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ESBIO

Development of a coherent approach to human biomonitoring in Europe

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Socio economic consequences

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1. Background

The Implementation Group on Human Biomonitoring in Europe proposes in their recommendations a basic scenario covering the following four pollutants: Lead, Cadmium, Methylmercury and Cotinine. For an advanced scenario they propose more specific and not yet well tested pollutants. The requirements for Member States to participate in the pilot project are to join the basic scenario. The advanced scenario is an additional, voluntary part for those Member States who want to take the frame of the pilot project to measure also more “unknown” pollutants.

For the present deliverable the focus is laid on the basic scenario with its four pollutants. Basis for the present deliverable is the proposed organisation structure (deliverable 5.3).

Take already established structures into account

In most of the countries human biomonitoring activities have been performed or are ongoing, functional structures have already been established. The project team strongly recommends to use and to integrate these structures in the structure of the pilot project to ensure on the one hand side functionality and on the other hand to reduce resources and costs on the Member States level.

The following calculations are based on assumptions and experiences from experts of the ESBIO consortium. They can vary if already established structures within the MS are used.

The calculations should be regarded as an indication how much costs have to be covered and how different approaches and structures affect the total costs.

Parameter for the pilot project

A call for tender concerning the pilot project has been published by the European Commission (FP7) DG Research in December 2006. The aim of the proposed project shall be to carry out activities to **coordinate** and **harmonise** research and protocols on data collection, methodologies and models, in view of integrating human biomonitoring data with health/environment monitoring data and to allow for extrapolation of human biomonitoring results with health effects. The project will include validation of precise and non-invasive biomarkers of exposure, effect, and susceptibility, and can include small-scale pilot studies. Account should be taken of recent initiatives in the field, including relevant pollutant selection, and it should support the aims of the **EU Environment and Health Action Plan on human biomonitoring**. It can propose priorities for exposure reduction strategies and should provide recommendations for consideration of ethical issues in the pilot study. The expected impact shall be: A Coordinated approach to human biomonitoring in Europe and development of validated biomarkers usable for human biomonitoring, discussed with relevant government bodies and regulatory authorities. Policy support for the implementation of the Environment and Health Action Plan, especially research aspects of Action 3 (human biomonitoring pilot project) shall be considered.

The funding scheme shall be a network of excellence with a maximum budget of 7 Million Euro.

2. Assumed concept for the pilot project

Basic concept

For all cost calculations the basic organisational structure proposed within deliverable 5.3 is assumed consisting of the modules Central Unit and individual Member States Units. The tasks allocated to the different Units can be seen in figure 1. This basic concept can further be enlarged by additional modules if needed and appropriate.



Figure 1 Basic modules of the structure proposed for the EU HBM pilot project

Additional modules assumed for the calculation1. Reference Laboratory

Reference Laboratory

In addition to the laboratories in the Member States one Reference Laboratory is responsible to ensure the quality of data and to facilitate data comparison by carrying out analysis checks from different Member States. Also the assistance for MS in case of capacity building should be part of the tasks of the Reference Laboratory.

2. Central Laboratory

Central Laboratory

One possibility to handle the analysis of the samples is to measure all samples in one central laboratory. Further tasks of the Central Laboratory should be the organization of the sampling transport, handling and preparation, to conduct quality measures and to provide data (samples and quality control) in short term.

3. Network of stakeholders and other research projects

Network of stakeholders

An important additional module is a network of stakeholders (e.g. NGOs) and other research projects in order to ensure the involvement of all relevant institutions. This could e.g. be helpful in case of needed advice but also the further use of the obtained data can be discussed e.g. is there more research needed or how can policy makers react on specific possible findings.

For the further elaboration optional:

4. Research module

Research Unit

Within the discussion with Member States it became obvious that some MS would like to use the frame of the pilot project not only to perform the basic requirements in the sense of harmonisation but would like to have also more advanced tasks included like the measuring of more specific pollutants and biomarkers often combined with necessary research in this field of interest. The tasks can cover methodology development, validation to the point of research on new biomarker.

3. Assessment of costs for the pilot project

Calculation basis

Coordination and Management		cost estimation [€/y]
Central Unit: Project management, training, dissemination Central Unit	<i>overall coordination, training activities e.g. for medical staff, overall dissemination e.g. communication with participants etc., IT platform, hotline for participants</i>	140.000,00
Selection of laboratories for analysis	<i>criteria will be given in the protocol, Media campaign, info material, costs for mail, phone & physical visits</i>	10.000,00
MS Unit: organisation and coordination	<i>development of sampling strategy, preparation of field work, recruitment of participants, selection of geographical areas (criteria will be given in the protocol), local coordination</i>	20.000,00
Ethics aspects	<i>preparation of documents for the ethical committee</i>	10.000,00
MS Unit: Supervision of laboratories	<i>assistance and control of the laboratories, travel & accommodation</i>	10.000,00
Reference lab: Supervision of laboratories	<i>assistance and control of the laboratories</i>	35.000,00
Field work assuming a self-explanatory questionnaire per sample	<i>sampling, handling, transport, storage of specimen, equipment, external quality control, incentives, training and material for field workers, equipment (fridges, freezer), computer & software</i>	300,00
Field work assuming an interview guided questionnaire per sample	<i>sampling, handling, transport, storage of specimen, equipment, external quality control, interview, incentives, training and material for field workers, equipment (fridges, freezer), computer & software</i>	350,00
Data check and preparation	<i>check of incoming data from laboratories</i>	10.000,00
External quality assurance		70.000,00
Questionnaire		
Preparatory work	<i>translation, lay-out, printing, etc.</i>	20.000,00
Validation	<i>validation of translated questionnaire</i>	5.000,00
Follow up work	<i>verification, translation of written answers into English, reporting to the Central Unit</i>	10.000,00
Communication		
MS: communication	<i>written communication (letter, leaflets, poster, press), communication with participants</i>	20.000,00
Assessment of Results		
Data management	<i>entry, storage and treatment of data</i>	70.000,00 €

Findings treatment	<i>communication of results to participants</i>	20.000,00 €
Statistics	<i>generation of statistics</i>	70.000,00 €
Report/Generation of hypothesis		70.000,00 €
Analysis		estimates/sample
Sample management	<i>storage, transport, organization of analysis</i>	28,00
QC/QM	<i>internal quality assurance, control /reference material</i>	15,00
<i>costs for analysis of</i>		
Methylmercury		15,00 €
Lead		10,00 €
Cadmium		10,00 €
Cotinine		11,00 €
<i>material costs for</i>		
blood analysis		3,50 €
urine analysis		22,00 €
hair analysis		5,00 €
round robin test	<i>implementation and execution</i>	250.000,00 €

Table 1: calculation basis

For the compilation of the costs as indicated above several cost calculations from ongoing or already finalised Human Biomonitoring projects for example from the German Environmental Survey, the Flemish programme, the Czech programmes as well as experiences and estimations from other countries performing HBM like the U.K., Poland, Denmark and Sweden have been taken into consideration. For the cost for analysis different laboratories have been asked to give information on their costs. In addition input from many other ESBIO members could be received concerning the cost for analysis in their countries.

As the main objective of the pilot project is the harmonisation, it is essential that as many MS as possible will participate. As not all Member States have the same costs for MS Unit an average is assumed above. Different cost levels e.g. for personnel costs have to be taken into consideration for the further work. The indication above gives a first idea about the average costs to be planned.

Excel tool

In order to see how different approaches or project structures may influence the costs the project team of WP 5 has elaborated an Excel tool. On the first sheet cost have to be indicated which will be integrated and calculated on the following sheets (one for each approach).

The clear advantage of the Excel tool is that the costs as well as the number of participating countries and the number of samples can be changed easily to obtain new calculations as soon as for all options prepared in the tool. Up to now the system is fed with three options – one consisting only of the basic modules, a second consisting of the basic modules and the additional module reference

laboratory as well as the third consisting of basic modules and the additional module central laboratory.

Calculations for the following options and assumptions have been elaborated:

Option	Integrated modules	Number of samples per MS assumed	Number of participating MS assumed
A	Basic (Central Unit, MS Unit)	250	25
B	Basic (Central Unit, MS Unit) Additional (central laboratory) Additional (network of stakeholders)	250	25
C	Basic (Central Unit, MS Unit) Additional (reference laboratory) Additional (network of stakeholders)	250	25

In the following detailed cost compilations are presented for each option..

Option A

Basic modules Central Unit + MS Unit		
indicate no. of participating countries Scenario 1:		25
indicate total number per MS of samples Scenario 1:		250
total number of samples Scenario 1:		6250
CENTRAL UNIT		
<i>COORDINATION AND MANAGEMENT</i>		
Project management, training, dissemination		140.000,00 €
Quality assurance		70.000,00 €
other costs		0,00 €
<i>ASSESSMENT OF RESULTS</i>		
Data management		70.000,00 €
Findings treatment		20.000,00 €
Statistics		70.000,00 €
Report/Generation of hypotheses		70.000,00 €
other costs		0,00 €
TOTAL COSTS CENTRAL UNIT		440.000,00 €
MS UNITS		
<i>PREPARATORY WORK</i>		
	one MS UNIT	all MS UNITS (assuming same costs)
Organisation and coordination	20.000,00 €	500.000,00 €
Selection of laboratories for analysis	10.000,00 €	250.000,00 €
Ethical aspects	10.000,00 €	250.000,00 €
<i>QUESTIONNAIRE</i>		
Preparatory work	20.000,00 €	500.000,00 €
Validation	5.000,00 €	125.000,00 €
Follow up work	10.000,00 €	250.000,00 €
other costs	0,00 €	0,00 €
<i>ANALYSIS</i>		
Sample management	7.000,00 €	175.000,00 €
QC/QM	3.750,00 €	93.750,00 €
Supervision of laboratories	10.000,00 €	250.000,00 €
Data check and preparation	10.000,00 €	250.000,00 €
Field work assuming a self-explanatory questionnaire	75.000,00 €	1.875.000,00 €
<i>COMMUNICATION</i>		
communication	20.000,00 €	500.000,00 €
TOTAL COSTS MS UNIT	200.750,00 €	5.018.750,00 €
LABORATORY		
<i>COST FOR ANALYSIS OF</i>	per MS	total
Methylmercury	3.750,00 €	93.750,00 €
Lead	2.500,00 €	62.500,00 €
Cadmium	2.500,00 €	62.500,00 €
Cotinine	2.750,00 €	68.750,00 €
<i>MATERIAL COSTS FOR</i>		
blood analysis	875,00 €	21.875,00 €
urin analysis	5.500,00 €	137.500,00 €
hair analysis	1.250,00 €	31.250,00 €
Other laboratory costs	0,00 €	0,00 €
TOTAL COSTS LABORATORY	19.125,00 €	478.125,00 €
Total costs		5.936.875,00 €

Option B

Basic modules Central Unit + MS Unit Additional modules Central laboratory		
indicate no. of participating countries Scenario 1:		25
indicate total number per MS of samples Scenario 1:		250
total number of samples Scenario 1:		6250
CENTRAL UNIT		
<i>COORDINATION AND MANAGEMENT</i>		
Project management, training, dissemination		140.000,00 €
Quality assurance		70.000,00 €
Supervision of laboratory		10.000,00 €
<i>ASSESSMENT OF RESULTS</i>		
Data management		70.000,00 €
Findings treatment		20.000,00 €
Statistics		70.000,00 €
Report/Generation of hypotheses		70.000,00 €
other costs		0,00 €
TOTAL COSTS CENTRAL UNIT		450.000,00 €
CENTRAL LABORATORY		
<i>ANALYSIS</i>		
Sample management		7.000,00 €
QC/QM		3.750,00 €
<i>COST FOR ANALYSIS OF</i>		
Methylmercury		93.750,00 €
Lead		62.500,00 €
Cadmium		62.500,00 €
Cotinine		68.750,00 €
<i>MATERIAL COSTS FOR</i>		
blood analysis		21.875,00 €
urin analysis		137.500,00 €
hair analysis		31.250,00 €
Other laboratory costs		0,00 €
TOTAL COSTS CENTRAL LAB		488.875,00 €
MS UNITS		
<i>PREPARATORY WORK</i>		
	one MS UNIT	all MS UNITS (assuming same costs)
Organisation and coordination	20.000,00 €	500.000,00 €
Ethical aspects	10.000,00 €	250.000,00 €
<i>QUESTIONNAIRE</i>		
Preparatory work	20.000,00 €	500.000,00 €
Validation	5.000,00 €	125.000,00 €
Follow up work	10.000,00 €	250.000,00 €
other costs	0,00 €	0,00 €
Field work assuming a self-explanatory questionnaire	75.000,00 €	1.875.000,00 €
<i>COMMUNICATION</i>		
Communciation	20.000,00 €	500.000,00 €
TOTAL COSTS MS UNIT	160.000,00 €	4.000.000,00 €
Total costs		4.938.875,00 €

Option C

Basic modules Central Unit + MS Unit Additional modules Reference laboratory		
indicate no. of participating countries Scenario 1:		25
indicate total number per MS of samples Scenario 1:		250
total number of samples Scenario 1:		6250
CENTRAL UNIT		
<i>COORDINATION AND MANAGEMENT</i>		
Project management, training, dissemination		140.000,00 €
Quality assurance		70.000,00 €
other costs		0,00 €
<i>ASSESSMENT OF RESULTS</i>		
Data management		70.000,00 €
Findings treatment		20.000,00 €
Statistics		70.000,00 €
Report/Generation of hypotheses		70.000,00 €
other costs		0,00 €
TOTAL COSTS CENTRAL UNIT		440.000,00 €
REFERENCE LABORATORY		
round robin test		250.000,00 €
Supervision of laboratories		35.000,00 €
TOTAL COSTS REFERENCE LABORATORY		285.000,00 €
MS UNITS		
<i>PREPARATORY WORK</i>		
	one MS UNIT	all MS UNITS (assuming same costs)
Organisation and coordination	20.000,00 €	500.000,00 €
Selection of laboratories for analysis	10.000,00 €	250.000,00 €
Ethical aspects	10.000,00 €	250.000,00 €
<i>QUESTIONNAIRE</i>		
Preparatory work	20.000,00 €	500.000,00 €
Validation	5.000,00 €	125.000,00 €
Follow up work	10.000,00 €	250.000,00 €
other costs	0,00 €	0,00 €
<i>ANALYSIS</i>		
Sample management	7.000,00 €	175.000,00 €
QC/QM	3.750,00 €	93.750,00 €
Data check and preparation	10.000,00 €	250.000,00 €
Field work assuming a self-explanatory questionnaire	75.000,00 €	1.875.000,00 €
<i>COMMUNICATION</i>		
Communication	20.000,00 €	500.000,00 €
TOTAL COSTS MS UNIT	190.750,00 €	4.768.750,00 €
LABORATORY		
<i>COST FOR ANALYSIS OF</i>		
	per MS	total
Methylmercury	3.750,00 €	93.750,00 €
Lead	2.500,00 €	62.500,00 €
Cadmium	2.500,00 €	62.500,00 €
Cotinine	2.750,00 €	68.750,00 €
<i>MATERIAL COSTS FOR</i>		
blood analysis	875,00 €	21.875,00 €
urin analysis	5.500,00 €	137.500,00 €
hair analysis	1.250,00 €	31.250,00 €
Other laboratory costs	0,00 €	0,00 €
TOTAL COSTS LABORATORY	19.125,00 €	190.625,00 €
Total costs		5.684.375,00 €

Results

Number of samples per MS assumed		250			
Number of participating MS assumed		25			
Option	Integrated modules	Central level / year	MS level / year	Total MS level / year	TOTAL / year
A	Basic (Central Unit, MS Unit)	0.4 Mio €	0.22 Mio €	5.5 Mio €	5.9 Mio €
B	Basic (Central Unit, MS Unit)	0.5 Mio €	0.16 Mio €	4 Mio €	4.9 Mio €
	Additional (central laboratory)	0.5 Mio €			
	Additional (network of stakeholder)	-			
C	Basic (Central Unit, MS Unit)	0.4 Mio €	0.21 Mio €	4.9 Mio €	5.6 Mio €
	Additional (reference laboratory)	0.3 Mio €			
	Additional (network of stakeholder)	-			

Table 2 Preliminary results for one year of the project

As shown in Table 2 three different options have been assessed.

For option A consisting of only a Central Unit and a Member State Unit, cost of altogether 5.9 Mio. € are assumed for a number of samples of 250 and the maximum number of participating countries. The part thereof for the Central Unit is about 0.4 Mio. €, the cost for the individual Member States will be about 0.2 mio. €.

For option B (option A + central laboratory) and the same assumptions total cost of about 4.9 Mio. € are assumed. The share of the Central Unit and the Central Laboratory is about 1 Mio. €, the costs for the individual MS are lower than in option A (see therefore detailed cost calculations on page 9-11) as the laboratory cost are not included on MS level but on Central level. The network of stakeholder is assumed not to implicate extra costs.

In option C the Central laboratory is exchanged with a reference laboratory on Central level. The total costs are assumed to be about 5.6 Mio. €. In this option the cost for the Central Unit is the same as in option A plus extra 0.3 Mio. € for the Reference Laboratory. Costs on MS level are assumed to be about 0.21 Mio. €.

It can clearly be seen that the different options not extremely effects the cost calculations. Only relatively small shiftings can be identified. Nevertheless taking into account the assumed number of participating MS of 25, even small shiftings causes changes in the total amount.

Cross check of calculation - variations among different MS

A team of experts responded to the call for tenders concerning the pilot project beginning of 2007. Within this application institutes from 24 MS agreed on a common approach based on ESBIO results. The funding in the proposal is based on the principle that Members States have to provide about 50% equity ratio.

In the overall calculation for this application the costs per MS can clearly be seen taking into account the different needs and different expectations towards an EU HBM pilot project. In the following list the costs for 24 MS are presented within 3 categories.

MS	Range of total costs for scenario I for three years		
	< 300,000€	300,000 – 600,000	> 600,000
AT		X	
BE		X	
CY		X	
CZ	X		
DE		X	
DK		X	
EE	X		
ES		X	
FI	X		
FR			X
GR	X		
HU	X		
IE		X	
IT		X	
LT	X		
LU		X	
NL		X	
PO	X		
PT		X	
RO		X	
SE		X	
SI	X		
SK	X		
UK			X

Table 3 Costs for the pilot project

It could be shown that the majority of the MS calculated costs between 300,000 and 600,000€ for three years project running time. The calculations of ESBIO work package 5 resulted in about 160,000€ per year this means about 480,000€ for three years which is quite near to the average within this category above.

For the costs on central level about 1 million € have been assumed for one year this means 3 million for the whole project. In the afore mentioned proposal these cost have been calculated with about 3.8 million €. The higher costs can be explained by the inclusion of a research component which has to be linked to all the other activities.

Taking into account the restricted resources for the project and the large participating number of Member States it can be concluded that the calculations made by project team of work package 5 provided a good indication for the dimension of the overall calculation for the pilot project.

4. Assessment of other socio economic impacts for the pilot project

Impacts on jobs and qualification

In order to assess the impacts of a HBM pilot project on the job situation within Europe experts from 24 MS have been asked to provide data on the necessary work force for a three years project within their country. As shown in Figure 2 a range from 15 person months (PM) to nearly 140 PM has been reported. 16 of the 24 MS calculated equal to or less than 40 PM only 8 MS reported more than 40PM. In total an average of 48 PM can be stated. The person months are allocated to several different groups of workers namely:

- Senior researchers / experts
- Research staff
- Managerial staff
- Laboratory manager
- Laboratory assistants
- Medical staff (e.g. nurses)
- Social scientists
- PhD students
- Communication experts

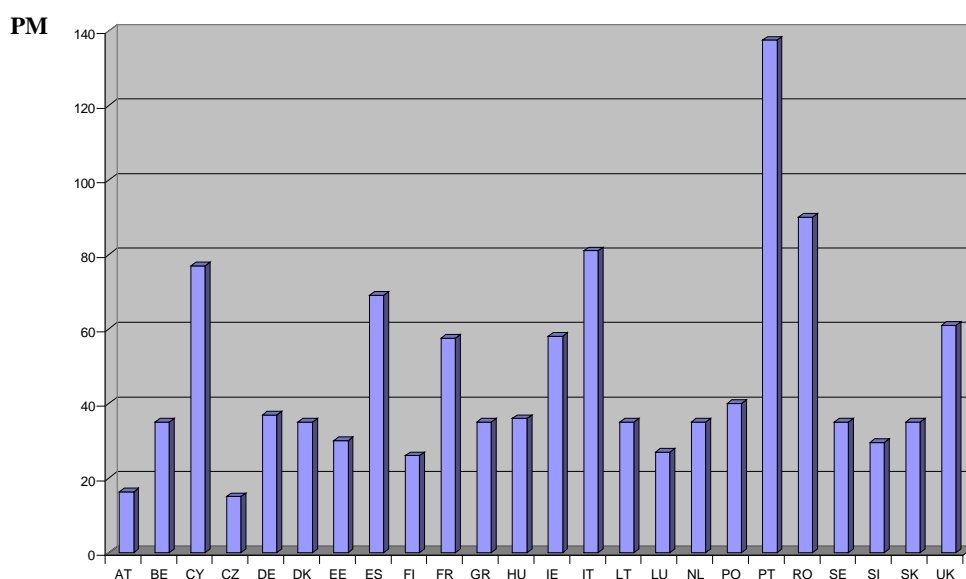


Figure 2 person months necessary for a three years HBM pilot project

Consequences on training and education

During the last two years ESBIO aimed beside others to provide a basis to build up a network on HBM in Europe and to find a commonly acceptable basic for an EU human biomonitoring pilot project. During the negotiations with Member State representatives as well as HBM experts it became obvious that large differences in the level of expertise and experiences exist among European countries.

Performing a European HBM pilot project is therefore directly linked to an effective and efficient training and education programme and corresponding capacity building. The work within a training and capacity building programme should allow mutual access to infrastructure, equipment, material, data and knowledge and should foresee extensive training efforts and exchanges of researchers and technicians.

Identification of training requirements

A first necessary task within such a programme should be to identify training requirements in the different stages (preparation, implementation and integration) which differs significantly concerning the content and the corresponding work. As not all training needs will be obvious from the beginning this will be a continuous task and the identification has to be updated consequently during the whole project.

The first stage focuses on preparatory work and it is expected that training focuses in this stage on general aspects whereas the second stage includes also the laboratory work which will bear different training needs. In stage three the main training needs will focus on the interpretation of data.

Each MS contact should be asked to identify training requirements stating precisely the problems which have to be overcome and what actions have been undertaken in this regard up to now.

Identification of training capacities / possibilities

On the other hand training capacities and possibilities have to be identified. This comprises the identification of experienced persons to do the training as well as the possibilities concerning the way to do the training (e.g. telephone conference to discuss the problem or visit of an expert, etc.).

In an EU wide HBM pilot project several different ways of training should be considered like exchange training visits, training workshops or e.g. homepage sections or electronic tools. In case a personal visit is necessary, identified experts should be contracted. A detailed work plan for the implementation of exchange visits should be elaborated already at an early stage taking into account possible combinations to avoid travel expenses. In addition there will be questions and problems which will come up in several participating MS. For these topics a quarterly compilation should be foreseen as a kind of FAQs. In addition workshops and seminars on specific topics might be helpful. As an interactive training possibility training section should be set up FAQs, an exchange forum and training courses as far as appropriate.

5. Discussion and recommendations

Taking into account the different elaborations concerning the different approaches before, it can clearly be seen that the simplest approach is assumed to cause the highest costs. The reason therefore is that the maximum of tasks have to be covered by Member States and - assuming the participation of 25¹ MS - these not that high extra efforts have to be calculated by 25 resulting in a higher total sum for the MS Units.

Not only that the additional modules bring extra advantages but also obviously reduction of costs. For example to include a central laboratory responsible for all measurements is assumed to save about 1 Mio. €. in comparison to option A. The reason for this is that all tasks regarding selection of laboratories and analysis (including QC/QM, data check and preparation, etc.) cease to apply on MS level. In contrast the cost for a Central Laboratory has to be added on central level resulting in the lowest overall costs of the options elaborated so far.

Also in option C where a Reference Laboratory is included instead of the Central Lab costs are slightly lower than in option A. As the reference lab will take over the supervision of all participating labs these cost are no longer included on MS level.

Beside the fact of higher and lower costs, advantages and disadvantages of options have to be taken into account as well. Not necessarily the cheapest option is the one with the best achievable output. It has to be considered if an option has an added value which can be achieved with only relatively small extra costs.

Option B is assumed to be the cheapest one of the three options elaborated so far. But the additional module "Central Laboratory" bears some significant disadvantages like to have no "learning effect" for the involved MS and to have no check of data by comparison. In contrast option C has some obvious advantages like the ensured quality control of the whole project results and the professional advisory function for all participating laboratories. As the quality control has to be one of the crucial aspects in the whole project the extra effort of 0.7 Mio. € (0.05 Mio. € per MS extra effort and even a lower burden on the central level) in comparison to option B seems to have a good cost-value ratio.

Against this background the workpackage 5 team highly recommends option C- basic modules and additional a reference laboratory to ensure a functional quality control element for the HBM pilot project.

In general several aspects have to be taken into consideration for a socio economic optimisation for an EU HBM pilot project which obvious leads to contradictions which have to be overcome during the planning phase.

In Figure 3 the individual steps are shown.

¹ This number has been assumed for all calculations within WP 5.

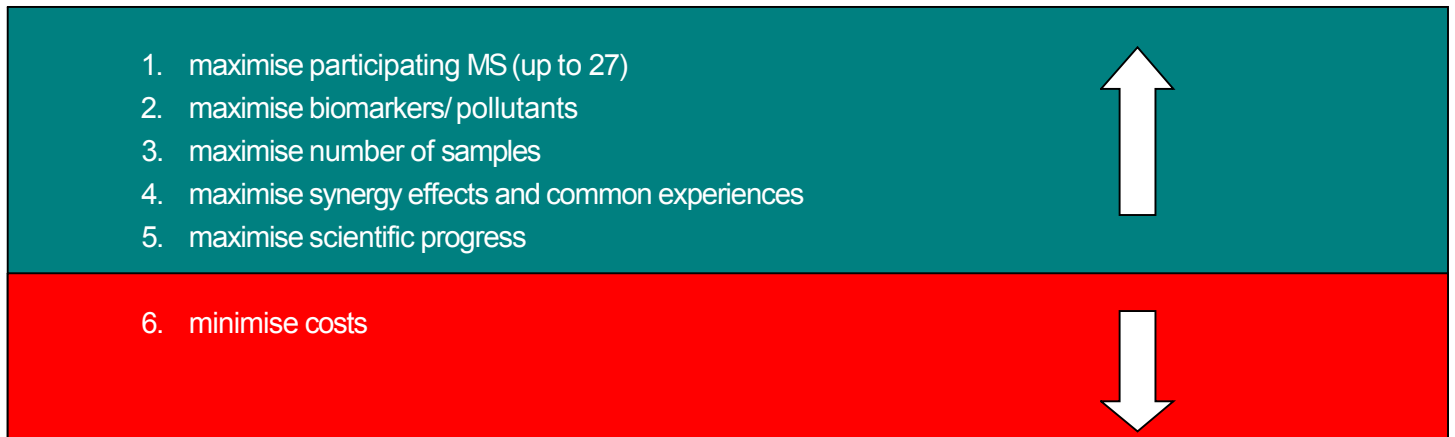


Figure 3 aspects for a socio economic optimisation

Each individual point above can afterwards be elaborated in detail:

Starting with the last but most important point to **minimise the costs** the funding possibilities have to be seen. After the failure as an Article 169 initiative a Network of Excellence has been proposed within the 7th Framework programme. This funding scheme is limited to maximum 7 Million €.

Necessary consequence thereof:

- maximise contributions of MS
- maximise in kind contributions of participating institutions
- maximise industry contribution (without generation of conflicts of interest)

6

To **maximise the number of participating MS** is of high priority due to the required “European” Pilot Project. The question which has to be answered is: What is the minimum number of participating MS to have a “European” Pilot Project?

Answer received by European experts:

- For scenario I² min 15 MS
- For scenario II³ min 5 MS (Implementation Group)

1

Strategy:

- Maximise number of MS for scenario I (see also 4)
- Accept lower resources per MS
- Accept lower resources for points 2, 3, 5

² As defined by the Implementation Group in their 3rd recommendation

³ As defined by the Implementation Group in their 3rd recommendation

In order to **maximise the number of biomarkers** the recommendation of the Implementation Group should be followed:

Scenario I: lead, cadmium, methylmercury, cotinine [out of broad list] 2

Remaining optimisation needs do exist for scenario II:

Strategy:

Collect all suggestions that meet the “min 5” – criterion⁴

Distribute resulting resources and check feasibility

In order to **maximise the number of samples** the recommendation of the Implementation Group should be followed:

Number of samples scenario I: 2 x 120 (mothers and children) 3

→ allows the establishment of preliminary reference values

Remaining optimisation: number of samples for scenario II

Point 4 synergies → use of scenario I samples for scenario II

In order to **maximise synergy effects** and common experiences and to **maximise scientific progress** the following steps have to be considered. 4

- detailed step by step optimisation with compromises between different interests
- specific work packages for training and synergies 5
- inclusion of as many scientific capacities as possible

Taking into account all these different aspects – cost considerations, impacts on work force and training, steps needed for an optimisation - will lead to a successful concept for an EU HBM pilot project approach which will meet its aims and expectations while expending minimal necessary resources.

⁴ Min 5 criterion: Suggestion of the Implementation Group on HBM in Europe in their 3rd recommendation that for substances to be included in the EU HBM pilot project at least 5 Member States have to express their interest as otherwise no harmonised approach can be tested.