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Development of a coherent approach to human biomonitoring in Europe

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Concept for coordination and follow up of the pilot project

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1. Background

For the implementation of a European pilot project on Human Biomonitoring numerous organisational tasks have to be covered. In the following concepts for the organisational structure, the information flow and decision procedures are developed.

Take already established structures into account

As harmonisation on a European scale is one key objective of the pilot project the involvement of as many Member States as possible is essential. In most of the countries human biomonitoring activities have been performed or are ongoing, functional structures have already been established. In order to keep the “organisational” requirements for the Member States as low as possible, already established structures are taken into consideration.

Input from other work packages

Especially the work already performed in ESBIO WP 2 is an essential input for the following deliverable. Within the work on deliverable 2.5 “interlaboratory comparison and proposal for laboratory work” three different options have been elaborated. These options are taken into account in the following suggestions.

Parameter in the call

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 as well as policy support for the implementation of the Environment and Health Action Plan, especially research aspects of Action 3.

The funding scheme shall be a network of excellence.

2. Concept for coordination of the pilot project

2.1. BASIC CONCEPT

Facing the fact that the EU is a community of 27 different Member States it seems obvious to be confronted with several different levels of expertise, several different needs as well as several different expectations towards an EU wide Human biomonitoring pilot project. This is reflected in the recommendations elaborated by the Implementation group on HBM in Europe proposing different scenarios which have been elaborated together with MS as well as stakeholders during the last two years.

Several European Member States have surveys in place. Leading institutions and laboratories across Europe have standard operating procedures (SOPs) as well as internal and external quality assessment schemes available for many of the biomarkers used in population studies. However, for many other Member States there are no national human biomonitoring programmes and/or it is economically unviable to keep up with a progress in instrumental analyses and address newly upcoming substances of environmental relevance. Action 3 of the EU Environment and Health Action Plan 2004-2010 requires the development of a coherent approach based on existing expertise and experiences in EU MS.

The concept is that Member States that already have significant experience in the development and execution of HBM programs might take the lead in developing the project framework and protocols based on their acquired knowledge, and provide support for Member States with less practical experience in this field. This way, experience and knowledge are exchanged among scientists, partner institutes and Member States, and an optimal transfer of knowledge and technology is guaranteed.

In Figure 1 the overall concept is shown graphically. A series of WP's for work on European Scale will deal with the adjustment of harmonised approaches, coordinate and assist the activities of the pilot project at the national level, and coordinate the evaluation of the results.

A group of WP's for Scenario I¹ will ensure all activities needed for the pilot study in the participating MS. In view of the harmonisation of the approaches and the comparability of results, all these WPs will in principle adopt the same approach and follow the same timeframe to fulfil their activities. For each participating MS a separate work package should be foreseen. In order to provide a possibility for more experienced MS, work packages for Scenario II² should deal with 'high focus' substances include harmonizing analysis and data interpretation of substances identified by EU MS.

¹ As defined in the 3rd recommendations of the Implementation Group on HBM in Europe

² See footnote 1

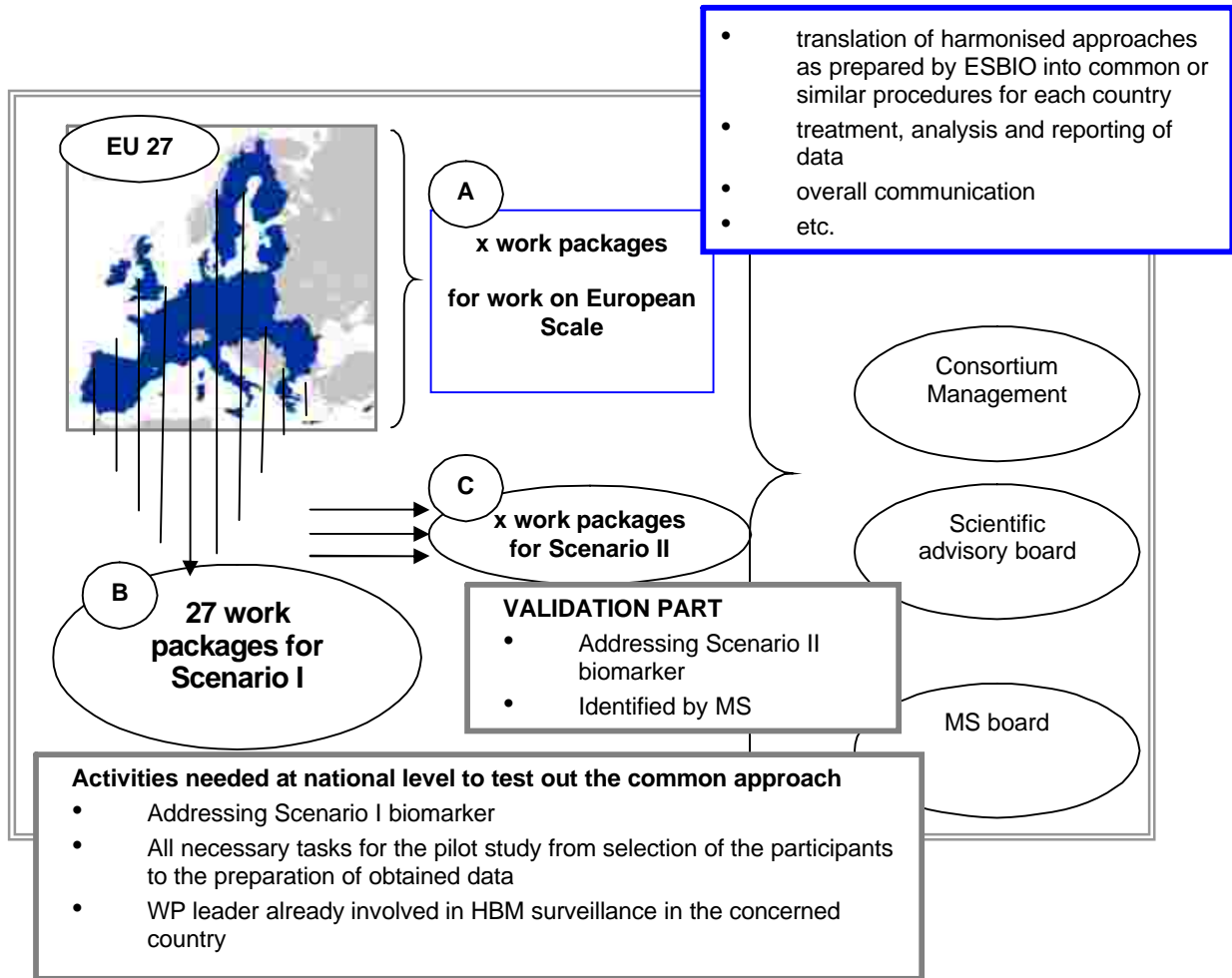


Figure 1 Overall concept

Against this background the concept proposed by the team of work package 5 is a modular conception. This means different modules are elaborated and can be combined according to the needs. Among the several modules there are basic modules which are essential for the performance of the pilot project and can not be omitted. Other more “advanced” modules can be integrated by interested Member States but are not essential to perform the pilot project.

2.2. BASIC MODULES FOR WORK ONE EU AND MS LEVEL

A) Central Unit

The Central Unit is the core module and is planned to consist of at least an EU HBM Steering Group, a Coordination & Management Unit and a Data & Information Unit. In the following the tasks and criteria for the different groups are compiled:

EU HBM Steering Group	
Composition	<ul style="list-style-type: none"> • Key experts in the field of HBM in Europe • Key experts in the filed of policy support • Management experts • (optional: Experts in the filed of HBM research) • Well balanced concerning Member States
Maximum size	5-10 experts
Tasks	<p>The main responsibility of this group should be to control and supervise the Coordination & Management Unit as well as of the Data & Information Unit (time management, financial management, quality of data, etc.) and assure the timely reporting to the European Commission as well as other EU Institutions. This group also should focus on the involvement of NGOs and industry representatives as active partners with specified roles. HBM actions may have a strong impact on societal perception of environmental health as they get pollution very personal. They should support and evaluate policy measures and contribute to knowledge of the effect of the environment on health. Therefore they need a strong collaboration with all stakeholders. Another aspect which should be covered is the communication to Sœence. The dissemination of scientific information is critical; important and far ranging issues, such as how scientific information may be used by other scientists, and how research findings are shaped to refine government regulation should be addressed.</p> <p>The EU HBM Steering Group should address also the aspect of Training and capacity building and should aim to promote knowledge and experience exchange and development in the field of HBM within the network and Europe by closely inter- related activities focusing on capacity building throughout Europe. By identifying training requirements as well as training capacities (identification of experts in different fields) an efficient and justified training work programme should be ensured.</p> <p>Beside all these tasks another important aspect which should be covered is the identification of synergies whenever possible as well as the monitoring of the harmonisation and the realisation of the overall communication.</p> <p>Based on the experiences, the synergies realised and the harmonisation achieved recommendations should be developed how HBM should be performed in the EU community to support a future oriented E&H oriented policy.</p>

Coordination & Management Unit	
Composition	<ul style="list-style-type: none"> • Management experts • Experienced in the field of HBM • Experienced to work on an EU wide project
Maximum size	2-5 persons
Tasks	<p>This Unit should address field work, such as enrolment and consent, specimen sampling and processing (handling, transport, storage), organisation of sampling conduct and confirmatory interviews (training material for staff involved) and sample processing (QA/QM, assignment and assessment of laboratory tasks, internal/ external quality control, data and result reporting, check of raw data) by means of descriptive guidelines for the implementation of harmonized protocols at MS level. All material for conducting the pilot study will be prepared, building further on the results of discussions and negotiations with MS, Commission and stakeholders. The implementation of guidelines to national operational procedures will be supported and the execution of corresponding pilot study elements in the MS will be assisted. Associated training for capacity building activities will be offered.</p>

Data & Information Unit	
Composition	<ul style="list-style-type: none"> • Experienced in the field of HBM • Statistical experts • Experienced to work on an EU wide project
Maximum size	2-5 persons
Tasks	<p>This Unit should address the format, collection and processing of data, statistical analysis, collection of additional environmental and health data at personal (questionnaires) and collective level, interpretation including description of procedure to harmonize MS results and to involve MS representatives in this process. Build upon the knowledge that has been gathered by the preparatory work of the ESBIO project, a harmonized framework for analysis and interpretation of the HBM data gathered and to analyse the data at the European level will be provided. This includes examining links of the HBM data with environment and health information from individual questionnaires and from other monitoring networks. The implementation of guidelines to national operational procedures will be supported and the execution of corresponding pilot study elements in the MS will be assisted. Associated training for capacity building activities will be provided.</p>

In addition there are several other aspects which have to be dealt with on a European level like the following:

STUDY COMMUNICATION

A specific group should focus on communication and should support communication aspects related to recruitment of participants and communication of pilot study results at individual level.

ETHICS

In close cooperation an other group should not only provide support for a strict respect of all ethical and socio-legal requirements in HBM activities and obtaining ethical approval etc, but should also continuous monitor and analyse the process to provide recommendations for steps needed to improve an EU approach to socio-legal and ethical aspects in HBM studies. This group should - based on ESBIO results- further develop the suggested common information for ethical approval and integrate the directory of EU ethical committees and data protection authorities.

B) Member States Unit

The Member States Unit should in any case be designed in a way that Member States have flexibility in the establishment and the composition of involved institutes and can use as many already established structures as possible. Therefore the number of responsible persons, the structure and specific tasks of the Units can not be defined as one structure for all MS. The following description should be regarded as a guideline for what aspects should be covered within each country.

MS Unit	
Composition	<ul style="list-style-type: none"> • Experts in the field of HBM • Experts in the performance of HBM programmes • Experts for analysis • Statistical experts • ...
Maximum size	Depends on MS
Tasks	<ul style="list-style-type: none"> • Perform all tasks of the pilot project within the MS

In any case the MS Units have to cover several tasks - therefore different working fields are recommended below which seems to be essential on the MS level. How these working fields can be combined and maybe included in the already established country specific systems should be defined by the MS representatives. For example a strong involvement of national authorities for health or environment combined with laboratories performing the analysis could be one approach.

The following working fields should be covered by the Member States:

Management and Coordination

- Adaptation of study design and procedures to national situation - including ethical aspects
- Tender of (MS) laboratories selected for Scenario I biomarkers
- National adaptation, translation of information for recruitment of participants,
- Questionnaire (prep. work, translation, validation of the translation, printing, follow up)
- Sampling material and equipment (tested proof for contamination)
- Specimen management regarding lab tasks, reporting formats and specifications and biobanking procedures

Field work

- Information to and training of field workers
- Interlaboratory comparisons, analytical quality controls and evaluation of results also including provision of documents & equipment
- Enrolment; consent; sending questionnaires, confirmatory interviews
- Specimen sampling, handling, transport and storage
- Sample analysis

Data handling (analytical results and questionnaires)

- Analytical quality control data report format
- Laboratory results and questionnaire data check (plausibility, report format, missing values, etc)
- Data preparation and transfer to Data and Information Unit (generation of raw data files)
- Fusion of raw data for national data base

Data analysis and interpretation

- Collection of available national data on environment/ health for linkage with HBM data
- Statistical processing and evaluation of results
- Generation of national report (for use in MS and EU)

Communication protocol covering communication before, during and after the project

- At individual level (to national participants)
- At collective level (anonymous data to stakeholders)

To ensure a proper project performance and the communication (in all cases e.g. for problems but also for the results and data) a central coordinator of all activities in the concerned MS is strongly recommended. This means one expert or a small team of experts which are responsible on the MS level to run the project and to act as interface between MS and Central Unit.

Figure 2 shows schematically the different Units and the correlations between them.

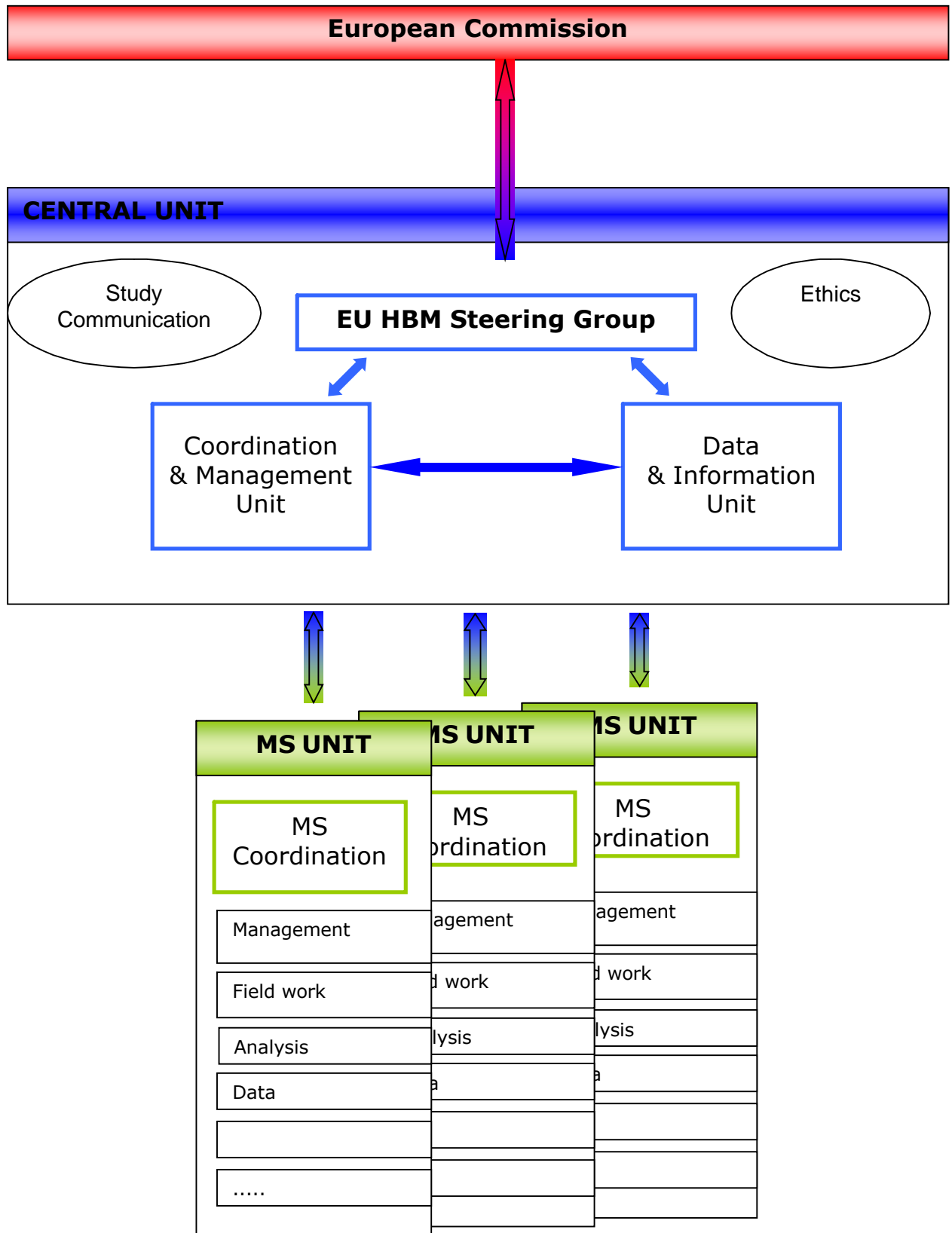
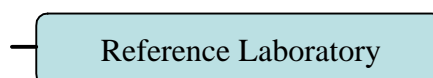


Figure 2 Basic organisational concept for the European HBM pilot project

2.3. ADDITIONAL MODULES

Below different additional modules are elaborated. It should be mentioned that some of the additional modules have to be established at the central or “EU” level others should be available on the MS level this means each MS is responsible for the establishment of the module in their MS.

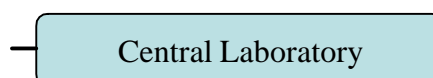
Reference Laboratory



In addition to the laboratories in the Member States one Reference Laboratory should be 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.

Advantage	Disadvantage
Quality control	No obvious disadvantages
Possible advice for all other labs	
...	

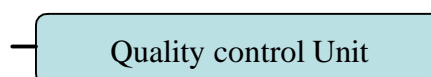
Central Laboratory



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.

Advantage	Disadvantage
Easily comparable data	No “learning effect” for Member States
Efficient use of resources	High logistical effort
	No check of data by comparison
...	...

Quality control module



Quality assurance is a crucial part of the whole project. Beside the quality control concerning the analysis (e.g. internal and external QC like round robin tests) also for the field work and the management a quality assurance system should be in use. For the performance of the quality control the Member State Units together with the labs should be responsible. The module “Quality control

Unit” can be seen as an overall check unit to ensure that all MS have well established and functional quality control systems.

Advantage	Disadvantage
Quality control can be assured in all participating MS	High extra effort
Advice for the MS on quality control issues	
...	

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.

Advantage	Disadvantage
Transparency	
Advice and input from relevant institutions	
Use of obtained data	
...	

Member States Board

Member States Board

In order to ensure the involvement of MS and the fine tuning of the project MS should play an important role within the project.

Advantage	Disadvantage
Transparency	
Advice and input from relevant institutions	
Policy relevance	
Use of obtained data	
...	

1. 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.

Advantage	Disadvantage
MS can obtain new data	Due to high costs and equipment not possible for all MS
...	...

2. Self evaluation module

Self evaluation Unit

In order to learn from the pilot project as much as possible for further human biomonitoring programmes each Member State should carry out an evaluation what could be improved and what experiences has been gained. This should comprise the Member States structure, especially the field work and the sampling treatment as well as the measurements.

Advantage	Disadvantage
Possibility to learn from the pilot project	Higher amount of work for MS
Weak points can be advanced	
...	

3. Conclusions and recommendation

Taking all these considerations into account the team of WP 5 recommends up to now the following concept for the structure of the pilot project:

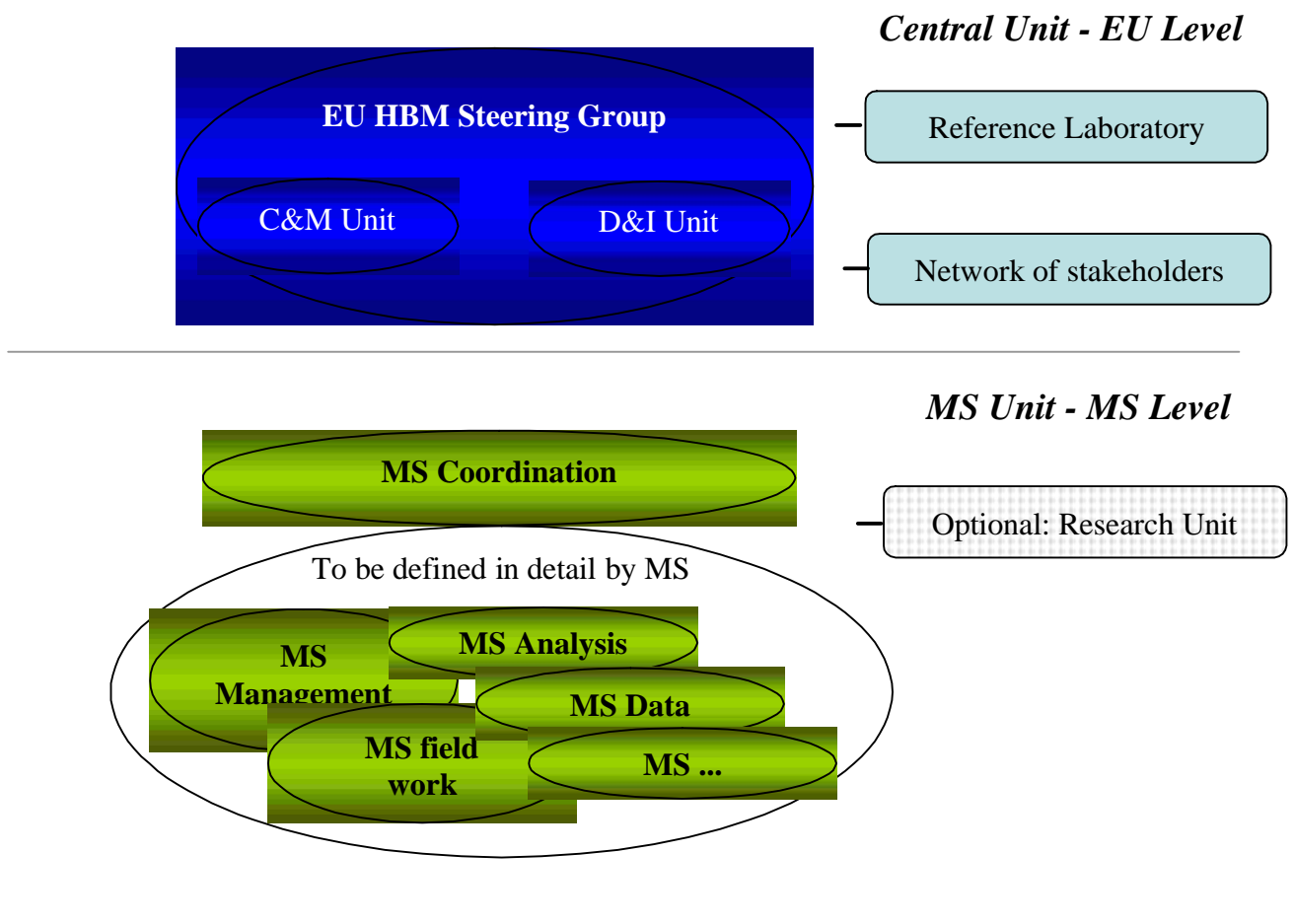


Figure 3: recommended structure

As shown in figure 2 the two basic modules Central Unit covering a EU HBM steering group and the Units coordination & management as well as data & information and the MSUnit consisting of a MS coordination and different other units to be defined by the Member States accompanied by a reference laboratory on MS level as well as a network of stakeholders is recommended.

In order to ensure reliable and comparable data in all participating countries the selection of laboratories is one of the key components. Beside criteria for the selection of laboratories (e.g. round robin test) a continuous quality control of laboratory results should in any case be included in the concept. Another positive effect would be that the reference laboratory can act as a supervision unit for all participating labs to assist them in all problems and questions.

The network of stakeholders is another essential module which is recommended to be established. Beside the possibility of a advisory function in case needed a deeply involved network of stakeholder

ensures the further use of the obtained data and the follow up work e.g. to discussed on more research needed or how can policy makers react on specific possible findings.

As some of the Member States indicated to include research as a prerequisite for their participation the module Research Unit is recommended as a option on MS level. These research modules can interact with all other MS Units as well as build up a network of Research Units to cope with more advanced tasks including the measuring of more specific pollutants and biomarkers often combined with necessary research in this field of interest as well as methodology development, validation and even research on new biomarker like the “omics”.

4. Concept for organisation and technical realisation of information flow

Background

In the performance of the EU pilot project the information flow has to be ensured for the entire project duration. Beside the communication within the project this means between involved institutions the communication with stakeholders like NGOs, industry, academia as well as the general public has to be ensured.

As not for all target groups the same content seems important organisation and realization of the information flow is elaborated in the following from different point of views.

Basis for the elaboration is the identification of a communication strategy, clear aims, target groups, tools to be used as well as the content to be communicated.

The following aims have been identified for the information flow. The list might be supplemented if further aims come up in the future discussion.

- Internal project communication to ensure the performance of the project
- Awareness raising at the political level
- Awareness raising at scientific level
- Awareness raising at public level
- Support for recruitment of study participants
- Answers and complementarities to industry / NGO campaigns
- Inform the public and stakeholders about the campaign
- Information about the individual and collective results and their significance for public health

It is necessary to differentiate target groups as the aims are not relevant to all possible actors or the whole European population. At a first approach it seems to be adequate to have five target groups.

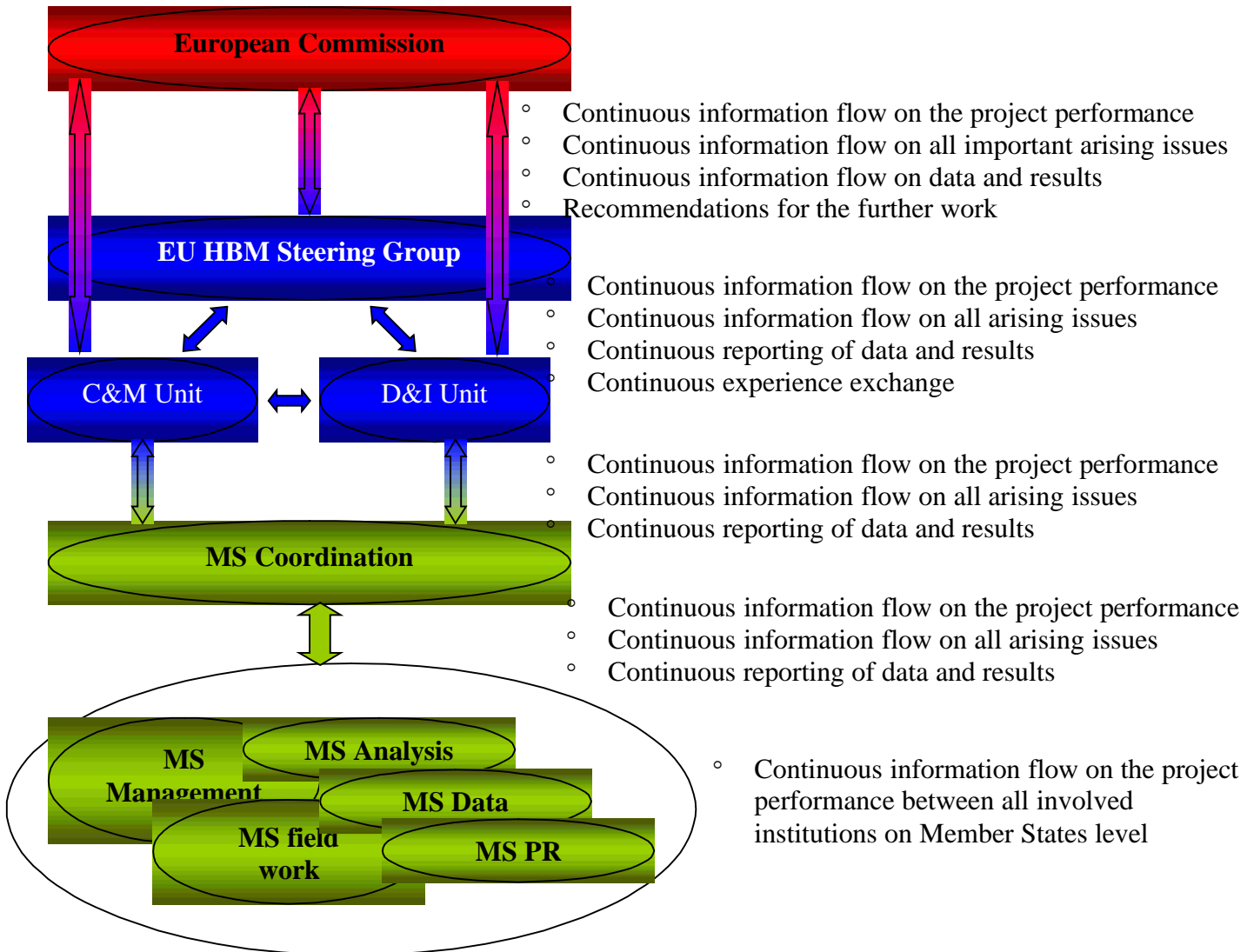
- In the project directly involved institutions
- Whole population
- Stakeholders, NGOs, Industry, Scientific community
- Possible study participants and directly involved actors in HBM (hospitals, laboratories, etc.)
- Decision makers at EU level
- Decision makers at MS level

There are different tools available to reach the target groups and to achieve the aims like brochures, videos or events. Also here it depends on the target group which tool is needed and appropriate.

The identification of contents to be communicated is a continuous task. The task should be done in close cooperation with Commission Services and Member States during the whole project duration.

Internal project information flow

To ensure an objective driven project performance some regular information flows have to be in use. Assuming the basic modules from the structural concept above the following information flows should be ensured:



For the additional tools the information flow depends on the level (MS or Central level) the module is established. In case of the MS level the communication with the MS Steering Group should be ensured, for Central Level the communication flows should be established with the Coordination & Management (C&M) Unit, the Data & Information (D&I) Unit or directly with the EU HBM Steering Group.

In any case it should be guaranteed that the defined ways for the information flow are followed to avoid confusions and exclusions of relevant institutions.

To ensure these continuous information flows regular dates should be defined accompanied by the way used for the communication (e.g. meeting, status reports, deliverables, etc.).

Meetings and Reports

On the Member States level all involved actors are encouraged to establish regular meetings to exchange experiences and to discuss on the data obtained and the further work. It is recommended to have at least one meeting every quarter accompanied by status reports.

On the central level meetings of the EU HBM Steering Group on the one hand side with the MS Steering Groups and on the other hand the EU Commission Services have to be established. The meetings with the MS Steering Groups are recommended to take place every half year; status reports should be requested more often. Meetings with the Commission Services should take place quarterly also accompanied by status reports.

To elaborate these fields of interest more precise information on the performance of the pilot project is needed. Therefore these elaborations can be regarded as a first assumption but can be adapt as soon as the parameters are known.

External project information flow

According to the basic concept described in the paragraph background, the external communication is manifold. Different target groups have different aims of communication and needs therefore different content to be communicated.

In the further work on this topic target groups have to be defined as well as the aim and the content to communicate. In any case the overall communication with stakeholders, the scientific world as well as the general public should be carried out by the EU HBM Steering Group and in specific cases by the MS Coordinations. However the communication with participants should be done in coordination with the MS Coordination.

5. Concept for decision procedures

As essential requirement for a functional decision management clearly defined structures have to be identified. Taking into account that decisions have to be taken mostly fast and without complications one essential requirement is to keep the main circle of involved actors which are in the position to decide as small as possible but still appropriate and functional. Based on the recommended organisational structure the following units should be considered within the concept for decision procedures to be in the position to decide:

- European Commission
- EUHBM Steering Group
- MS Coordination

For all other units and participating or involved institutions should have advisory function but should not have the possibility to decide without the acceptance of one of the above mentioned units.

The approach proposed is a bottom up/ top down approach as shown in the figure below.

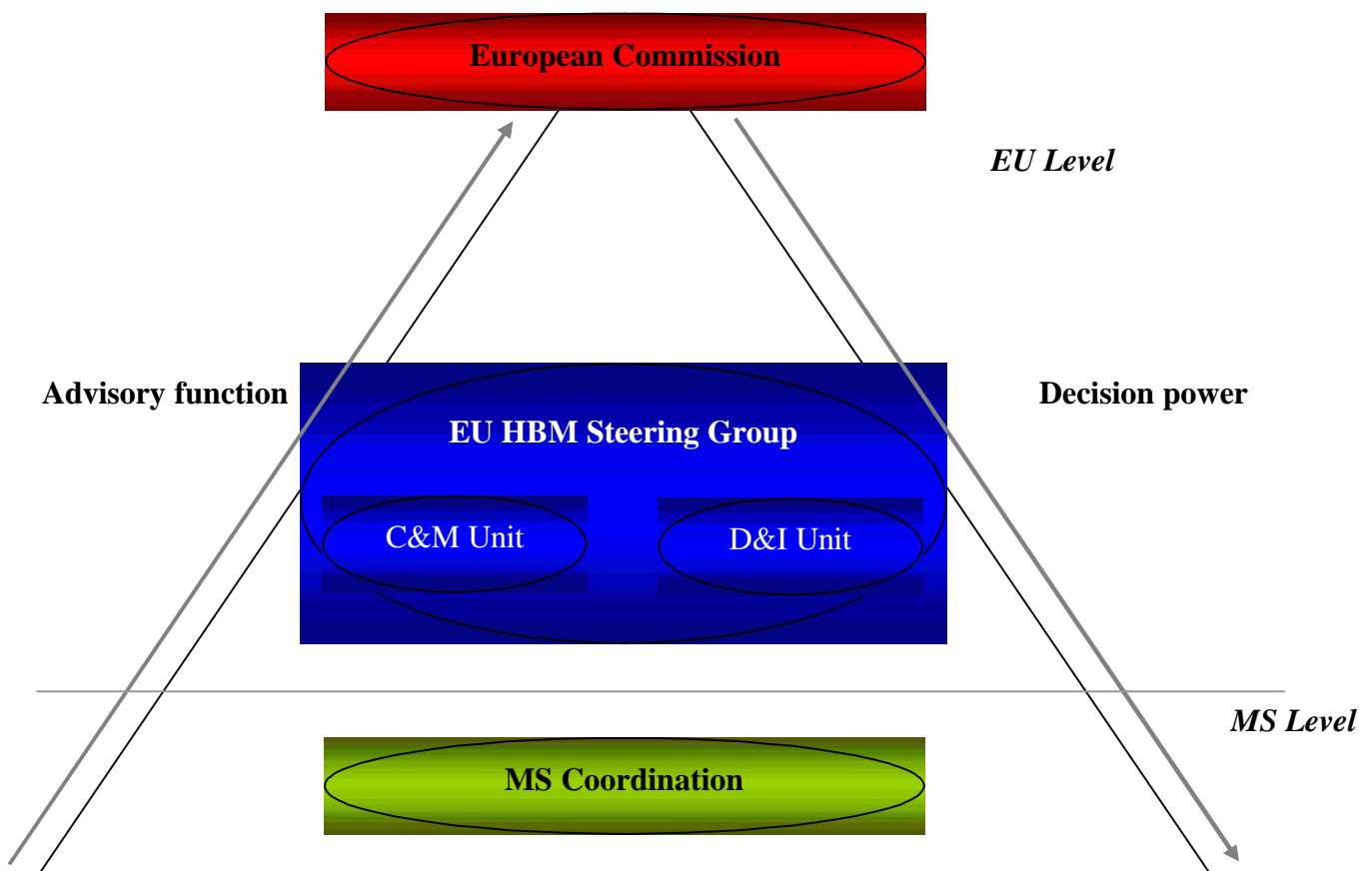


Figure 4: top down / bottom up approach

On the one hand side the decision power decreases from European Commission over the EU HBM Steering Group to the MS Coordination but on the other hand the advisory function increases in this order.

It can be clearly seen that the European Commission followed by the Central Unit (top down) hold the overall decision power. Issues arising at the EU level can not be decided without the acceptance of the European Commission. Decisions having to be taken on MS level have to be accepted by the EU HBM Steering Group and the EC.

In order to avoid decisions based only on one Unit the advisory function has to be established. This means that no decision can be taken without asking for advice of the other involved parties. Here the bottom up approach is followed. The European Commission can not take a decision without asking the HBM Steering Group for advice as well as the EU HBM Steering Group has to ask for advice of the MS Coordination.

As a lot of details are still unknown in the concept for the pilot project it is foreseen to elaborate the decision procedure further in the following months.

6. Follow up of the pilot project

During the project running time a special focus was laid on the expectations and needs of Member States, policy representatives as well as scientists. From Member States especially the following expectations could be noted:

- To support existing national public health policies (e.g. promoting tobacco free society);
- To check efficiency of reduction measures of emission sources (do forbidden substances disappear?);
- To deal with concerns about increased exposure, emerging public health concerns (flame retardants);
- To deal with concern about exposure at levels close to those where effects can be expected/ measured;
- To support Existing Substances Regulation under REACH;
- To produce status quo assessments of exposure;
- To support health education;
- To assess respective contribution of sources;
- To deal with legal obligation to assess current levels in specific subpopulations;
- To answer request from EU Parliament (to measure methyl mercury);
- To envisage possible linkage to existing cohort studies and other monitoring infrastructure.

These expectations face a number of perspectives which might be realised by an HBM pilot project:

- Structures and (standard operational procedures) available for further European projects, data assessment and analysis of critical chemicals;
- Possibility to get national activities involved in a European context; comparability of national and EU wide data;
- Long term assessment factor for European and national policy;
- Potential for a pan European radar for upcoming endangerments (warning system);
- Prevention framework e.g. in case of disasters, terrorist attacks (relation number of samples information value);
- Possibility to use results in REACH and other policy programmes;
- Systematic integration of scientific progress in environmental health care system;
- EU wide educational tool (involving citizens in environmental health issues- highlights transboundary character);

Against this background a possible scenario for human biomonitoring after a successful HBM pilot project might be as shown in the following:

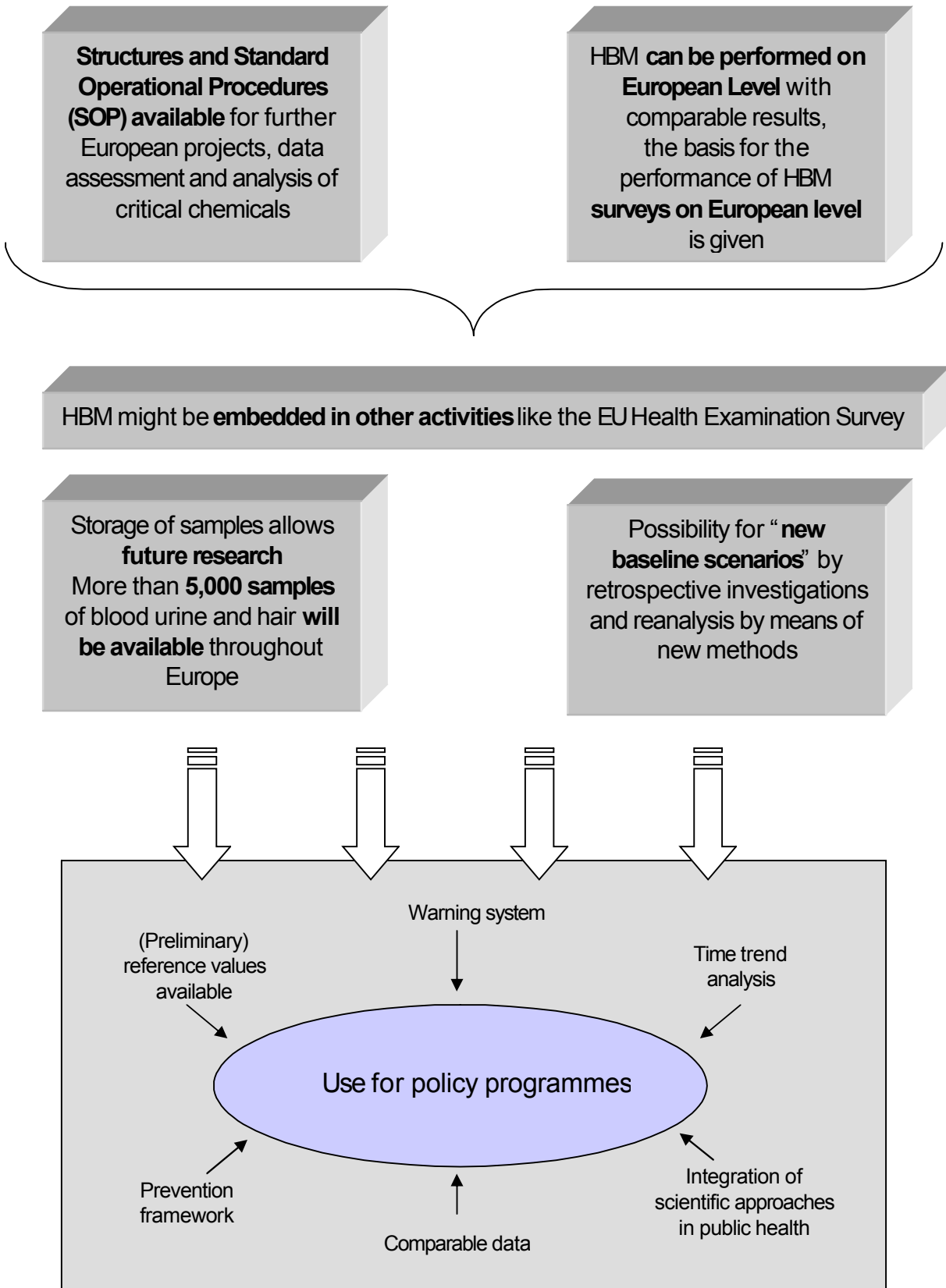


Figure 5 follow up of the pilot project