research have a particular relevance to this theme as risk factors, biological mechanisms, clinical, manifestation, causes, consequences for disease and disorders may differ in men and women. The possibility of gender/sex differences[12] must therefore be considered in all areas of health research, unless it can be demonstrated that gender/sex is inappropriate, with respect to the health of the subjects or the objectives of the research. Gender/sex issues should be considered in:

- the formulation of research hypotheses, in the development of research protocols, choice of research methodologies and in the analysis of results
- biological, pre-clinical and epidemiological, behavioural research/studies on both human and animal subjects
- the use of cells, tissues and other specimen, where appropriate
- the choice for a particular study population that should be thoroughly justified and the sex of the participants described in full.

These aspects will be taken into account in the evaluation process[13].

Innovation aspects and SME participation

Life sciences and biotechnology, as frontier technologies, can contribute significantly to the Lisbon objective of Europe becoming the most competitive knowledge based economy in the world by 2010[14]. This thematic priority emphasises the importance of innovation and the integration of SMEs in order to reach the Lisbon goal. Therefore project consortia need to integrate all relevant competencies to address innovation related aspects[15], such as technology transfer, intellectual property rights, clinical trials, etc., with a view of ensuring optimal use of the generated knowledge. Research intensive and innovative SMEs play a vital role for exploiting the EU biotechnology and life sciences knowledge base and in fact 15% of the budget is reserved for SME participation.

Child health

Attention should be paid to childhood disease, whenever appropriate. Research on children has so far been very limited because children cannot give consent, which is a basic requirement for all research involving human beings. Providing appropriate

[11] See section “General Introduction”.

[12] Because of the inconsistent and often confusing use of the terms sex and gender, their use should be clarified: sex refers to differences attributed to biological origins, gender refers to social influences that lead to differences. Males and females differ not only in their basic biology but also in ways they interact with and are treated by society.

[13] See relevant sections in the “Guide for Proposers”.

[14] See also "Life sciences and biotechnology - A strategy for Europe".

[15] See relevant section in the “Guide for Proposers”.

ethical requirements are taken into consideration, research involving children should be taken into account.

Clinical research and clinical trials

Since the development of applications towards human health and the improvement of patient-oriented strategies will be important to the success of this priority, clinical research is expected to be a major tool used by the applicants to meet these objectives[16]. This clinical research may include clinical trials. Community contribution will however only be available for Phase I and II clinical trials. Within the context of the European and Developing Countries Clinical Trials Partnership, EDCTP, funding may be considered for Phase II and Phase III trials. In implementing a clinical research project consortia are encouraged to include small and medium sized enterprises (SMEs) wherever appropriate.

Causes, clinical manifestation, consequences and treatment of disease and disorders often differ between women, men and children. Therefore, all activities funded within this thematic priority must take the possibility of such differences into account in their research protocols, methodologies and analysis of results, in particular when conducting clinical research.

Integration of ethical, social, legal and wider cultural aspects

Ethics has a special relevance in thematic priority 1. Ethical issues such as research with human beings (clinical trials in adults and children), use of human embryonic stem cells, use of biological materials of human origin and research with animals will be dealt with in this priority. Experts in ethics, law and social sciences are encouraged to participate actively in research projects. Transdisciplinary collaboration between all stakeholders should ensure that due account is taken of the ethical and societal concerns, our obligations towards future generations and the rest of the world. It should also allow for mutual education and dialogue, and ensure that ethicists have the means to continuously assess the societal relevance and adequacy of their analysis and evaluation.

Fostering ethical awareness in research and foresight attention in research

All applicants will be requested to address, in the application form, the potential ethical aspects of the proposed research regarding its objectives, the methodology and the possible implications of the results. This should justify the research design, explain how ethical requirements will be fulfilled and indicate the relevant national legal and/or regulations of the country(ies) where the research takes place. [17, 18]

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[16] See relevant section in the " Guide for Proposers".

[17] As stipulated in the decision of the specific programme for research, technological development and demonstration: "Integrating and strengthening the European Research Area" (http://europa.eu.int/eur-lex/en/dat/2002/l_294/l_29420021029en00010043.pdf). The following fields of research will not be financed under the 6th Framework Programme:

- Research activity aiming at human cloning for reproductive purposes.
- Research activity intended to modify the genetic heritage of human beings which could make such changes inheritable. Research relating to cancer treatment of the gonads can be financed.
- Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

International Cooperation

International co-operation is supported and encouraged in all areas within the Theme. Co-operation with organisations from INCO target countries (see Annex C) and countries with signed Scientific and Technical co-operation agreements[19] is particularly welcomed. Within the theme, the area 'Confronting the major communicable diseases linked to poverty' places a particular emphasis on involving groups and organisations from developing countries. Funding may be provided to third country participants according to the participation rules[20].

Support to policies

This thematic priority will also contribute to the action plan of the Communication from the Commission entitled "Life sciences and biotechnology - A strategy for Europe" [21], which is a follow-up of the March 2001 Stockholm European Council.[22]

1.3 TECHNICAL CONTENT

i) Advanced genomics and its applications for health

a) Fundamental knowledge and basic tools for functional genomics in all organisms

The strategic objective of this line is to foster the basic understanding of genomic information, by developing the knowledge base, tools and resources needed to decipher the function of genes and gene products relevant to human health and to explore their interactions with each other and with their environment. Research actions will encompass the following:

- ***Gene expression and proteomics***

  The objectives are to enable researchers to better decipher the functions of genes and gene products as well as to define the complex regulatory networks that control fundamental biological processes.

The Council and the Commission agreed that detailed implementing provisions concerning research activities involving the use of human embryos and human embryonic stem cells, which may be funded under the 6th Framework Programme, shall be established by 31 December 2003. The Commission stated that, during that period and pending establishment of the detailed implementing provisions, it will not propose to fund such research, with the exception of the study of banked or isolated human embryonic stem cells in culture. (Doc 12523/02, ADD 1 REV 1, RECH 150 from 21 October 2002). Note that this provision may change after December 2003 as a result of a decision of the Council.

18 See "Annex B Common evaluation criteria for evaluating proposals – The ethical review of proposals" and the "Guide for Proposers".

19 Countries with signed S&T agreements March 2003: Argentina, Australia, Canada, China, Chile, India, Russia, South Africa, Ukraine and United States

20 Amended Proposal COM (2001) 822 final of 10.01.2002

21 http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf

22 See section on "Strategic Specific Support Actions across Thematic Priority 1".

Topic for second call:

LSH-2003-1.1.1-1: Global *in situ* gene expression analysis in rodent models and human tissues – *INTEGRATED PROJECT*. The focus should be to develop high throughput tools and approaches to generate and validate data for a database of *in situ* gene expression patterns in mammalian embryonic development.

- ***Structural genomics***

  The objective is to enable researchers to determine, more effectively and at a higher rate than is currently feasible, the 3-D structure of proteins and other macromolecules which is important for elucidating protein function and is essential for drug design.

Topics for second call:

LSH-2003-1.1.2-1: Comparative structural biology of viral replication – *INTEGRATED PROJECT.* The focus should be on developing new approaches, tools and technologies for collecting comprehensive structural information on the replicative machinery of RNA viruses to facilitate the identification of potential new drug targets.

LSH-2003-1.1.2-2: Structure determination of large protein complexes – *INTEGRATED PROJECT.* The focus should be on the high throughput isolation of cellular protein complexes under physiological conditions and their structural analysis.

- ***Comparative genomics and population genetics***

  The objectives are to enable researchers to use well-characterised model organisms for predicting and testing gene function and to take full advantage of specific population cohorts available in Europe to determine the relationship between gene function and health or disease.

Topics for second call:

LSH-2003-1.1.3-1: Developing new molecular tools and approaches for high throughput molecular phenotyping of human populations – *INTEGRATED PROJECT.* The focus should be on developing new technologies and approaches for standardised high throughput analysis of large numbers of patient and control samples. The topic addresses the development of new technologies and approaches but does not address epidemiological studies *per se*.

LSH-2003-1.1.3-2: Standardisation and integration of genomic and phenotypic information to characterise bacterial diversity with relevance to human health – *NETWORK OF EXCELLENCE*. The focus should be on co-ordinating high

throughput, advanced technology capabilities in an integrated effort to characterise the diversity of bacteria relevant to human health.

LSH-2003-1.1.3-3: Coordination and standardisation of high throughput genotyping in human populations in Europe – *NETWORK OF EXCELLENCE.* The focus should be on co-ordinating epidemiological studies in large population cohorts with an emphasis on standardising genotyping protocols, sample collection and data storage and analysis.

- ***Bioinformatics***

  The objectives are to enable researchers to access efficient tools for managing and interpreting the ever-increasing quantities of genome data and for making it available to the research community in an accessible and usable form.

Topics for second call:

LSH-2003-1.1.4-1: Bioinformatics grid for European genomics research - *NETWORK OF EXCELLENCE.* The focus should be to develop and implement methods for joining large amounts of heterogeneous, locally generated and stored information resources from the different disciplines of genomics, including experimental data, annotation, analysis, and interpretation of genome information. The grid should also provide methods for the remote access to bioinformatics tools.

LSH-2003-1.1.4-2: Development of an integrated software platform to tackle genomic sequence-structure-function relationships – *INTEGRATED PROJECT*. The focus should be on generating a widely applicable and accessible software suite for high level integration of computational analysis and prediction techniques for sequence, expression and functional genomics data. A close collaboration with molecular biologists will be essential.

- ***Multidisciplinary functional genomics approaches to basic biological processes***

  The objectives are to enable researchers to study fundamental biological processes by integrating the above innovative approaches.

  Research will focus on the study of fundamental biological processes relevant to human health (including studies on microorganisms, plants and animals where appropriate). This research will be of a multidisciplinary nature, involving the different disciplines of functional genomics: gene expression and proteomics, structural genomics, comparative genomics and population genetics and bioinformatics.

Topics for second call:

LSH-2003-1.1.5-1: Functional genomics approaches in animal models to study human kidney disease – *INTEGRATED PROJECT OR NETWORK OF*

EXCELLENCE. The focus should be on integrating different expertise, animal models and functional genomics platforms to discover the genetic mechanisms that underlie kidney development and cause kidney disease.

LSH-2003-1.1.5-2: Functional genomics approaches to the study of peroxisomes in health and disease – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.* The focus should be on using functional genomics approaches and cell and animal models to decipher the entire spectrum of biological functions performed by peroxisomes and to evaluate their roles in disease.

LSH-2003-1.1.5-3: Functional genomics of inner ear development and disorders – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.* The focus should be on using functional genomics approaches and animal models to further understand the mechanism of hearing, to identify the genes that are essential for inner ear functions and those that predispose to severe hearing impairment, thereby facilitating development of new preventive and therapeutic tools.

LSH-2003-1.1.5-4: Functional genomics of the retina in health and disease – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.* The focus should be on using a multidisciplinary approach to identify the genetic and cellular interactions responsible for retina development, the mechanisms of retinal disorders leading to blindness and mechanisms of retinal repair, thereby facilitating the creation of new therapeutic tools.

LSH-2003-1.1.5-5: DNA damage and repair mechanisms in health and disease – *INTEGRATED PROJECT.* The focus should be on using multidisciplinary functional genomics approaches to decipher the core molecular mechanisms of DNA damage and repair.

LSH-2003-1.1.5-6: Functional genomics approaches in animal models to study human immunological disease – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.* The focus should be on bringing together different expertise from academic and industrial (including SMEs) laboratories to generate a joint programme of activities that combines research on model organisms and functional genomics to investigate the immune system for elucidating the genetic basis of immunological disease, thereby facilitating the development of new diagnostics and therapeutic tools.

LSH-2003-1.1.5-7: Functional genomics approaches in animal models to study human muscle disease – *NETWORK OF EXCELLENCE.* The joint programme of activities should focus on promoting a durable integration of research activities in different model organisms and in functional genomics to find the genetic determinants underlying muscle formation and repair (excluding heart muscle).

LSH-2003-1.1.5-8: Genetic and molecular determinants of X-linked mental retardation – *NETWORK OF EXCELLENCE.* The joint programme of activities should create a multidisciplinary integrative network bringing together advanced technology platforms in genomics and post-genomics with the aim to scale up production of knowledge concerning genetic and molecular determinants of X-linked mental retardation thereby facilitating development of new diagnostic and therapeutic tools.

Research areas for second call utilising STREP/CA/SSA:

LSH-2003-1.1.0-1: For Specific Targeted Research Projects (STREP), research should focus on multidisciplinary fundamental genomics approaches (gene expression and proteomics, structural genomics, comparative genomics, population genetics and bioinformatics), in all organisms to study the following topics: low abundance mRNAs and proteins; the biological role of small RNAs; identifying and characterising multi-protein complexes of biotechnological interest (nanomachines); programmed cell death across the eukaryotic kingdom; comparative genomics in protozoa in relation to human health. Proposals concerned with the development of new tools and approaches, including the standardisation of protocols, to facilitate generation of new knowledge in functional and structural genomics and proposals dealing with *in silico* prediction of the structure of biological macromolecules will also be considered.

Topics already addressed in the calls for new instruments will not be considered for STREP.

LSH-2003-1.1.0-2: Coordination Action (CA) proposals should focus on structuring European research in mouse genomics, in models complementary to mouse, and in systems biology. Proposals aimed at developing a coherent European policy for management and maintenance of essential resources for all model organisms important in functional genomics research are also encouraged. Actions for harmonising and optimising management and experimental use of important human biobanks in epidemiological research will also be considered.

LSH-2003-1.1.0-3: Strategic Specific Support Actions (SSAs) can take the form of workshops, conferences[23], training activities, or publications. The activities supported should be in the context of wider research policy objectives but have a clear link to fundamental genomics. Activities should address entrepreneurship (e.g. through specific courses), or strengthen the international dimension in fundamental genomics research (e.g. through workshops linking European researchers and researchers from specific third countries). Furthermore they should aim at structuring research activities in important areas not yet addressed or newly emerging, including technology foresight meetings to identify future opportunities within the field.

b) Application of knowledge and technologies in the field of genomics and biotechnology for health

The strategic objective of this line is to foster the competitiveness of Europe's biotechnology industry by exploiting the wealth of biological data produced by genomics and advances in biotechnology. Research actions will encompass the following:

[23] See section on "Strategic Specific Support Actions across Thematic Priority 1". Annual workshops and conferences that would take place anyway without Commission support, will not be considered a significant priority for funding. However funding of specific European sessions within or linked to such events could be considered.

– ***Technological platforms for the developments in the fields of new diagnostic, prevention and therapeutic tools***: In the context of preventing and treating diseases, the objectives are to foster academic and industrial collaboration through technological platforms where multidisciplinary approaches using cutting edge technologies arising from genomic research may contribute to health care progress and cost reduction through more precise diagnosis, individualised treatment and more efficient development pathways for new drugs and therapies (such as the selection of new drug candidates), and other novel products of the new technologies.

Support will be aimed in particular towards innovative research in genomic start-ups and research-based SMEs to strengthen Europe's biotechnology industry. The **integration of SMEs** must be an integral part of projects and must be reflected in the consortia. The innovation aspect within the technological platforms need to be visible through clear dissemination and exploitation plans.

Considering the Community's interest in the Human Frontier Science Programme (HFSP) and the commonality of objectives with this theme, a contribution, which will provide the possibility for non G8 Member States to fully benefit from the programme, will be made available for 2003 and 2004 through subsidies. Subject to the continued Community's interest, this contribution can be made available for the following two years of the Framework Programme.

With a view to ensuring socially responsible choices, public acceptance and an efficient development pathway for these new technologies, an active and early involvement in the above activities of regulators, experts on ethics, patients and society at large will be necessary.

- ***Rational and accelerated development of new, safer, more effective drugs including pharmacogenomics approaches***

  The emphasis shall be on the use and translation of the knowledge and methods derived from genomics into concrete applications for drug design and development, involving e.g. combinatorial biosynthesis, therapeutic targeting, rational drug design. The innovative design and development of new, safer and more effective drugs, based on genomics information is the focus of this area.

<u>Topics for the second call:</u>

LSH-2003-1.2.1-1: Medicines for children – ***NETWORK OF EXCELLENCE***. The work should focus on the structuring of efforts devoted to the development of tailor made medicines for children, based on knowledge coming from genomics and proteomics. The network should cover all aspects involved (e.g. metabolism and immune system of new-borns and babies, dosage forms, clinical studies etc.), in order to develop safe and efficient medicines for the prevention and treatment of diseases in infants; particular emphasis should be laid on the design of medicines for new-borns and babies. A close collaboration among academia, pharmaceutical industry, ethical bodies and regulatory authorities will be necessary.

LSH-2003-1.2.1-2: Computer assisted modelling for drug discovery and testing – *NETWORK OF EXCELLENCE*. The network should focus on the structuring of efforts devoted to the development of simulation models for the design, selection and testing of drugs. *In silico* simulation models using pharmacokinetic, function mechanism and side-effect describing parameters and interaction profiles should be developed for biological systems (cells and tissues) enabling to predict the efficacy of drugs. The integration of regulatory and industrial aspects is particularly important to the success of research under this line.

LSH-2003-1.2.1-3: Novel therapeutic substances for neurodegenerative diseases in CNS and PNS – *INTEGRATED PROJECT.* The work should focus on the identification of genomic loci involved in neuro-degenerative disorders and on the use of this information for the development of novel bio-therapeutic compounds. The characterisation of new targets and the construction of models to screen for therapeutics shall lead to the design of new therapeutic substances for the prevention and/or treatment of neurodegenerative disorders.

LSH-2003-1.2.1-4: Networking of the European SME bioincubators active in biopharmaceutical development – *CA*

LSH-2003-1.2.1-5: Enhancement and improvement of biopharmaceuticals' clinical testing and their approval - *SSA*

LSH-2003-1.2.1-6: Workshop on the creation of biopharmaceutical development platforms with involvement of biotech SMEs and pharmaceutical industry - *SSA*

- ***Development of new diagnostics***

  New diagnostic tests and development of new tools and non-invasive methods for early diagnosis, monitoring of disease progression and interpretation of *in-vivo* data so as to increase the possibilities and effectiveness of the existing therapies.

<u>Topics for the second call:</u>

LSH-2003-1.2.2-1: Development of genetic tests allowing for harmonisation, validation and standardisation – *NETWORK OF EXCELLENCE*. The network should focus on research, development and use of genetic tests of high technical quality and fulfilling the criteria for a medically meaningful interpretation of results. Harmonisation and quality assurance should include specific protocols and guidelines. The use of multiparametric genetic tests for diagnosis, classification and therapeutic interventions should also be properly addressed. Ethical, social and legal aspects will be the object of specific consideration.

LSH-2003-1.2.2-2: *In vivo* molecular imaging: identification of new markers for diagnostic purposes – *NETWORK OF EXCELLENCE.* The network should focus on non-invasive and repeatable *in vivo* multidisciplinary methods for molecular imaging as a tool to develop improved techniques for diagnostics and therapeutic

monitoring of major diseases through the development of new molecular probes and imaging acquisition methods.

LSH-2003-1.2.2-3: Molecular diagnostics in mitochondrial diseases – *STREP.* The objective is to foster research into the understanding of function, regulation and structure of mitochondria as vital metabolic organelles, thereby providing insight into diagnostics and treatments of diseases related to mitochondrial dysfunctioning.

LSH-2003-1.2.2-4: Advances in synchrotron radiation technology for diagnostic purposes - *SSA.* Medical research based on synchrotron radiation has already demonstrated high relevance in the diagnosis and treatment of major diseases. However additional coordination and structuring efforts are necessary to ensure this technology is used for future medical applications.

- ***Development of new in vitro and in silico tests to replace animal experimentation***

  This area will focus on the development of *alternatives* that will replace the need for animal experiments, reduce the number of animals required, or reduce significantly experimental animal suffering. The topics considered will have to contribute directly to the aims of Directive 86/609/EEC [24] regarding the protection of animals used for experimental and other scientific purposes, and to be in line with the protocol annexed to the Treaty of Amsterdam on the welfare requirements regarding the formulation and implementation of Community policies including research. Priority will be given to the development of those alternative methods that will reach the level of maturity for formal validation according to international standards for subsequent international regulatory acceptance and finally for world-wide application in industry, regulatory establishments and elsewhere.

  In vitro methods will play a major role under the future chemicals system of the Community on the registration, evaluation and authorisation of chemicals. *In vitro* methods should accelerate testing and render it more efficient. The challenge is therefore to develop robust and effective *in vitro* methods that will withstand the requirements of international validation.

Topics for the second call:

LSH-2003-1.2.3-1: Optimisation of test batteries for human acute toxicity – *INTEGRATED PROJECT.* Research should focus on the development of scientifically sound, standardised and reliable alternative test methods for toxicokinetics and organ toxicity. The methodology can also include QSARs (quantitative structure-activity relationships) or computer modelling, providing data for an efficient risk assessment strategy. The focus will be on the development of models of neurotoxicity and biotransformation. Attention will also be given to biokinetic studies, prediction models, study of barrier functions (including the Blood Brain Barrier) and *in vitro* tests for chronic toxicity. The results generated should lead

[24] OJ L 358, 18.12.1986, p. 1.

to the production of globally accepted test guideline statistically valid for formal validation purposes and dissemination of knowledge and competencies that can pave the way for regulatory acceptance of these.

LSH-2003-1.2.3-2: Non-animal test methods for chemicals, medicines, biologicals and bio-materials: a prospective analysis - *SSA*

LSH-2003-1.2.3-3: Mathematical models as alternative methods to animal experiments for human health and eco-toxicological endpoints - *SSA*

- ***Development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (in particular stem cell therapies*[25]*, for example those on neurological and neuromuscular disorders) and immunotherapies.***

  Cell and tissue engineering, including stem cell therapy, have the potential to meet the challenges posed by many diseases, increased human longevity and the concomitant public health challenges facing European society. The integration of different research activities in areas as diverse as genetics, fundamental and clinical research and ethics, will provide standardised research materials such as stem cell banks, clinical research protocols and novel preventive and therapeutic instruments at a European level. Collectively these will offer new solutions for diseases such as diabetes mellitus, Alzheimer, Parkinson's disease and haemopoietic disorders, which impose considerable significant impairments to citizens' quality of life, as well as burdens on health care services in Europe.

Topics for the second call:

LSH-2003-1.2.4-1: Improved gene delivery systems for the therapy of severe acquired diseases – *INTEGRATED PROJECT.* The research should focus on the development of viral and non-viral vectors, giving efficient gene transfer and sustained expression to targeted tissues. An early involvement of ethical and regulatory bodies as well as industrial partners will be critical. The research would lead to the production of novel clinical gene therapy protocols for the treatment of, for example, cardiovascular, neurodegenerative or neoplastic disorders.

LSH-2003-1.2.4-2: Gene therapy of inherited diseases – *INTEGRATED PROJECT.* The research should focus on concentrating and integrating EU efforts to overcome the existing technological and safety constraints through a better understanding of the fundamental biological processes involved in gene therapy of genetic diseases. Research should lead to design of gene transfer protocols based on safe vectors and ready to enter clinical trials. The project should take full account of ethical and regulatory issues and involve patients' associations. Examples of inherited

[25] Id 17

diseases to be targeted would include major ones, such as cystic kidney diseases, and rare ones, such as neuromuscular, metabolic and central nervous system disorders, haemoglobinopathies or immunodeficiencies.

LSH-2003-1.2.4-3: Design of rational protocols for safety, quality and standardisation of stem cells[26] **and establishment of a European registry of stem cells – *INTEGRATED PROJECT.*** The project should contain two components. First, pre-normative research to establish rational protocols for safety, quality and standardisation of stem cells from adult, foetal and embryonic sources. Second, the establishment of a European registry of validated stem cell lines, differentiated and undifferentiated, and cultured under GMP conditions and without them. Co-operation with similar initiatives at international level will be a prerequisite. The research would contribute to the establishment of public stem cell banks providing easy and affordable access to the different cell lines, including existing human embryonic stem cell lines.

LSH-2003-1.2.4-4: Regeneration therapies for pancreas and/or liver [27] **– *INTEGRATED PROJECT.*** Research should focus on combining stem cell therapy and tissue engineering for regenerative treatment of diseases, such as diabetes, liver cirrhosis, metabolic disorders and pancreatitis. Research should involve stem cell biology, molecular biology and bioengineering. The research would lead to the integration of European efforts to translate knowledge in these fast-developing areas into successful clinical application.

LSH-2003-1.2.4-5: New improved vaccines based on genomic and proteomic information – *INTEGRATED PROJECT*. Research should focus on using genomic and proteomic information to elucidate mechanisms involved in antigen recognition and presentation, with a view to developing new vaccines for neoplastic and infectious disorders. The research would lead to the use of genomic information as a platform for vaccine production. Particular attention should be paid to product efficacy, safety, stability and cost-effectiveness.

LSH-2003-1.2.4-6: Dendritic cells for novel immunotherapies - *NETWORK OF EXCELLENCE*. Activities should aim at exploiting developments in dendritic cell biology as a new approach to immunotherapy. The network should be multidisciplinary and include scientists working on dendritic cell biology, clinicians and SMEs active in the field. It should particularly focus on translating genomic and proteomic information on dendritic cells into immunotherapeutic applications in areas such as cancer, infectious disease or inflammatory disease.

LSH-2003-1.2.4-7: Molecular strategies to improve precision in gene transfer for therapeutic applications – *STREP.* In order to maximize safety and efficacy this project aims to develop improved gene transfer techniques which are precise and controlled.

[26] Id 17
[27] Id 17

LSH-2003-1.2.4-8: Use of gene transfer for curative therapy of human skin disease – *STREP.* The project should lead to proof of principle for gene transfer protocols for therapy of acquired or inherited disorders.

LSH-2003-1.2.4-9: Publications (books or brochures) for communicating background to and status of research on somatic gene and/or cell therapies to non-specialists - *SSA*

LSH-2003-1.2.4-10: Inventory of stem cell and gene therapy research in Associate Candidate Countries - *SSA*

LSH-2003-1.2.4-11: Workshop to examine the potential and perspectives for cell-based therapies for autoimmune diseases - *SSA*

- ***Innovative research in post-genomics, which has high potential for application***

  The objective is to use cutting edge technologies in a multidisciplinary approach to address areas of research that will benefit from the developments resulting from genomics.

Topics for the second call:

LSH-2003-1.2.5-1: RNA as a human therapeutic tool – *INTEGRATED PROJECT.* The use of RNA molecules provides a powerful new strategy for the development of diagnostic and therapeutic tools. Research should focus on RNA interference methodology for gene expression silencing, and the role of untranslated RNA in expression. Research should be multidisciplinary and include chemistry, molecular and cell biology techniques. The aim of the research should be the development of compounds able to modulate gene expression.

LSH-2003-1.2.5-2: Post-genomic approaches to the study of human pathogens – *NETWORK OF EXCELLENCE.* Development of a Technology Platform for new tools on the rapid diagnosis of pathogenic infection and new targets for antimicrobial and antifungal agents. DNA and protein arrays could be used to characterise naturally acquired immunity and to produce new vaccine agents.

LSH-2003-1.2.5-3: Induction of transplant tolerance using post-genomic approaches - *INTEGRATED PROJECT.* Research should focus on the study of genes, molecules and cells for preventing organ transplant rejection. In particular, genomic and immunological approaches should be used to study transplantation tolerant patients. The project should lead to the development of intervention strategies to improve the outcome of organ transplantation.

LSH-2003-1.2.5-4: New bioassays and biosensors using post-genomic approaches for detection of harmful microbes - *STREP.* The aim is to develop methodologies for the simultaneous detection of various specific indicators of microbial presence, making use of (bio) sensor arrays in combination with intelligent signals.

LSH-2003-1.2.5-5: The fungal cell-wall as a target of antifungal therapies - *STREP*. The aim is the understanding of the biosynthesis of the cell wall and the mechanisms that ensure its structural integrity. The project should exploit genomic and post-genomic approaches to identify targets for the development of new antifungal therapies.

LSH-2003-1.2.5-6: Biotechnological and post-genomic approaches for the development of novel biosafe propagation deficient virus vectors aimed at prevention and treatment of infectious diseases (e.g. enteric, respiratory) - *STREP*. The research should focus on the development of new biosafe virus vectors for vaccine production to combat emerging or major viral enteric and respiratory infectious diseases. Two principles should be taken under consideration: the use of novel biotechnological techniques and exploitation of the knowledge acquired by the progress of genomic research.

LSH-2003-1.2.5-7: Exploitation of fungal genomics and application of filamentous fungal biotechnology for the benefits of human health - *CA*. Analysis, survey of the state-of-the-art of the progress on fungal genomes and post genomic exploitable information.

LSH-2003-1.2.5-8: Advance course or workshop on the use of RNAi as a tool of post-genomic analysis – *SSA*

ii) <u>Combating major diseases</u>

a) Application-orientated genomic approaches to medical knowledge and technologies

The strategic objective of this line is to develop improved strategies for the prevention and management – using also advanced technologies for health - of human disease and for living and ageing healthily. It will concentrate exclusively on integrating a genomic approach through all relevant organisms into more established medical approaches for investigating disease and health determinants**.** The emphasis will be on translational research aimed at bringing basic knowledge through to clinical application.

Research actions will focus on the following:

<u>Topics for the second call:</u>

General

LSH-2003-2.1.0-1: Eicosanoids and nitric oxide: mediators of cardiovascular, cerebral and neoplastic diseases – *INTEGRATED PROJECT*. The project should address the functional genomics and proteomics of the pathways of nitric oxide and eicosanoid signalling and their interactions through *in vitro* and *in vivo* studies. Emphasis is put on the identification of new targets for the development of innovative treatments.

LSH-2003-2.1.0-2: Coordination of clinical trials in Europe – *SSA.* This SSA will assess the feasability of setting up and implementing a European network to coordinate independent academic clinical trials for treatment and prevention (including the development of evidence-based clinical intervention guidelines). To this aim it will examine how to mobilise the relevant national and regional programmes.

- ***Combating, cardiovascular disease, diabetes and rare diseases***

  The objectives are to improve the prevention and management of important causes of mortality and ill health in Europe and to pool Europe's research resources for tackling rare diseases.

Topics for the second call:

LSH-2003-2.1.1-1: Impaired salt and water homeostasis in hypertension and heart failure - *INTEGRATED PROJECT.* The project should focus on the long-term control of salt and water homeostasis by the kidney (medulla) for which the pathological mechanisms are still unknown. New targets will be identified for the development of novel therapies in hypertension and salt and water retaining conditions such as heart failure. The results will benefit patients, and the biotechnology and pharmaceutical industries.

LSH-2003-2.1.1-2: Molecular basis of exercise effects on the metabolic syndrome and insulin resistance – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.* Investigation of exercise effects on gene activation, production of new proteins and/or function in humans with particular focus on insulin resistance is foreseen. Role of reduced physical activity in discrepancy between energy intake and energy expenditure in the pathogenesis of metabolic syndromes at the molecular level will be clarified. These questions will be addressed from the clinical, the epidemiological, as well as from the laboratory research side.

LSH-2003-2.1.1-3: Functional genomics of type 2 diabetes – *NETWORK OF EXCELLENCE.* This network will integrate European research aimed at understanding the functional genomics of the development of type 2 diabetes. Emphasis will be on the role of the liver, skeletal muscle and adipose tissue in the pathogenesis of the disease and on integrating human and rodent functional genomics. This should accelerate the application of this knowledge towards better treatment and prevention of the disease.

LSH-2003-2.1.1-4: Prader-Willi Syndrome: gene expression, obesity and mental health – *STREP.* This project should gather a sufficient number of European Prader-Willi patients and explore the genetic determinants of the disease, their gene expression and role in brain function, human development and behaviour. This should lead to insights that can accelerate the development of innovative treatments for Prader-Willi syndrome and have implications for understanding obesity, mental illness and mental retardation.

LSH-2003-2.1.1-5: Rare autoimmune disorders: from genes to individualised medicine – *STREP.* The development of targeted therapies for rare autoimmune disorders, including paediatric diseases, relies on the characterisation of genes and polymorphisms involved in the pathogenesis. A multidisciplinary approach based on animal and human studies applying genomics, proteomics as well as structural and functional studies will help in deciphering the mechanisms common to different autoimmune diseases, along with susceptibility genes determining the specificity of a particular disease. This should lead to new diagnostic, prognostic and therapeutic agents, taking pharmacogenomics into consideration.

LSH-2003-2.1.1-6: Molecular basis of vascular events leading to thrombotic stroke – *STREP.* The aim of this project is to identify molecular protagonists e.g. cytokines and chemokines leading to thrombotic stroke. This knowledge will be utilised for the development of preventive interventions, for which markers are of critical importance. The aim is to reduce the significant morbidity and mortality associated with stroke.

LSH-2003-2.1.1-7: Combating rare genetic skin disorders – *CA.* This action is devoted to linking activities in the field of severe genetic skin disorders, from genomics and proteomics to clinical investigation of sufficient numbers of patients at the European level, thereby fostering translational research. Accessibility to new techniques and knowledge will also be improved. This will ameliorate the quality of life of patients through new diagnostic agents (including prenatal testing) and treatments.

LSH-2003-2.1.1-8: Combating disorders of inborn errors of metabolism – *CA.* This action is intended to organise, develop and link resources in the field of inborn errors of metabolism. Sharing expertise in genomics, proteomics, glycomics, lipidomics and metabolomics, using appropriate models, will pave the way for improved early diagnostics and the development of innovative treatments for patients.

LSH-2003-2.1.1-9: Application of spectroscopic and imaging techniques in the cardiovascular and diabetes fields - SSA. The workshop should focus on the application of non-invasive *in vivo* approaches such as magnetic resonance spectroscopy and positron emission tomography to post-genomic research on cardiovascular and/or diabetes models. The possible exploitation of those techniques for diagnosis and therapeutic monitoring will also be highlighted.

LSH-2003-2.1.1-10: Prevention of autoimmune destruction and replacement of β-cells in type 1 diabetes - SSA. This workshop is aimed at discussing the latest techniques addressing the islet destruction in type 1 diabetes. This includes approaches to prevent the destruction as well as cellular replacement therapies and transplantation. The workshop should also highlight the involvement of SMEs in the development of these new treatments.

- ***Combating resistance to antibiotics and other drugs***

  The objectives are to confront the major threat to public health caused by drug resistant pathogens. Research exclusively devoted to development or use of

antimicrobials in the context of animal health without attention to human health will not be considered in this sub area.

Topics for the second call:

LSH-2003-2.1.2-1: Functional genomics of antibiotics-producing organisms – *INTEGRATED PROJECT.* The focus should be on using functional genomic approaches to investigate gene function, antibiotic production, ecology and physiology of *Streptomyces* and other antibiotics-producing organisms aiming at novel antimicrobial drugs and drug targets.

LSH-2003-2.1.2-2: New molecular targets for the development of drugs against pathogens causing severe resistance problems – *INTEGRATED PROJECT.* The focus should be on new targets for novel anti-bacterial drugs that better circumvent the emergence of drug resistance.

LSH-2003-2.1.2-3: Novel approaches to address antimicrobial resistance through non-antimicrobial based therapies – *STREP/CA.* Development of novel treatment approaches, such as antibody-engineered derivatives, peptides, cytokines/chemokines or other novel concepts for replacing or supplementing anti-microbial treatments.

- ***Studying the brain and combating diseases of the nervous system***

  The objectives are to use genome information to understand better the functioning and dysfunctioning of the brain, in order to gain new insight into mental processes, to combat neurological disorders and diseases, and to improve brain repair.

Topics for second call:

LSH-2003-2.1.3-1: Genomics and mechanisms of addiction – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE.* An integrated multidisciplinary European approach is needed to address the mechanisms of drug addiction. This project should focus on (i) identification of genes involved in the development and mediation of addiction to various drugs (including nicotine, alcohol and polydrug exposure), (ii) functional genomics of newly identified genes, (iii) developing and establishing suitable animal models of addiction.

LSH-2003-2.1.3-2: Neuronal networks, learning and memory: from genes to behaviour – *INTEGRATED PROJECT.* The main goal of this project will be a better understanding of the molecular and cellular basis of learning and memory. It should address: (i) the mechanisms and role of synaptic and network plasticity and their genetic determinants, (ii) cortical circuitry and information processing underlying learning and memory, and (iii) the development and establishment of suitable animal models for behavioural studies of memory function and dysfunction in diseases.

LSH-2003-2.1.3-3: Molecular mechanisms of neuronal degeneration – *NETWORK OF EXCELLENCE.* This network will address neuronal degeneration,

and regeneration, in neurodegenerative diseases (Parkinson's disease, Alzheimer's disease, Huntington's disease, and amyotrophic lateral sclerosis), and in spinal cord injury. The network should focus on translational activities and gather multi-disciplinary expertise spanning from functional genomics and proteomics to clinical studies. It should address the need for common infrastructures, databases and training.

LSH-2003-2.1.3-4: Stem cells and nervous system – *NETWORK OF EXCELLENCE*.[28] This project should lead to an improved co-ordination of research efforts to explore the basic biological features of stem cells in the nervous system and their potential clinical use for brain and spinal cord repair strategies. Relevant ethical issues should be addressed.

LSH-2003-2.1.3-5: Cortical development – *STREP/CA*. This project should lead to a better understanding of cortical development by addressing gene expression, molecular interactions, and the development of cortical networks and circuitry. The establishment of suitable models should be emphasised. The project should have a clear impact on improving the diagnosis and understanding of human cortical developmental disorders.

LSH-2003-2.1.3-6: Excitotoxic neuronal cell death – *STREP/CA*. This project should address the molecular and cellular mechanisms and pathways in excitatory amino acid induced neuronal cell death, including the identification of new genes and regulatory proteins. This approach should also address molecular mechanisms of neuronal survival and include the development of novel neuroprotective strategies.

LSH-2003-2.1.3-7: Genetics and neurobiology of autism – *STREP/CA*. This project should lead to a better understanding of the genetic and molecular etiology of autism leading to improved diagnosis and new treatments.

LSH-2003-2.1.3-8: Specific support action on neuroscience funding and brain diseases in Europe – *SSA*. Support will be provided for a study with the aim to collect, present and publish reliable data on neuroscience funding and on the occurrence and costs of diseases of the nervous system throughout Europe.

LSH-2003-2.1.3-9: Specific brain research support actions – *SSA*. The aim is to provide support for the organisation of high impact scientific workshops, courses, or dissemination activities in the fields of basic and clinical neuroscience.

- ***Studying human development and the ageing process***

  The objective is to better understand human development, with special emphasis on the ageing process, in order to develop the evidence base for improving public health strategies to promote healthy living and healthy ageing.

[28] Id 17

Topics for second call:

LSH-2003-2.1.4-1: Regulation of mitochondrial activity – *INTEGRATED PROJECT OR NETWORK OF EXCELLENCE*. Mitochondria are a key organelle for the understanding of longevity and ageing on a cellular level. The project will address the regulation of mitochondrial activity by intracellular communication and extrinsic factors. The focus of this project should be on model organisms and systems and not on the etiology of diseases.

LSH-2003-2.1.4-2: Molecular mechanisms of embryo implantation - *NETWORK OF EXCELLENCE*. The objective is the integration of research capacities in functional genomic research and advanced cellular techniques with clinical groups to address the mechanism of embryo implantation[29]. The analysis of the molecular and cellular events at the materno-foetal interface as a result of embryo implantation will improve our understanding of early human development.

LSH-2003-2.1.4-3: Coordinating European research in ageing and longevity - *CA*. The goal is to provide a platform for the coordination of European ageing research. Initiatives include workshops and meetings that address (i) development of common research strategies, (ii) interspecies studies of ageing processes, and (iii) standardization of data collection (e.g. phenotype analysis) and data processing including statistical analysis.

LSH-2003-2.1.4-4: European research on ageing – *SSA*. The aim is to provide support for the organization of a conference on the state of the art and future perspectives of European ageing research.

b) Combating Cancer

This area is closed for the second call.

c) Confronting the major communicable diseases linked to poverty

This area is closed for the second call.

Strategic Specific Support Actions (SSA) across thematic priority 1

As described in the "General Introduction"[30] to the Work Programme, and in addition to the SSAs identified in the individual research areas of the theme, only proposals that contribute to the strategic objectives of the theme will be considered for support. Significant emphasis will be placed on SSA for:

[29] Id 17
[30] See section "Strategic Specific Support Actions" of the "General Introduction".

- **LSH-2003-3-1: Promotion of SME participation:** Activities aiming to stimulate and facilitate the active participation of SMEs in the programme. These activities may address SME participation across the Theme or within specific areas of the Theme. Activities aiming at stimulating and strengthening links for collaboration between SMEs and researchers in specific areas supported by the Theme will also be considered for support.

- **LSH-2003-3-2: Stimulating international co-operation[31]:** Promotion and facilitation of international co-operation in areas relevant to the objectives of this priority. Particular emphasis will be on activities involving countries having S&T co-operation agreements with the EU. Actions should aim at networking scientists for stimulating the creation of research consortia and the identification of priorities of common interest in areas supported by the Theme.

- **LSH-2003-3-3: Promotion of cooperation with Associated Candidate Countries (ACC) [32]:** Stimulation, encouragement and facilitation of the participation of organisations from the Associated Candidate Countries (ACC)[33] in this priority thematic area. Actions should address the following:

  Organisation of conferences in the associated candidate countries, that would involve researchers from both associated candidate countries and member states.

  Organisation of brokerage events and seminars where researchers from the associated candidate countries can meet other researchers and scientists from the same sector from other associated candidate countries and from member states with a view to participating particularly in proposals for integrated projects and networks of excellence;

  Evaluation:

  - Evaluation of the policies in a given research field as well as of performing studies aimed at the establishment of useful elements for the definition of the research policies in this field;

  - Independent evaluations undertaken in individual sectors;

  The creation of detailed databases of researchers and research organisations in the candidate countries which contain information that would facilitate partner searching for the creation of consortia.

- **LSH-2003-3-4: Stimulating exploitation:** Promotion and facilitation of assessment, dissemination, transfer, exploitation, and/or broad take-up of research results stemming from past and present EU programmes. These activities must aim over and above the standard diffusion and exploitation activities of individual

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31 See relevant section in the "Guide for Proposers"

32 See section "Cross cutting issues", para b on Proposers in Associated States of the "General Introduction"

33 ACC – Bulgaria, Cyprus, Czech Rep., Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia and Turkey

projects, and may include modelling, experience-sharing or other fact-finding activities at the junction of initiatives of public and private partners involved in innovation.

- **LSH-2003-3-5: Scientific and project management:** Activities aiming at training and support to scientists wanting to develop management skills for scientific and innovation management. Actions in particularly addressing young scientists are welcomed.

- **LSH-2003-3-6: Realising ERA objectives:** Activities contributing to the strategic objectives of the European research area in fields covered by this priority, such as pilot initiatives on benchmarking, cartography, networking, the debate on human values and technology options, or the collective management of the knowledge infrastructures of the future, etc. Activities leading to the creation of European technology platforms bringing together technological know how, industry, regulators and financial institutions to develop a strategic agenda for leading technologies will be particularly supported through this call.

- **LSH-2003-3-7: EU Strategy for Life Sciences and Biotechnology: Strategic** Specific Support Actions will be funded as necessary to implement any of the thirty Actions listed in the Action Plan attached to COM(2002)27 (http://europa.eu.int/comm/biotechnology).
  Particular attention will be paid to support those actions relating to the Resource Base: investing in education and training, research, exploitation of Intellectual property, the capital base and networks in Europe; to Governing Life Sciences and Biotechnology: social scrutiny and dialogue, consideration of ethical values and societal goals and to those actions relating to the European response to Global Challenges: international collaborations, poverty related diseases and the developing world. Initiatives to improve and facilitate the science communication process with the involvement of the media will be particularly supported through this call.

- **LSH-2003-3-8: Supporting policy development:** Activities supporting future research policy developments such as prospective and foresight studies, analysis and evaluation of impact of past EU research programmes. Prospective studies on impact of research policy on other policies (i.e. industry, health, trade, etc) and vice versa is also welcomed;

as opposed to awareness and information exchange activities, e.g. annual Workshops and Conferences, that would take place anyway without Commission support.

There will be two closing dates for strategic SSA proposals submitted in response to the second call.

1.4 LINKS TO OTHER RESEARCH TOPICS

Co-ordination within this thematic priority

The general principles for the submission of proposals are that proposals must clearly address the objectives and priorities set out in the relevant work programme section and should be submitted to the priority area to which they are most closely linked.

Co-ordination with other thematic priorities for research

There will be close interaction between activities in this and the other thematic priorities, in particular:

1.1.2 Information society technologies – coordination with the Strategic objective on eHealth.
1.1.3 Nano-technologies and nano-sciences; knowledge based multifunctional materials and new production processes and devices
1.1.5 Food quality and safety
1.1.6 Sustainable development, global change and ecosystems
1.2 .1 Policy support and anticipating scientific and technological needs
- i) Policy oriented research
- ii) Research to explore new and emerging scientific and technological problems and opportunities

Further information on this can be found in the "Guide for Proposers".

1. 5 IMPLEMENTATION PLAN AND RELATED ISSUES

For general aspects of the evaluation procedure, refer to the **FP6 "Guidelines on Proposal Evaluation Procedures"** available from Cordis [http://www.cordis.lu/fp6/eval-guidelines] and to the general Annex B to this Work-Programme.

All applicants are advised to consult the relevant "Guide for Proposers".

The weightings of the evaluation criteria and thresholds for this thematic area are detailed in Annex B of the Work Programme.

There will be one closing date for the second call in 2003 for IPs, NoEs, STREP, CA and area specific SSAs submitted to Theme 1. There will be two closing dates for the second call for strategic SSA across thematic priority 1, one in 2003 and one in 2004.

The selected topics may be open only for the call indicated and it is envisaged that up to one project utilising a new instrument will be funded for each topic. There may be competition between proposals submitted to address different topic areas as well as proposals submitted to address the same topic. This may result in some topics not being supported. For each topic the instrument to be used is indicated.

INDICATIVE ROAD MAP FOR CALL FOR PROPOSALS AND BUDGET

	Second Call		Future Calls
	Deadline November 2003	**Deadline April 2004**	**Deadline November 2004**
Area	**Indicative Budget M €**	**Indicative Budget M €**	**Indicative Budget M €**
i a) Fundamental knowledge and basic tools for functional genomics in all organisms	**126***		**151***
i b) Application of knowledge and technologies in the field of genomics and biotechnology for health	**165***		**131***
ii a) Application-orientated genomics approaches to medical knowledge and technologies	**116***		**232***
b) Combating cancer **	**0**		
c) Confronting the major communicable diseases linked to poverty	**0**		**44***
Strategic Specific Support Actions across thematic priority 1	**4**	**4**	**6**
Total (M€)	**411**	**4**	**564**

*** Includes 1.5% for Strategic Specific Support Actions**

****Other cancer related topics are expected to be supported up to 140 M€ from the total budget, under "Advanced genomics and its application for health"**

1.6 CALL INFORMATION

1. **Specific Programme**: Integrating and strengthening the European Research Area

2. **Activity**: Priority thematic area of research "Life sciences, genomics and biotechnology for health".

3. **Call title**: Thematic call in the area of "Life sciences, genomics and biotechnology for health".

4. **Call identifier**: [34] FP6-2003-LIFESCIHEALTH-I

5. **Date of publication**[35]: 15 July 2003

6. **Closure date(s)**[36]: 13 November 2003 at 17.00 (Brussels local time).

7. **Total indicative budget:** 411 million €, broken down as follows:

Instrument[37]	€ (millions)
IP or NOE	308 – 328
STREP or CA or area specific SSA	82 – 102
Strategic SSA across Thematic Priority 1	4

8. **Areas called and Instruments**:

Proposals are invited in the following topics, which are described using short titles only. For the full titles and definition of topics, applicants must refer to the Work Programme (Section 1.3 Technical Content). The evaluation of proposals will be based on the full definition of topics as described in the Work Programme. For each topic the instrument to be used is indicated.

i) <u>Advanced genomics and its applications for health</u>

a) Fundamental knowledge and basic tools for functional genomics in all organisms

Topic Ref.	Short Titles of Topics	Instrument
	• ***Gene expression and proteomics***	
LSH-2003-1.1.1-1	Global *in situ* gene expression analysis in rodent models and human tissues	IP

[34] The call identifier shall be given in the published version of this call.

[35] The director-general responsible for the publication of this call may publish it up to one month prior or after its envisaged publication date.

[36] When the envisaged date of publication date is advanced or delayed (see previous footnote), closure date(s) will be adjusted accordingly.

[37] IP = Integrated project; NOE = Network of excellence; STREP = Specific targeted research project; CA = Coordination action; SSA = Specific support action

	• ***Structural genomics***	
LSH-2003-1.1.2-1	Comparative structural biology of viral replication	IP
LSH-2003-1.1.2-2	Structure determination of large protein complexes	IP
	• ***Comparative genomics and population genetics***	
LSH-2003-1.1.3-1	Developing new molecular tools and approaches for high throughput molecular phenotyping of human populations	IP
LSH-2003-1.1.3-2	Standardisation and integration of genomic and phenotypic information to characterise bacterial diversity with relevance to human health	NoE
LSH-2003-1.1.3-3	Coordination and standardisation of high throughput genotyping in human populations in Europe	NoE
	• ***Bioinformatics***	
LSH-2003-1.1.4-1	Bioinformatics grid for European genomics research	NoE
LSH-2003-1.1.4-2	Development of an integrated software platform to tackle genomic sequence-structure-function relationships	IP
	• ***Multidisciplinary functional genomics approaches to basic biological processes***	
LSH-2003-1.1.5-1	Functional genomics approaches in animal models to study human kidney disease	IP or NoE
LSH-2003-1.1.5-2	Functional genomics approaches to the study of peroxisomes in health and disease	IP or NoE
LSH-2003-1.1.5-3	Functional genomics of inner ear development and disorders	IP or NoE
LSH-2003-1.1.5-4	Functional genomics of the retina in health and disease	IP or NoE
LSH-2003-1.1.5-5	DNA damage and repair mechanisms in health and disease	IP
LSH-2003-1.1.5-6	Functional genomics approaches in animal models to study human immunological disease	IP or NoE
LSH-2003-1.1.5-7	Functional genomics approaches in animal models to study human muscle disease	NoE
LSH-2003-1.1.5-8	Genetic and molecular determinants of X-linked mental retardation	NoE
	• ***Across the area***	
LSH-2003-1.1.0-1	For STREP, research should focus on multidisciplinary fundamental genomics approaches (gene expression and proteomics, structural genomics, comparative genomics, population genetics and bioinformatics), in all organisms to study the following topics: low abundance mRNAs and proteins; the biological role of small RNAs; identifying and characterising multi-protein complexes of biotechnological interest (nanomachines); programmed cell death across the eukaryotic kingdom; comparative genomics in protozoa in relation to human health. Proposals concerned with the development of new tools and approaches, including the	STREP

	standardisation of protocols, to facilitate generation of new knowledge in functional and structural genomics and proposals dealing with *in silico* prediction of the structure of biological macromolecules will also be considered.	
LSH-2003-1.1.0-2	CA proposals should focus on structuring European research in mouse genomics, in models complementary to mouse, and in systems biology. Proposals aimed at developing a coherent European policy for management and maintenance of essential resources for all model organisms important in functional genomics research are also encouraged. Actions for harmonising and optimising management and experimental use of important human biobanks in epidemiological research will also be considered.	CA
LSH-2003-1.1.0-3	Strategic Specific Support Actions (SSAs) can take the form of workshops, conferences, training activities, or publications. The activities supported should be in the context of wider research policy objectives but have a clear link to fundamental genomics. Activities should address entrepreneurship (e.g. through specific courses), or strengthen the international dimension in fundamental genomics research (e.g. through workshops linking European researchers and researchers from specific third countries). Furthermore they should aim at structuring research activities in important areas not yet addressed or newly emerging, including technology foresight meetings to identify future opportunities within the field.	SSA

b) Application of knowledge and technologies in the field of genomics and biotechnology for health

Topic Ref.	Short Titles of Topics	Instrument
	• ***Rational and accelerated development of new, safer, more effective drugs including pharmacogenomics approaches***	
LSH-2003-1.2.1-1	Medicines for children	NoE
LSH-2003-1.2.1-2	Computer assisted modelling for drug discovery and testing	NoE
LSH-2003-1.2.1-3	Novel therapeutic substances for neurodegenerative diseases in CNS and PNS	IP
LSH-2003-1.2.1-4	Networking of the European SME bioincubators active in biopharmaceutical development	CA
LSH-2003-1.2.1-5	Enhancement and improvement of biopharmaceuticals' clinical testing and their approval	SSA
LSH-2003-1.2.1-6	Workshop on the creation of biopharmaceutical development platforms with involvement of biotech SMEs and pharmaceutical industry	SSA

	• ***Development of new diagnostics***	
LSH-2003-1.2.2-1	Development of genetic tests allowing for harmonisation, validation and standardisation	NoE
LSH-2003-1.2.2-2	*In vivo* molecular imaging: identification of new markers for diagnostic purposes	NoE
LSH-2003-1.2.2-3	Molecular diagnostics in mitochondrial diseases	STREP
LSH-2003-1.2.2-4	Advances in synchrotron radiation technology for diagnostic purposes	SSA
	• ***Development of new in vitro and in silico tests to replace animal experimentation***	
LSH-2003-1.2.3-1	Optimisation of test batteries for human acute toxicity	IP
LSH-2003-1.2.3-2	Non-animal test methods for chemicals, medicines, biologicals and bio-materials: a prospective analysis	SSA
LSH-2003-1.2.3-3	Mathematical models as alternative methods to animal experiments for human health and eco-toxicological endpoints	SSA
	• ***Development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (in particular stem cell therapies, for example those on neurological and neuromuscular disorders) and immunotherapies***	
LSH-2003-1.2.4-1	Improved gene delivery systems for the therapy of severe acquired diseases	IP
LSH-2003-1.2.4-2	Gene therapy of inherited diseases	IP
LSH-2003-1.2.4-3	Design of rational protocols for safety, quality and standardisation of stem cells[38] and establishment of a European registry of stem cells	IP
LSH-2003-1.2.4-4	Regeneration therapies for pancreas and/or liver [39]	IP
LSH-2003-1.2.4-5	New improved vaccines based on genomic and proteomic information	IP
LSH-2003-1.2.4-6	Dendritic cells for novel immunotherapies	NoE
LSH-2003-1.2.4-7	Molecular strategies to improve precision in gene transfer for therapeutic applications	STREP
LSH-2003-1.2.4-8	Use of gene transfer for curative therapy of human skin disease	STREP
LSH-2003-1.2.4-9	Publications (books or brochures) for communicating background to and status of research on somatic gene and/or cell therapies to non-specialists	SSA
LSH-2003-1.2.4-10	Inventory of stem cell and gene therapy research in Associate Candidate Countries	SSA

[38] Id 17

[39] Id 17

LSH-2003-1.2.4-11	Workshop to examine the potential and perspectives for cell-based therapies for autoimmune diseases	SSA
	• ***Innovative research in post-genomics, which has high potential for application***	
LSH-2003-1.2.5-1	RNA as a human therapeutic tool	IP
LSH-2003-1.2.5-2	Post-genomic approaches to the study of human pathogens	NoE
LSH-2003-1.2.5-3	Induction of transplant tolerance using post-genomic approaches	IP
LSH-2003-1.2.5-4	New bioassays and biosensors using post-genomic approaches for detection of harmful microbes	STREP
LSH-2003-1.2.5-5	The fungal cell-wall as a target of antifungal therapies	STREP
LSH-2003-1.2.5-6	Biotechnological and post-genomic approaches for the development of novel biosafe propagation-deficient virus vectors aimed at prevention and treatment of infectious diseases (e.g. enteric, respiratory)	STREP
LSH-2003-1.2.5-7	Exploitation of fungal genomics and application of filamentous fungal biotechnology for the benefits of human health	CA
LSH-2003-1.2.5-8	Advance course or workshop on the use of RNAi as a tool of post genomic analysis	SSA

ii) <u>Combating major diseases</u>

a) Application-orientated genomic approaches to medical knowledge and technologies

Topic Ref/	Short Titles of Topics	Instrument
	• General	
LSH-2003-2.1.0-1	Eicosanoids and nitric oxide: mediators of cardiovascular, cerebral and neoplastic diseases	IP
LSH-2003-2.1.0-2	Coordination of clinical trials in Europe	SSA
	• ***Combating, cardiovascular disease, diabetes and rare diseases***	
LSH-2003-2.1.1-1	Impaired salt and water homeostasis in hypertension and heart failure	IP
LSH-2003-2.1.1-2	Molecular basis of exercise effects on the metabolic syndrome and insulin resistance	IP or NoE
LSH-2003-2.1.1-3	Functional genomics of type 2 diabetes	NoE
LSH-2003-2.1.1-4	Prader-Willi Syndrome: gene expression, obesity and mental health	STREP
LSH-2003-2.1.1-5	Rare autoimmune disorders: from genes to individualised medicine	STREP

LSH-2003-2.1.1-6	Molecular basis of vascular events leading to thrombotic stroke	STREP
LSH-2003-2.1.1-7	Combating rare genetic skin disorders	CA
LSH-2003-2.1.1-8	Combating disorders of inborn errors of metabolism	CA
LSH-2003-2.1.1-9	Application of spectroscopic and imaging techniques in the cardiovascular and diabetes fields	SSA
LSH-2003-2.1.1-10	Prevention of autoimmune destruction and replacement of β-cells in type 1 diabetes	SSA
	• ***Combating resistance to antibiotics and other drugs***	
LSH-2003-2.1.2-1	Functional genomics of antibiotics-producing organisms	IP
LSH-2003-2.1.2-2	New molecular targets for the development of drugs against pathogens causing severe resistance problems	IP
LSH-2003-2.1.2-3	Novel approaches to address antimicrobial resistance through non-antimicrobial based therapies	STREP/CA
	• ***Studying the brain and combating diseases of the nervous system***	
LSH-2003-2.1.3-1	Genomics and mechanisms of addiction	IP or NoE
LSH-2003-2.1.3-2	Neuronal networks, learning and memory: from genes to behaviour	IP
LSH-2003-2.1.3-3	Molecular mechanisms of neuronal degeneration	NoE
LSH-2003-2.1.3-4	Stem cells and nervous system	NoE
LSH-2003-2.1.3-5	Cortical development	STREP/CA
LSH-2003-2.1.3-6	Excitotoxic neuronal cell death	STREP/CA
LSH-2003-2.1.3-7	Genetics and neurobiology of autism	STREP/CA
LSH-2003-2.1.3-8	Specific support action on neuroscience funding and brain diseases in Europe	SSA
LSH-2003-2.1.3-9	Specific brain research support actions	SSA
	• ***Studying human development and the ageing process***	
LSH-2003-2.1.4-1	Regulation of mitochondrial activity	IP or NoE
LSH-2003-2.1.4-2	Molecular mechanisms of embryo implantation	NoE
LSH-2003-2.1.4-3	Coordinating European research in ageing and longevity	CA
LSH-2003-2.1.4-4	European research on ageing	SSA

SSA across thematic priority 1

Topic Ref.	Short Titles of Topics
LSH-2003-3-1	Promotion of SME participation
LSH-2003-3-2	Stimulating international co-operation
LSH-2003-3-3	Promotion of cooperation with Associated Candidate Countries (ACC)
LSH-2003-3-4	Stimulating exploitation
LSH-2003-3-5	Scientific and project management
LSH-2003-3-6	Realising ERA objectives
LSH-2003-3-7	EU Strategy for Life Sciences and Biotechnology
LSH-2003-3-8	Supporting policy development

9. Minimum number of participants[40]:

Instrument	Minimum number of participants
IP, NOE, STREP and CA	3 independent legal entities from 3 different MS or AS, with at least 2 MS or ACC.
SSA	1 legal entity from a MS or AS.

10. Restriction on participation: None.

11. Consortia agreements:

- Participants in IP and NOE are required to conclude a consortium agreement.
- Participants in STREP, CA and SSA resulting from this call are encouraged, but not required, to conclude a consortium agreement.

12. Evaluation procedure:

- The evaluation shall follow a single stage procedure;
- Proposals will not be evaluated anonymously;
- The evaluation process may involve "remote" evaluation of proposals;
- Applicants may be invited to discuss their proposal.

[40] MS = Member States of the EU; AS (incl. ACC) = Associated States; ACC = Associated candidate countries.
Any legal entity established in a Member State or Associated State and which is made up of the requested number of participant may be the sole participant in an indirect action.

13. Evaluation criteria: See Annex B of the work programme for the applicable criteria (including their individual weights and thresholds and the overall threshold) per instrument.

14. Indicative evaluation and contractual timetable:

- evaluation results: estimated to be available within some 4 months after the closure date

- contract signature: it is estimated that the first contracts related to this call will come into force by the end of 2004.

1. **Specific Programme**: Integrating and strengthening the European Research Area

2. **Activity**: Priority thematic area of research "Life sciences, genomics and biotechnology for health".

3. **Call title**: Thematic call in the area of "Life sciences, genomics and biotechnology for health".

4. **Call identifier**: [41] FP6-2003-LIFESCIHEALTH-II

5. **Date of publication**[42]: 15 July 2003

6. **Closure date(s)**[43]: 15 April 2004 at 17.00 (Brussels local time).

7. **Total indicative budget:** 4 million € in 2004

Instrument[44]	€ (millions)
Strategic SSA across Thematic Priority 1	4

8. **Areas called and Instruments**:

Proposals are invited in the following areas, which are described using short titles only. For the full titles and definition of areas, applicants must refer to the Work Programme (Section 1.3 Technical Content). The evaluation of proposals will be based on the full definition as described in the Work Programme.

SSA across thematic priority 1

Topic Ref.	Short Titles of Topics
LSH-2003-3-1	Promotion of SME participation
LSH-2003-3-2	Stimulating international co-operation
LSH-2003-3-3	Promotion of cooperation with Associated Candidate Countries (ACC)
LSH-2003-3-4	Stimulating exploitation
LSH-2003-3-5	Scientific and project management
LSH-2003-3-6	Realising ERA objectives

[41] The call identifier shall be given in the published version of this call.

[42] The director-general responsible for the publication of this call may publish it up to one month prior or after its envisaged publication date.

[43] When the envisaged date of publication date is advanced or delayed (see previous footnote), closure date(s) will be adjusted accordingly.

[44] IP = Integrated project; NOE = Network of excellence; STREP = Specific targeted research project; CA = Coordination action; SSA = Specific support action

LSH-2003-3-7	EU Strategy for Life Sciences and Biotechnology
LSH-2003-3-8	Supporting policy development

9. Minimum number of participants[45]:

Instrument	Minimum number of participants
SSA	1 legal entity from a MS or AS.

10. Restriction on participation: None.

11. Consortia agreements:

- Participants in SSA resulting from this call are encouraged, but not required, to conclude a consortium agreement.

12. Evaluation procedure:

- The evaluation shall follow a single stage procedure;
- Proposals will not be evaluated anonymously;
- The evaluation process may involve "remote" evaluation of proposals;
- Applicants may be invited to discuss their proposal.

13. Evaluation criteria: See Annex B of the work programme for the applicable criteria (including their individual weights and thresholds and the overall threshold) for SSA.

14. Indicative evaluation and contractual timetable:

- evaluation results: estimated to be available within some 4 months after the closure date

- contract signature: it is estimated that the first contracts related to this call will come into force by the end of 2004.

[45] MS = Member States of the EU; AS (incl. ACC) = Associated States; ACC = Associated candidate countries.
Any legal entity established in a Member State or Associated State and which is made up of the requested number of participant may be the sole participant in an indirect action.

1. Life sciences, genomics and biotechnology for health	(i) FP6-2002-Lifescihealth - publication 17/12/2002; closure 25/03/2003; budget 513 M€ (ii) FP6-2003-Lifescihealth-I - publication 15/07/2003; closure 13/11/2003; budget 411 M€ (iii) FP6-2003-Lifescihealth-II - publication 15/07/2003; closure 15/04/2004; budget 4 M€
2. Information Society technologies	(i) FP6-2002-IST-1- publication 17/12/2002; closure 24/04/2003; budget 1070 M€ (ii) FP6-2002-IST-C-publication 17/12/2002; closing 31/12/2004; budget 60 M€ (iii) FP6-2002-IST-NMP-1(joint) - publication 17/12/2002; closing 24/04/2003; budget 60 M€ (iv) FP6-2002-IST- publication 17/06/2003; closure 15/10/2003; budget 525 M€
3. Nano-technologies and nano-sciences, knowledge-based multifunctional materials, and new production processes and devices	(i) FP6-NMP-1- publication 17/12/2002; closures 6/03/2003 and 10/04/2003; budget 400 M€ (ii) FP6-2002-IST-NMP-1-(joint) publication 17/12/2002; closing 24/04/2003; budget 60 M€ (iii) FP6-NMP-2- publication 17/12/2002; closure 10/04/2003; budget 40 M€
4. Aeronautics and space	(i) FP6-Aero-1- publication 17/12/2002; closure 20/03/2003; budget 240 M€ (ii) FP6-Aero-2- publication 17/12/2002; closure 20 March 2003 and 23 September 2003; budget 7 M€ (iii) FP6-2002-TREN1 (joint)-publication 17/12/2002; closures 18,20/03/2003 and 15/04/2003; budget 140 M€ (iv) FP6-2002-TREN2 (joint)-publication 17/06/2003 closure 17/12/2003; budget 175 M€ (v) FP6-2002-Space 1- publication 17/12/2002; closure 20/03/2003; budget 60 M€
5. Food quality and safety	(i) FP6-2002-Food 1 - publication 17/12/2002; closure 15/04/2003; budget 167 M€
6.Sustainable development, global change and ecosystems	(a) Sustainable Energy Systems: (i) FP6-2002-TREN1(joint)-publication 17/12/2002; closures 18,20/03/2003 and 15/04/2003; budget 140 M€ (ii) FP6-2002-Energy 1- publication 17/12/2002; closure 18/03/2003; budget 198 M€ (iii) FP6-2003-TREN2(joint)- publication 17/06/2003; closure 17/12/2003; budget 175 M€ (iv) FP6-2003-Energy 2- publication Sept 2003; closure December 2003; budget 4 M€
	(b) Sustainable surface transport: (i) FP6-2002-TREN1(joint)-publication 17/12/2002; closures 18,20/03/2003 and 15/04/2003; budget 140 M€ (ii) FP6-2002-TREN2 (joint)-publication 17/06/2003 closure 17/12/2003; budget 175 M€ (iii) FP6-2002-Transport 1- publication 17/12/2002; closure 15/04/2003; budget 170 M€ (iv) FP6-2002-Transport 2- publication 17/12/2002; closure 3 April 2003 and 23 September 2003, budget 5 M€
	(c) Global change and ecosystems: (i) FP6-2002-Global 1-publication 17/12/2002; closure 8/4/2003; budget 170 M€ (ii) FP6-2003-Global 2-publication 3/07/2003; closure 9 October 2003 and 17 February 2004; budget 180 M€
7. Citizens and governance in a knowledge-based society	(i) FP6-2002-Citizens 1-publication 17/12/2002; closure 15/04/2003; budget 20 M€ (ii) FP6-2002-Citizens 2-publication 17/12/2002; closure 15/04/2003, budget 33 M€ (iii) FP6-2002-Citizens 3-publication 17/12/2002; closure 10/12/2003; budget 48 M€
8. Policy support and anticipating scientific and technological needs	(a) Policy-oriented research: (i) FP6-2002-SSP 1 - publication 17/12/2002; closure 13/03/2003; budget 149,1 M€ (ii) FP6-2003-SSP-SARS 1 - publication 3/7/2003; closure 30/09/2003; budget 9 M€
	(b) New and Emerging S&T problems and opportunities: (i) FP6-2003-NEST-A-publication 26/02/2003; closure 22/10/2003; budget 28M€
9. Horizontal research activities involving SMEs	(i) FP6-2002-SME 1-publication 17/12/2002; closure 27/11/2003; budget 155 M€ (ii) FP6-2002-SME 2-publication 17/12/2002; closure 6/03/2003; budget 40 M€
10. Specific measures in support of international co-operation	(i) FP6-2002-INCO DEV 1- publication 17/12/2002; closure 11/09/2003, budget 50 M€ (ii) FP6-2002-INCO MPC 1-publication 17/12/2002; closure 7/05/2003; budget 25 M€ (iii) FP6-2002-INCO WBC1-publication 17/12/2002; closure 7/05/2003, budget 13.5 M€ (iv) FP6-2002-INCO DEV/SSA 1-publication 17/12/2002; closure 6/03/2006; budget 1 M€ for 2003 (v) FP6-2002-INCO MPC/SSA 2-publication 17/12/2002; closure 6/03/2006; budget 0.6 M€ for 2003 (vi) FP6-2002-INCO WBC/SSA3-publication 17/12/2002; closure 6/03/2006; budget 0.6 M€ for 2003 (vii)FP6-2002-INCO-Russia+NIS/SSA-4 - publication 17/12/2002; closure 6/03/2006; budget 0.6 M€ for 2003 (viii)FP6-2002-INCO-COMultilatRTD/SSA 5 - publication 17/12/2002; closure 6/03/2006; budget 0.6 M€ for 2003
11. Support for the co-ordination of activities	(i) FP6-2002-ERA-NET/1/CA-SSA - publication 17/12/2002; closing 4/10/2005; budget 24 M€ for 2003
12. Support for the coherent development of policies	None foreseen under the current work programme.
D. Promotion of co-operation with Associated Candidate Countries	(i) FP6-2003-ACC-SSA-General - publication 26/03/2003; closure 26/06/2003, budget 9 M€ (ii) FP6-2003-ACC-SSA-*NMP;* FP6-2003-ACC-SSA-*Aero-Space;* FP6-2003-ACC-SSA-*Food;* FP6-2003-ACC-SSA-*Energy;* FP6-2003-ACC-SSA-*Transport* - publication 26/03/2003; closure 26/06/2003, budget up to 4 M€

Common evaluation criteria for evaluating proposals

A number of evaluation criteria are common to all the programmes of the Sixth Framework Programme and are set out in the European Parliament and the Council Regulations on the Rules for Participation (Article 10). These are:

a) "Scientific and technological excellence and the degree of innovation;
b) Ability to carry out the indirect action successfully and to ensure its efficient management, assessed in terms of resources and competences and including the organisational modalities foreseen by the participants;
c) Relevance to the objectives of the specific programme;
d) European added value, critical mass of resources mobilised and contribution to Community policies;
e) Quality of the plan for using and disseminating the knowledge, potential for promoting innovation, and clear plans for the management of intellectual property."

Furthermore, in applying paragraph (d) above, the following criteria are also to be taken into account:

a) "For networks of excellence, the scope and degree of the effort to achieve integration and the network's capacity to promote excellence beyond its membership, as well as the prospects of the durable integration of their research capabilities and resources after the end of the period covered by the Community's financial contribution;
b) For integrated projects, the scale of the ambition of the objectives and the capacity of the resources to make a significant contribution to reinforcing competitiveness or solving societal problems;
c) For integrated initiatives relating to infrastructure, the prospects of the initiative's continuing long term after the end of the period covered by the Community's financial contribution."

As set out in the Rules for Participation, the calls for proposals determine, in accordance with the type of instruments deployed or the objectives of the RTD activity, how the criteria set out above are applied by the Commission.

The purpose of this annex is to indicate how these criteria shall be applied. In particular, as the Sixth Framework Programme contains a differentiated set of instruments, the way in which each criterion translates into the issues to be examined as the basis for marking proposals will differ. In evaluating against these criteria, the checklists of issues set out in the following pages are intended to be universal for each type of instrument.

Unless otherwise specified in the relevant parts of this work programme, the principal issues set out below (i.e. the main numbered headings) will be given equal weighting in the evaluation. For each principal issue, a minimum score to be achieved is also indicated as well as a minimum overall score for each instrument. Proposals that fail

to achieve these minimum threshold scores shall be rejected. Any departures from these threshold scores are indicated in the relevant part of this work programme.

In addition to the basic checklists below and any specific criteria or interpretations of the criteria required for a call, the following issues are also addressed for all proposals at any appropriate moment in the evaluation:

- Are there **gender** issues associated with the subject of the proposal? If so, have they been adequately taken into account?

- Have the applicants identified the potential **ethical** and/or **safety** aspects of the proposed research regarding its objectives, the methodology and the possible implications of the results? If so, have they been adequately taken into account in the preparation of the proposal?

  An ethical check will take place for all proposals during the evaluation. A specific ethical review will be implemented following the evaluation for proposals recommended for funding and which deal with specific sensitive issues or whenever recommended following the ethical check during the evaluation. To this end, additional information on ethical aspects may be requested from proposers to allow the specific ethical review to be carried out. (See the section "The ethical review of proposals" below for more details on the criteria to be applied).

When appropriate, the following additional issues may also be addressed during the evaluation:

- To what extent does the proposal demonstrate a readiness to engage with actors beyond the research community and the public as a whole, to help spread awareness and knowledge and to explore the wider **societal implications** of the proposed work?

- Have the synergies with **education** at all levels been clearly set out?

- If **third country participation** is envisaged in the proposal, is it well justified and the participation well integrated in the activities?

Integrated Projects (IP)

The following set of issues is intended to be a common basis for the evaluation of proposals for integrated projects.

1. Relevance (threshold score 3 out of 5)

- The extent to which the proposed project **addresses the objectives** of the work programme.

2. Potential impact (threshold score 3 out of 5)

The extent to which:

- the proposed project is **suitably ambitious** in terms of its strategic impact on **reinforcing competitiveness (including that of SMEs) or on solving societal problems**.
- the innovation-related activities and exploitation and/or dissemination plans are adequate to ensure **optimal use of the project results.**
- the proposal demonstrates a clear **added value** in carrying out the work at European level and takes account of research activities at national level and under European initiatives (e.g. Eureka).

3. S&T excellence (threshold score 4 out of 5)

The extent to which:

- the project has **clearly defined objectives**.
- the objectives represent **clear progress beyond the current state-of-the-art**.
- the **proposed S&T approach is** likely to enable the project to achieve its objectives in research and innovation.

4. Quality of the consortium (threshold score 3 out of 5)

The extent to which:

- the participants collectively constitute a **consortium of high quality.**
- the participants are **well-suited and committed to the tasks** assigned to them.
- there is **good complementarity** between participants.
- the **profiles** of the participants, including those to be included later, have been clearly described.
- the real involvement of **SMEs** has been adequately addressed.

5. Quality of the management (threshold score 3 out of 5)

The extent to which:

- the **organisational structure is** well matched to the complexity of the project and to the degree of integration required.
- the **project management** is demonstrably of high quality.
- there is a satisfactory plan for the **management of knowledge**, of intellectual property and of other innovation-related activities.

6. Mobilisation of resources (threshold score 3 out of 5)

The extent to which:

- the project mobilises the minimum **critical mass of resources** (personnel, equipment, finance…*)* necessary for success.
- the **resources** are **convincingly integrated** to form a coherent project.
- the overall **financial plan** for the project is adequate.

Overall threshold score 24 out of 30.

Networks of Excellence (NoE)

The following set of issues is intended to be a common basis for the evaluation of proposals for networks of excellence.

1. Relevance (threshold score 3 out of 5)

- The extent to which the proposed project **addresses the objectives** of the work programme.

2. Potential impact (threshold score 3 out of 5)

The extent to which:

- Europe has a **strategic need to strengthen S&T excellence on the topic** by means of a restructuring of the existing research capacities and the way research is carried out.
- the goals of the network are, in that connection, **suitably ambitious** particularly, in terms of achieving European leadership and acting as a world force on this topic.
- the proposal demonstrates a clear **added value** in carrying out the work at European level and takes account of research activities at national level and under European initiatives (e.g. Eureka).
- there is an effective plan for **spreading excellence**, exploiting results and disseminating knowledge, including to SMEs and to those outside the network.
- the proposed **approach is likely to have a durable structuring impact** on European research.

3. Excellence of the participants (threshold score 3 out of 5)

The extent to which:

- the **participants are** currently conducting **excellent research** relevant to the topic of the network or are capable of important contributions to the joint programme of activities.
- the participants are **well suited to the tasks** assigned to them.
- they **collectively have the necessary critical mass of expertise and resources** to carry out the joint programme of activities successfully.

4. Degree of integration and the joint programme of activities (threshold score 4 out of 5)

The extent to which:

- the expected **degree of integration** justifies supporting the proposal as a network of excellence.
- the **joint programme of activities is** sufficiently well designed to achieve the expected degree of integration.
- the participating organisations have made a convincing commitment towards a **deep and durable integration** continuing beyond the period of Community support.

5. Organisation and management (threshold score 3 out of 5)

The extent to which:

- the organisational structure of the network provides a **secure framework for any necessary structural decisions** to be taken
- the **management of the network is** demonstrably of high quality.
- there is a well-considered plan for **promoting gender equality** in the network.

Overall threshold score 20 out of 25.

Specific Targeted Research Projects or Innovation Projects

The following set of issues is intended to be a common basis for the evaluation of proposals for (1) Specific Targeted Research Projects or (2) Specific Targeted Innovation Projects.

1. Relevance (threshold score 3 out of 5)

- The extent to which the proposed project **addresses the objectives** of the work programme.

2. S&T excellence (threshold score 4 out of 5)

The extent to which:

- the project has clearly **defined and well focused objectives**.
- the objectives represent **clear progress beyond the current state-of-the-art**.
- the **proposed S&T approach is** likely to enable the project to achieve its objectives in research and innovation

3. Potential impact (threshold score 3 out of 5)

The extent to which:

- the proposed project is likely to have an **impact on reinforcing competitiveness or on solving societal problems.**
- the proposal demonstrates a clear **added value** in carrying out the work at European level and takes account of research activities at national level and under European initiatives (e.g. Eureka).
- exploitation and/or dissemination plans are adequate to ensure **optimal use of the project results.**

4. Quality of the consortium (threshold score 3 out of 5)

The extent to which:

- the participants collectively constitute a **consortium of high quality.**
- the participants are **well-suited and committed to the tasks** assigned to them.
- there is **good complementarity** between participants**.**
- the opportunity of involving SMEs has been adequately addressed.

5. *Quality of the management (threshold score 3 out of 5)*

The extent to which:

- the **project management** is demonstrably of high quality.
- there is a satisfactory plan for the **management of knowledge**, of intellectual property and of other innovation-related activities.

6. *Mobilisation of resources (threshold score 3 out of 5)*

The extent to which:

- the project foresees the **resources** (personnel, equipment, financial…*)* necessary for success.
- the **resources** are **convincingly integrated** to form a coherent project.
- the overall **financial plan** for the project **is adequate**.

Overall threshold score 21 out of 30.

Coordination Actions

The following set of issues is intended to be a common basis for the evaluation of proposals for coordination actions.

1. Relevance (threshold score 3 out of 5)

- The extent to which the proposed project **addresses the objectives** of the work programme.

2. Quality of the coordination (threshold score 4 out of 5)

The extent to which:

- the research actions/programmes to be coordinated are of **demonstrably high quality**.
- the **coordination mechanisms** proposed are sufficiently **robust** for ensuring the goals of the action

3. Potential impact (threshold score 3 out of 5)

The extent to which:

- the proposal demonstrates a clear **added value** in carrying out the work at European level and takes account of research activities at national level and under European initiatives (e.g. Eureka).
- the Community support would have a real impact on the action and its scale, ambition and outcome.
- the project mobilises a critical mass of resources in Europe
- exploitation and/or dissemination plans are adequate to ensure **optimal use of the project results,** where possible beyond the participants in the project.

4. Quality of the consortium (threshold score 3 out of 5)

The extent to which:

- the participants collectively constitute a **consortium of high quality.**
- the participants are **well-suited to the tasks** assigned to them.
- the project combines the **complementary expertise** of the participants to generate added value with respect to the individual participants' programmes.

5. Quality of the management (threshold score 3 out of 5)

The extent to which:

- the **project management** is demonstrably of high quality.
- there is a satisfactory plan for the **management of knowledge**, of intellectual property and of other innovation-related activities.

6. Mobilisation of resources (threshold score 3 out of 5)

The extent to which:

- the project provides for the **resources** (personnel, equipment, financial…*)* necessary for success.
- the **resources** are **convincingly integrated** to form a coherent project.
- the overall **financial plan** for the project **is adequate**.

Overall threshold score 21 out of 30.

Specific Support Actions

The following set of issues is intended to be common to all parts of FP6 for the evaluation of proposals for specific support actions.

1. Relevance (threshold score 4 out of 5)

The extent to which

- the proposal addresses key issues to defined in the work programme/call, specific programmes or ERA, as appropriate.

2. Quality of the support action (threshold score 3 out of 5)

The extent to which:

- the proposed objectives are sound and the proposed approach, methodology and work plan are of a sufficiently high quality for achieving these objectives.
- the applicant(s) represent(s) a high level of competence in terms of professional qualifications and/or experience.
- the proposed activities are innovative and original *(if applicable).*

3. Potential impact (threshold score 3 out of 5)

The extent to which:

- the impact of the proposed work can only be achieved if carried out at European level.
- the Community support would have a substantial impact on the action and its scale, ambition and outcome.
- exploitation and/or dissemination plans are adequate to ensure **optimal use of the project results,** where possible beyond the participants in the project.

4. Quality of the management (threshold score 3 out of 5)

- The extent to which the management structure is credible in terms of professional qualifications, experience, track record and capacity to deliver.

5. Mobilisation of resources (threshold score 3 out of 5)

The extent to which :

- the project provides for the **resources** (personnel, equipment, financial…*)* necessary for success.
- the overall **financial plan** for the project **is adequate**.

Overall threshold score 17.5 out of 25.

Specific Research Projects for SMEs

The following set of issues is intended to be a common basis for the evaluation of proposals for Horizontal Research Activities for SMEs (for (1) Co-operative Research projects - CRAFT and for (2) Collective Research projects).

(1) For Co-operative Research Projects (CRAFT)

1. Relevance to the objectives of co-operative research (threshold score 4 out of 5)

- The extent to which **the proposed project** addresses a specific scientific and/or technological problem or need of a group of SMEs.

2. S&T excellence (threshold score 3 out of 5)

The extent to which:

- the project has **clearly defined and well focused objectives.**
- the objectives represent substantial **progress beyond the current state-of-the-art.**
- the **proposed S&T approach is** likely to enable the project to achieve its objectives in research and innovation.

3. Potential impact (threshold score 3 out of 5)

The extent to which:

- the proposed project has **an impact on the competitiveness of European SMEs** and/or **contributes to solving societal problems.**
- the proposal demonstrates a clear **added value** in carrying out the work at European level and takes account of research activities at national level and under European initiatives (e.g. Eureka).
- exploitation and, where relevant, dissemination plans are adequate to ensure **optimal use of the project results.**

4. Quality of the consortium (threshold score 3 out of 5)

The extent to which:

- the participation of **other enterprises and end-users,** if relevant, **is in the interest of the SME participants.**
- the SMEs are **well-suited and committed to the tasks** assigned to them and to **exploiting** the results.
- the **RTD performers are of high quality** and there is **good complementarity** between them.
- there is a **balanced contribution** by the SMEs, other enterprises and end-users to the project.

5. Quality of the management (threshold score 3 out of 5)

The extent to which:

- the **project management** is demonstrably of high quality.

- there is a satisfactory plan for the **management of knowledge**, of intellectual property and of other innovation-related activities.

6. Mobilisation of resources (threshold score 3 out of 5)

The extent to which:
- the project foresees the **resources** (personnel, equipment, financial…) necessary for success.
- the **resources** are **convincingly integrated** to form a coherent project.
- the **financial plan is adequate**.

Overall threshold score 21 out of 30

(2) For Collective Research Projects

1. Relevance to the objectives of Collective Research (threshold score 4 out of 5)

- the extent to which **the proposed project** addresses a specific scientific and/or technological problem or need of large communities of SMEs.

2. S&T excellence (threshold score 3 out of 5)

The extent to which:
- the project has **clearly defined and well focused objectives.**
- the objectives represent substantial **progress beyond the current state-of-the-art.**
- the **proposed S&T approach is** likely to enable the project to achieve its objectives in research and innovation.

3. Potential impact (threshold score 3 out of 5)

The extent to which:
- the proposed project has an impact on the **competitiveness of large communities of European SMEs** and/or contributes to **solving societal problems.**
- the proposal demonstrates a clear **added value** in carrying out the work at European level and takes account of research activities at national level and under European initiatives (e.g. Eureka).
- dissemination and training plans and, where relevant, exploitation plans are adequate to ensure **optimal use of the project results.**

4. Quality of the consortium (threshold score 3 out of 5)

The extent to which:
- the industrial associations or industry groupings are committed to disseminating the project results, to the training of managers of SMEs and SME associations and, when appropriate, to **exploiting the project results.**
- the 'core group' of **SMEs** are **committed to exploiting** the project results.
- the **RTD performers are of high quality** and there is good **complementarity** between them.

5. *Quality of the management (threshold score 3 out of 5)*

The extent to which:

- the **project management** is demonstrably of high quality.
- there is a satisfactory plan for the **management of knowledge**, of intellectual property and of other innovation-related activities.
- the **'core group' of SMEs** associated to the project will contribute from the definition phase of the project to the dissemination of the results obtained.

6. *Mobilisation of resources (threshold score 3 out of 5)*

The extent to which:

- the project foresees the **resources** (personnel, equipment, financial, etc.) necessary for success.
- the **resources** are **convincingly integrated** to form a coherent project.
- the **financial plan for the project is adequate**.

Overall threshold score 21 out of 30.

The ethical review of proposals

In accordance with Article 3 of the Framework Programme and Article 10 of the Rules for Participation, the evaluation procedure includes a check of any ethical issues raised by proposals. A specific ethical review of proposals involving sensitive ethical issues may take place after the evaluation and before any selection decision by the Commission. For this purpose, an ethical review (ER) panel may be convened.

The ER panel assesses the following elements:

- The awareness of the proposers of the ethical aspects of the research they propose
- Whether the researchers respect the ethical requirements of the 6th Framework Programme. In this respect, a declaration to the minutes of the Council meeting of 30.09.2002 was made; this is set out at the end of this section.
- Whether the proposers have taken into account the legislation, regulations and/or guidelines in place in the country(ies) where the research takes place
- Whether the relevant international conventions and declarations are taken into account[46]
- Whether the relevant Community Directives are taken into account.
- Whether the proposer is seeking the approval/favourable opinion of relevant local ethics committees

For research involving human beings, the ER panel assesses in particular:

- The information which is given to the participants (healthy volunteers, tissue donors, patients, etc.)
- Measures taken to protect participants' personal data (including genetic data) and privacy
- Recruitment criteria and means by which the recruitment is to be conducted
- Level of care offered to participants

For research involving isolated or banked human embryonic stem cells in culture and foetal tissues and cells (for which restrictions apply, see the declaration to the Council minutes below) the ER panel assesses in particular:

- Whether the proposers have taken into account the legislation, regulations and/or codes of conduct in place in the country(ies) where the research using human embryonic stem cells in culture will take place.The procedures for obtaining informed consent
- The source of the human embryonic and foetal tissues/cells.

[46] Charter of Fundamental Rights of the European Union, signed in Nice, 7 December 2000
Convention on Human rights and Biomedicine – Oviedo, 4.04. 1997 - Council of Europe
and the Additional protocol on the prohibition of Cloning of human beings (1998)
Universal declaration on the Human genome and human rights - Unesco - 11 November 1997
Declaration of Helsinki (in its latest version) - World Medical Association
Convention on the Rights of the Child – United Nations - 20 November 1989
Amsterdam protocol on an animal protection and welfare

- Measures taken to protect personal data (including genetic data) and privacy
- The nature of financial inducements, if any.

For research involving animals, the ER panel assesses in particular:

- Whether the proposers are applying the 'Three Rs' principle: Replacement, Reduction and Refinement, and in particular:
  - ♦ Are animal experiments replaced by alternatives whenever possible?
  - ♦ Is animal suffering avoided or kept to a minimum?
  - ♦ Is animal welfare guaranteed and are the principles of biodiversity respected?

With respect to research involving human embryonic stem cells (as mentioned above), the relevant declaration to the minutes of the Council meeting of 30 September 2002 is as follows:

"The Council and the Commission agree that detailed implementing provisions concerning research activities involving the use of human embryos and human embryonic stem cells which may be funded under the 6th Framework Programme shall be established by 31 December 2003. The Commission states that, during that period and pending establishment of the detailed implementing provisions, it will not propose to fund such research, with the exception of the study of banked or isolated human embryonic stem cells in culture. The Commission will monitor the scientific advances and needs as well as the evolution of international and national legislation, regulations and ethical rules regarding this issue, taking into account also the opinions of the European Group of Advisers on the Ethical Implications of Biotechnology (1991–1997) and the opinions of the European Group on Ethics in Science and New technologies (as from 1998), and report to the European Parliament and the Council by September 2003.

The Council states that it intends to discuss this issue at a meeting in September 2003.

In the review of any subsequent proposal submitted to Council when applying Article 5 of the Decision 1999/468/EC the Commission recalls its statement concerning Article 5 of Decision 1999/468/EC, according to which the Commission, in order to find a balanced solution, will act in such a way as to avoid going against any predominant position which might emerge within the Council against the appropriateness of an implementing measure (cf. OJ C 203, 17.7.1999, p. 1).

The Council notes the intention of the Commission to submit to the programme Committee, established under the specific Research programme "Integrating and strengthening the ERA", procedural modalities concerning research involving the use of human embryos and human embryonic stem cells, in accordance with Article 6, paragraph 3, first indent.

The Council further notes the intention of the Commission to present to Council and Parliament in Spring 2003 a report on human embryonic stem cell research which will form the basis for discussion at an inter-institutional seminar on bioethics.

Taking into account the seminar's outcome, the Commission will submit, based on article 166 (4) of the Treaty, a proposal establishing further guidelines on principles for deciding on the Community funding of research projects involving the use of human embryos and human embryonic stem cells.

The Council and the Commission will do their utmost, counting on the support of the European Parliament, to complete the legislative procedure as early as possible and at the latest in December 2003.

The Council and the Commission expect that the above mentioned seminar will contribute, as suggested by the European Parliament, to a Europe-wide and well-structured discussion process on the ethical issues of modern biotechnology, particularly on human embryonic stem cells, in order to enhance public understanding.

The Council and the Commission note that the ethical acceptability of various research fields is related to the diversity among Member States, and is governed by national law in accordance with the principle of subsidiarity. Moreover, the Commission notes that research using human embryos and human embryonic stem cells is allowed in several Member States, but not in others."

Annex C : List of Groups of target countries for specific measures in support of International Co-operation

DEVELOPING COUNTRIES (ACP, ASIA, LATIN AMERICA)

- ACP

AFRICAN

- Angola
- Benin
- Botswana
- Burkina-Faso
- Burundi
- Cameroon
- Cape Verde
- Central African Republic
- Chad
- Comoros
- Congo (Republic)
- Congo (Democratic Rep. of)
- Côte d'Ivoire
- Djibouti
- Equatorial Guinea
- Eritrea
- Ethiopia
- Gabon
- Gambia
- Ghana
- Guinea
- Guinea-Bissau
- Kenya
- Lesotho
- Liberia
- Madagascar
- Malawi
- Mali
- Mauritania
- Mauritius
- Mozambique
- Namibia
- Niger
- Nigeria
- Rwanda
- Sao Tome and Principe
- Senegal
- Seychelles
- Sierra Leone
- Somalia
- South Africa
- Sudan
- Swaziland
- Tanzania
- Togo
- Uganda
- Zambia
- Zimbabwe

CARIBBEAN

- Antigua and Barbuda
- Bahamas
- Barbados
- Belize*
- Cuba*
- Dominica
- Dominican Rep.
- Grenada
- Guyana*
- Haiti
- Jamaica
- Saint Kitts and Nevis
- Saint Lucia
- Saint Vincent and Grenadines
- Suriname*
- Trinidad and Tobago

PACIFIC

- Cook Islands
- Fiji
- Kiribati
- Marshall Islands
- Micronesia, Federal States of
- Nauru
- Niue
- Palau
- Papua New Guinea
- Solomon Islands
- Tonga
- Tuvalu
- Vanuatu
- Western Samoa

- ASIA

- Bangladesh
- Bhutan
- Brunei
- Cambodia
- China**
- India**
- Indonesia
- Lao (People's Democratic Rep. of)
- Malaysia
- Maldives
- Mongolia
- Nepal
- Pakistan
- Philippines
- Singapore
- Sri Lanka
- Thailand
- Vietnam

- LATIN AMERICA

- Argentina
- Bolivia
- Brazil
- Chile
- Colombia
- Costa Rica
- Ecuador
- El Salvador
- Guatemala
- Honduras
- Mexico
- Nicaragua
- Panama
- Paraguay
- Peru
- Uruguay
- Venezuela

MEDITERRANEAN PARTNER COUNTRIES

- Algeria
- Egypt
- Israel[1]
- Jordan
- Lebanon
- Morocco
- Syrian Arab Rep.
- Tunisia
- West Bank and Gaza Strip

RUSSIA AND THE OTHER NEW INDEPENDENT STATES

- Armenia
- Azerbaijan
- Belarus
- Georgia
- Kazakhstan
- Kyrgyzstan
- Moldova
- Russia **
- Tajikistan
- Turkmenistan
- Ukraine
- Uzbekistan

WESTERN BALKAN COUNTRIES

- Albania
- Bosnia-Herzegovina
- Croatia
- Serbia & Montenegro[2]
- Former Yugoslav Republic of Macedonia (FYROM)

*For participation in the « Specific measures in support of international co-operation », these countries can be considered both in ACP and Latin American region

** For participation in the « Specific measures in support of international co-operation » China, India and Russia may be considered individually as a region, however, in this case, at least 3 different partners from different provinces or states within China, India or Russia are necessary

[1] When this country will become associated to the 6th framework programme, that status will take precedence

[2] Including Kosovo as defined by UNSC resolution 1244 of 10 June 1999