Call title: Call for Alternative Testing Strategies

Call identifier: FP7-HEALTH-2010-Alternative-Testing

Proposal submission and evaluation: Single-stage procedure

Date of publication: 30 July 2009.

Deadline: 3 February 2010 at 17:00:00 (Brussels local time).¹

- **Indicative budget**: EUR 25 million from the 2010 budget^{2 3}

The budget foreseen for this topic will be available exclusively for this area of the call. It can be transferred neither partially nor as a whole to other areas or to other calls for proposals.

ACTIVITY/AREA		Indicative budget ^{3 4} (EUR million)
4. OTHER ACTIONS ACROSS T HEALTH THEME	4.2. RESPONDING TO EU POLICY 4.2c Alternative Testing	NEEDS
	4.2.9 Towards the replacement of repeated dose systemic toxicity testing in human safety assessment	25

Table 1: Topics called:

Activity/Area **Topics** called **Funding Schemes and** particular requirements4 HEALTH.2010.4.2-9: Towards the replacement of repeated dose systemic toxicity testing in human safety assessment. 4.2.9.1 Optimisation of current methodologies and development of Collaborative project (Largenovel methods to achieve functional differentiation of scale integrating project). EC human-based target cells in vitro contribution per project: min. EUR 4 000 000 - max. EUR 5 000 000. Only up to one proposal can be selected. 4.2.9.2 Exploitation of organ-simulating cellular devices as Collaborative project (Largealternatives for long-term toxicity testing scale integrating project). EC contribution per project: min. EUR 4 000 000 - max. EUR 5 000 000. Only up to one proposal can be selected

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¹ The Director-General responsible for this call may delay this deadline by up to two months.

² Under the condition that the preliminary draft budget for 2010 is adopted without modifications by the budgetary authority.

³ This budget of EUR 25 million only relates to the contribution to be paid by the EC. The cosmetics industry has announced its commitment to provide additional funding equal to the contribution of the EC (see COLIPA website www.colipa.eu).

⁴ For each of the topics, the minimum and maximum amounts mentioned hereby only relate to the EC contribution. As stated in footnote 4, the cosmetics industry has announced it will provide additional funding for the proposals selected by the EC, equal in each case to the EC contribution (see COLIPA website www.colipa.eu).

4.2.9.3	Establishment of endpoints and intermediate markers in human-based target cells with relevance for repeated dose systemic toxicity testing	Collaborative project (Large- scale integrating project). EC contribution per project: min. EUR 3 500 000 – max. EUR 4 500 000. Only up to one proposal can be selected
4.2.9.4	Computational modelling and estimation techniques	Collaborative project (Large-scale integrating project). EC contribution per project: min. EUR 2 500 000 – max. EUR 3 500 000. Only up to one proposal can be selected
4.2.9.5	Systems biology for the development of predictive causal computer models	Collaborative project (Large-scale integrating project). EC contribution per project: min. EUR 4 000 000 – max. EUR 5 000 000. Only up to one proposal can be selected.
4.2.9.6	Integrated data analysis and servicing	Collaborative project (Large-scale integrating project). EC contribution per project: min. EUR 2 000 000 – max. EUR 3 000 000. Only up to one proposal can be selected.
4.2.9.7	Coordination project	Coordination and Support Action (Coordinating Action). EC contribution per project: max. EUR 1 500 000. Only up to one proposal can be selected.

Eligibility criteria for each proposal are checked by Commission staff before the evaluation begins. Proposals which do not fulfil these criteria will not be included in the evaluation.

Eligibility conditions:

• The general eligibility criteria are set out in Annex 2 of the work programme, and in the guide for applicants for each funding scheme.

Specific eligibility criteria apply to this call as set out below:

- Only information provided in part A of the proposal will be used to determine whether the
 proposal is eligible with respect to budget thresholds and/or minimum number of eligible
 participants.
- Please note that the completeness criterion also includes that part B of the proposal shall be readable, accessible and printable.

- It is important to note that the upper and lower limits for the EU contribution given per topic in table 1 of this call fiche, will be applied as an additional eligibility criterion and that proposals which do not respect these limits will be considered as ineligible.
- The minimum number and type of participating legal entities for all funding schemes is set out in the FP7 Rules for Participation and summarised in the following table for the funding schemes used in this call.
- In line with the objectives of each topic, additional eligibility criteria are indicated in the work programme.

The minimum number and type of participating legal entities for all funding schemes is set out in the FP7 Rules for Participation and summarised in the following table.

Table 2: Eligibility conditions for participation

Funding scheme	Minimum conditions
Collaborative Project	At least 3 independent legal entities, each of which is established in a MS or AC, and no 2 of which are established in the same MS or AC.
Coordination and Support Action (coordinating action)	At least 3 independent legal entities, each of which is established in a MS or AC, and no 2 of which are established in the same MS or AC.

Evaluation procedure: The basic principles of the evaluation criteria for proposals are described in Annex 2 of the work programme. However, for this call, the priority order for proposals with the same score will be determined in the manner described under 'Proposal ranking" (see below).

For all proposals submitted to this call the evaluation shall follow a single stage procedure. The proposers are requested to follow the instructions set out in the guide for applicants for the appropriate funding scheme and in the proposal part B template available through the EPSS, including page number limitations and a minimum font size of 11. The Commission will instruct the experts to disregard any pages in excess of these limits. The proposals will be evaluated by independent external experts on the basis of three evaluation criteria. The individual evaluation will be carried out remotely and the consensus meetings of evaluators will be held in Brussels.

Evaluation criteria and thresholds: For this call the following criteria and thresholds are applied. For each criterion marks from 0 to 5 will be given, with the possibility of half point scores. For proposals failing to achieve a threshold for a criterion, the evaluation of the proposal will be stopped at the first criterion failing a threshold. Therefore for such proposals the ESR (evaluation summary report) will not contain marks and comments for the remaining criteria. Successful proposals must pass the following minimum thresholds:

Table 3: Thresholds for evaluation criteria

Criterion	Minimum threshold
S/T quality	3/5
Implementation	3/5
Impact	3/5
Overall threshold	10/15

In line with the objectives of each topic, additional evaluation criteria may be indicated in the work programme.

• **Proposal ranking:** A priority list will be prepared by the panel of independent external experts for the indicative budget line as set out in this call fiche. The aspects taken into account for establishing a priority order for ranking of proposals are set out in Annex 2 of the work programme.

There will be only one proposal short-listed per topic according to the funding scheme and topic. However, there may be topics for which no proposal is of sufficient quality to be selected for funding.

The Commission ranked list of proposals to be retained for negotiation will be based on the priority list established by the panel of independent external experts taking into account the budget available (as indicated in this call for proposals). A number of proposals below the indicative budget cut-off line on the Commission ranked list may be kept on a reserve list to allow for eventualities such as the failure of negotiations on grant agreements, the withdrawal of proposals, budget savings agreed during negotiation, or the availability of additional budget from other sources.

- **Indicative evaluation and contractual timetable:** The evaluation should be finalised in March/April 2010. Overall evaluation results are estimated to be available within 4 months after the closure date for the call. It is expected that contract negotiations for short-listed proposals would begin in May/June 2010.
- Consortium agreements: Participants in large-scale integrating collaborative projects are required to conclude a consortium agreement. For small- and medium scale collaborative projects a consortium agreement is not mandatory but recommended. For coordination and support actions a consortium agreement is not required.
- The forms of grants and maximum reimbursement rates which will be offered are specified in Annex 3 to the Cooperation work programme. For projects selected in this specific call 50% of the total eligible cost will be paid by the European Commission independent from the funding schemes, the activities and type of organisations involved. Participants are encouraged to seek for complementary funding from third parties, e.g. industry ⁵.

⁵ The cosmetics industry has announced its commitment to provide additional funding, equal to the contribution of the EC (see COLIPA website www.colipa.eu).

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Flat rates to cover subsistence costs: In accordance with Annex 3 of this work programme, this call provides for the possibility to use flat rates to cover subsistence costs incurred by beneficiaries during travel carried out within grants for indirect actions. For further information, see the relevant Guides for Applicants for this call. The applicable flat rates are available at the following website: http://cordis.europa.eu/fp7/find-doc_en.html under 'Guidance documents/Flat rates for daily allowances'.