ESBIO
Expert team to Support
BIOmonitoring in Europe

022580 (SSPE)

ESBIO

Development of a coherent approach to human biomonitoring in Europe

Coordination Action

Priority 8.1

PUBLISHABLE FINAL ACTIVITY REPORT

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BiPRO GmbH

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1 PROJECT EXECUTION

1.1. ESBIO – GENERAL BACKGROUND

The European Environment and Health Strategy adopted by the European Commission in 2003 presented a new vision on how to address environment and health in an integrated way and puts health in the centre of environmental policy. Based upon the Strategy the Commission adopted in 2004 a Communication on the Environment and Health Action Plan 2004 – 2010. In Action 3 of this Action Plan the European Commission announces to develop a coherent approach to Human Biomonitoring in Europe in close cooperation with the Member States (MS).

For the implementation of Action 3 the Commission has set up a Technical Working Group on HBM (TWG), consisting of HBM experts from several EU MS including Croatia. This TWG has been expanded to include more Member States and is now called the Implementation Group (IG).

Given the complexity of the issues a STEP-BY-STEP approach has been set up for the realisation of action 3:

The first step (2004-2006) consisted of the technical preparation of the European pilot project. For this reason the EU Commission has launched the ESBIO project, scheduled for 24 months. The project team comprises 22 institutions from 17 EU Member States and Croatia.

During the two years project running time the team prepared successfully the second step - to test out the developed coordinated approaches in an EU HBM pilot project.

The ESBIO project tasks were allocated to 8 work packages dealing with:

- The establishment of an electronic inventory on HBM activities
- The drafting of guidelines for best practise on an co-ordinated approach
- The drafting of guidelines for integration scenarios
- Considerations on ethics issues
- Socio economic consequences, communication and follow up activities
- The utility and sensitivity of biomarkers
- Management of the consortium
- Overall communication

In Figure 1 the dependencies between them are shown graphically.

Work package 1, the updated inventory on ongoing biomonitoring had impacts on all other work packages in a direct and/or indirect way. WP 4, 5 and 6 aimed together with WP 2 at the establishment of a coordinated EU wide approach to be tested in a pilot project. A close relation between work packages 2 and 3 assured an appropriate regard of the integration of environment and health aspects in the coordinated approach. The overarching task of coordination and management of the consortium is related to all work packages.

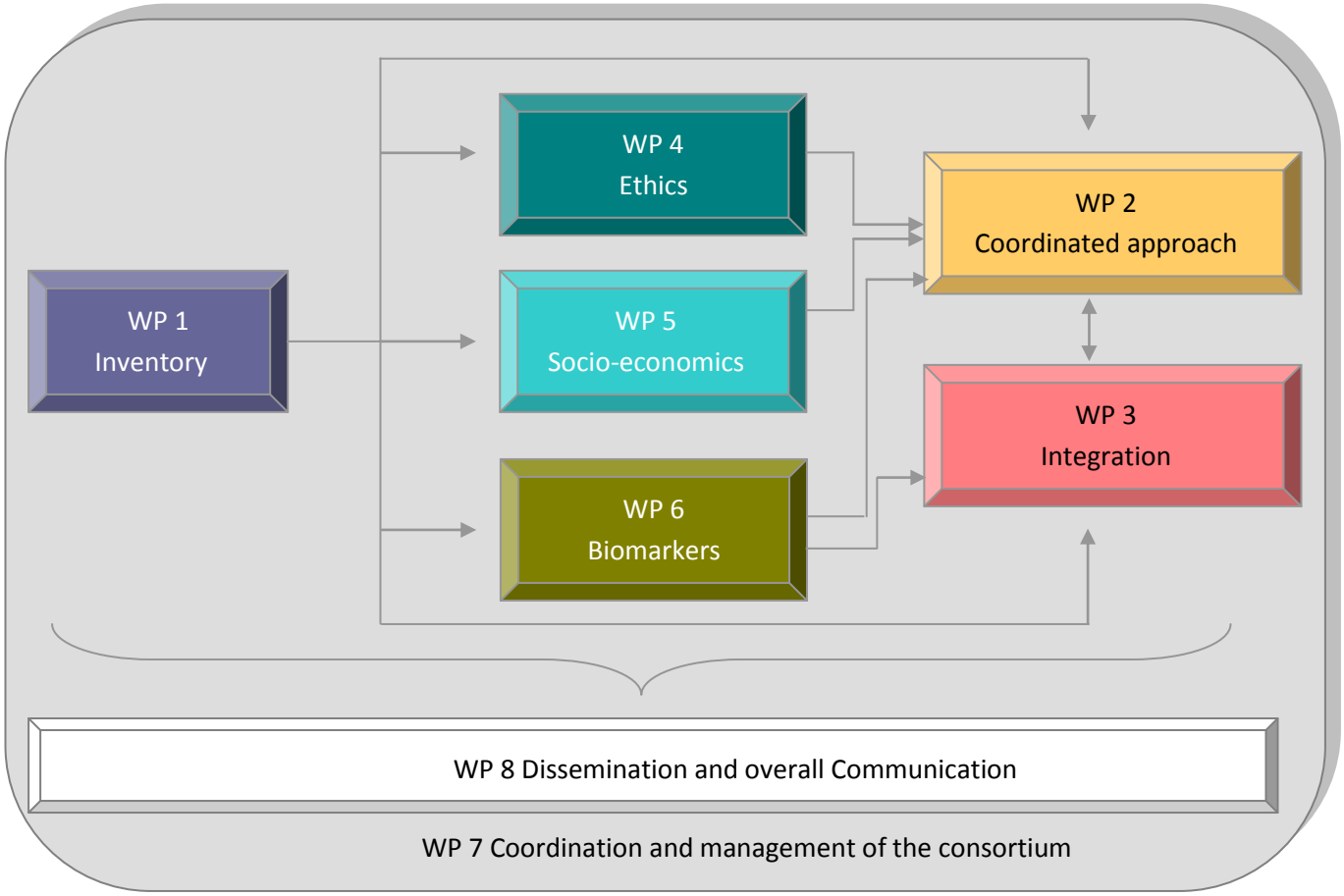

Figure 1 Dependency between work packages

1.2. PROJECT OBJECTIVES

The project was outlined as coordinated action which aimed to enable networking and co-ordination of those institutes playing an active role in European biomonitoring research with a focus on the integration of environmental monitoring and health data and those institutes transposing research results into policy programmes. Accordingly, very close and intensive networking and co-ordination of the involved parties was crucial in order to achieve the overall objectives:

(1) development of a coordinated approach for biomonitoring based on existing expertise and experiences available in Member States surveillance programmes and results from research

(2) elaborate how biomonitoring results can be integrated most efficiently with environmental monitoring and registered health data

(3) develop strategies to communicate biomonitoring results to stakeholders (populations affected, regulators, politicians) including the establishment of websites publicly available and with links to national and international activities resulting in full transparency for all stakeholders

(4) elaborate scenarios for the use of biomonitoring results for policy making

1.3. CONTRACTORS INVOLVED

ID	Participant name	Short name	Country
1	BiPRO GmbH	BiPRO	DE
2	Flemish centre of Environmental Technology	VITO	BE
3	Federal Environment Agency	UBA	DE
4	Nofer Institute for Occupational Medicine, WHO Collaborating Centre	NIOM	PL
5	Instituto de Medicina Preventiva, Faculdade de Medicina de Lisboa	IMP	PT
6	University of Copenhagen	UCPH	DK
7	University of Leuven	KUL	BE
8	National Institute of Public Health Surveillance	InVS	FR
9	ENVIRON	ENV	NL
10	State General Laboratory, Ministry of Health	SGL	CY
11	Initiativ Liewensufank asbl International Baby Food Action Network	IL-IBFAN	LU
12	Shell Health Services / CONCAWE	SHELL	BE
13	Institute for Medical Research and Occupational health	IMI	Croatia
14	ARPA Lombardia	ARPA	IT
15	National Hellenic Research foundation	NHRF	GR
16	Institute of Environmental Medicine, Karolinska Institute	IMM, KI	SE
17	Regional Authority of Public Health Banská Bystrica	RAPH	SK
18	National Institute of Public Health	NIPH	CZ
19	Federal Environment Agency	UBA-A	AT
20	Finnish Institute of occupational Health	FIOH	FI
21	Health Protection Agency	HPA	UK
22	National Institute for Health Development	NIHD	EE

1.4. WORK PERFORMED AND WORK PACKAGE RESULTS

In **Fehler! Verweisquelle konnte nicht gefunden werden.** a brief overview on the work performed in the individual work packages is provided.

Table 1 work performed within ESBIO

WP	Working field
1	▪ Preparation of the conference "State of the art on HBM in Europe" ▪ Development and maintenance of an electronic inventory of Biomonitoring research and non research activities ▪ Preparation of the related website www.hbm-inventory.org ▪ Concept of an EU platform for exchange of expertise and experiences
2	▪ Objectives of EU HBM Approach and the EU pilot project ▪ Proposal for pollutants and biomarkers ▪ Draft questionnaire for the Pilot Study ▪ Proposal for harmonised way of collecting and analysing selected pollutants and for data management ▪ Models for inter-laboratory comparison and proposal for organisation of laboratory work ▪ Proposal for population sampling, recruitment and biological sampling
3	▪ Scenarios for integration of HBM data with environmental & health data (exposure-dose-response triad) ▪ Concept to establish biomonitoring as a policy making tool ▪ Guidelines for integration scenarios and implementation strategies for biomonitoring (Practical guidelines on what information will be needed for interpretation and which (statistical) analyses may be useful)
4	▪ Information sheets on regulations regarding data protection and on regional ethics committees for the majority of ESBIO countries ▪ Preparation of workshop on "Ethical practises and communication in human biomonitoring" ▪ Proposal for communication to study participants
5	▪ Cost calculations for the pilot project ▪ Socio economic optimisation ▪ Communication Concept ▪ Follow up of the pilot project
6	▪ Report on the utility and sensitivity of biomarkers
7	▪ Project coordination
8	▪ Preparation and maintenance of the website www.eu-humanbiomonitoring.org ▪ Preparation and maintenance of the website www.hbm-inventory.org ▪ Workshop on "Ethical practises and communication in human biomonitoring" ▪ Supplement issue in "Environmental Health" ▪ Conference "State of the Art on HBM in Europe" ▪ Special issue of the "International Journal of Hygiene and Environmental Health" ▪ Workshop on the utility and sensitivity of biomarker ▪ Overall communication ▪ Poster and brochure ▪ Link to other projects

In the following a summary for each work package comprising the work performed, results achieved and if appropriate methodologies applied are given.

1.4.1. WP 1 – INVENTORY

WP1's general aim was to address shortcomings in the registration and communication of European-wide HBM activities. Deficiencies in the availability of information and its exchange between stakeholders were judged to constitute an impairment to the development of a coherent approach to Human Biomonitoring (HBM) and were addressed specifically through the creation of an inventory of ongoing or recent European HBM activities and the organization of a conference dedicated to the state of the art of biomonitoring in Europe.

Concurrently, WP1 aimed to contribute to other WPs by providing them with an overview of the existing situation in terms of HBM activities conducted in Europe, allowing technical, synergic, socioeconomic and ethics strategies to be developed for application in the future European pilot project.

a) Conference on the "State of the art of human biomonitoring within Europe"

As part of the strategy of coordinating a European-wide approach to HBM, a Conference on the "State of the Art of Human Biomonitoring within Europe" was held in Lisbon from March 19th to March 21st 2006. Organization responsibilities were undertaken by WP1 leader's team along with other ESBIO participants, with the support of several national institutions, namely the University of Lisbon's Faculty of Medicine; the High Commissioner's Office for Health; the Directorate General of Health; the Institute for the Environment; and the Science and Technology Foundation at the Ministry of Science, Technology and Higher Education.

The Conference brought together providers of HBM information with the aim of improving existing information on HBM, identifying experts and institutions performing HBM research and surveillance activities, providing a forum for the discussion of problems in conducting HBM and stimulating the exchange of experiences.

Bridging a wide spectrum of topics in the thematic area of HBM, the Conference was divided into "Oral plenary sessions" given by invited speakers and "Oral and Poster presentations", by scientists and decision makers, providing a very comprehensive program, summarized as follows.

After the Conference welcome, the opening session included two keynote lectures on the "Context and background of Action 3 of the EC Environment and Health Action Plan 2004-2010" and "Introduction to ESBIO objectives and work".

Session 1 was dedicated to an "Introduction to HBM, objectives and key issues", the overall theme of Session 2 was "HBM activities within Europe" subdivided into three main topics: "country case studies", "HBM studies or activities developed in Europe by WHO, Industry and NGOs", and "state of the art and the way forward of updated inventory of HBM in Europe and of the pilot project to be launched by the end of 2006". Specific topics of these sessions were "HBM addressing exposure",

"HBM addressing adverse effects on health or quality of life", and "Integration of Environment and Health data: use of HBM as a tool for policymaking". Session 3, with a keynote lecture from the US Centre for Disease Control and Prevention, was dedicated to "USA perspectives on HBM".

More than 100 HBM experts from 20 European countries and beyond European borders listened to 14 keynote lectures and 26 oral presentations and participated in a 57-poster exhibition. Many productive discussions took place during the conference days and the aim to provide a forum for exchange of information was fully met. Short and full papers from keynote lectures, as well as from oral or poster conference presentations, were submitted and published in a special edition on HBM of the International Journal of Hygiene and Environmental Health[1].

b) Updated inventory and overviews

In order to benefit from experience and maximise existing efforts already made towards achieving similar aims by the Technical Working Group for Biomonitoring of Children, which had been set up by the European Commission in the framework of the "Environment & Health Strategy" [2,3], the starting point for the creation of the inventory was data on Environment & Health biomonitoring activities, either ongoing or recent (last ten years), and related to children within Europe, collected through a questionnaire sent by the TWG for Biomonitoring of Children to institutions and researchers all over the continent.

A new strategy was designed and implemented to update the existing inventory and overview in a form that would facilitate their continuous updating over time. Working steps included, in a first phase, an analysis of content[4] of all the 103 returned questionnaires to the former inventory. In this "analysis phase", all responses to every question were compared to each other, in order to identify a maximum number of specific keywords related to the question under analysis.

In a second phase, a systematic organization of identified keywords in a coherent set of questions (the "new form") was performed[5], having in mind three complementary objectives: 1) maintenance, as much as possible, of the structure of the "old" questionnaire; 2) short, clear and closed questions on all issues addressed by the "old" questionnaire; 3) availability of as many alternatives for answer as

1 International Journal of Hygiene and Environmental Health: Volume 210; Issues 3-4; May 2007.

2 TWG Biomonitoring of Children, 2004a. Baseline Report 'Biomonitoring of Children' in the framework of the European Environment and Health Strategy, COM(2003) 338 final http://www.brusselsconference.org/Download/baseline_report/BR_Biomonitoring_final.pdf

3 TWG Biomonitoring of Children, 2004b. Report on an Action Plan and Options for Action for 'Biomonitoring of Children' in the framework of the European Environment and Health Strategy, COM(2003) 338 final, http://europa.eu.int/comm/environment/health/finalreports_en.htm

4 Bardin, L., 2004. Análise de conteúdo. Edições 70, 3ª edição, Lisboa (in Portuguese)

5 Hill, M. and Hill, A., 2002. Investigação por questionário. Edições Sílabo, Lda, 2ª edição revista e corrigida, Lisboa (in Portuguese)

possible (based on identified keywords and from literature search) and the possibility to insert new alternatives in an additional field, in order to ensure no question went unanswered.

The third phase was simultaneously devoted to the construction of a website (http://www.hbm-inventory.org) to make the "new form" available online, and of a mailing list, as complete as possible, to send out the website link and to invite institutions and researchers involved in HBM activities to fill in the form for every HBM activity in progress or finished during the last 10 years. Invited users were also asked to send that link to other potential responders. In the following picture the welcome page of the website is shown.

Figure 2 Welcome page www.hbm-inventory.org

Based on this new form designated as the "European Inventory on Human Biomonitoring Activities (EIHBA)", another form was prepared to complement the updated inventory on HBM activities within Europe. The work began with a literature search, resulting in an extensive review of papers published during the last 10 years, mainly on surveillance and research involving human biomonitoring in Europe. Similarly to the procedure for returned questionnaires, the content of collected papers was also analysed, in order to identify relevant keywords. Identified keywords were also included in a coherent questionnaire structure, comprising another new form named "Database of Published Articles on European Human Biomonitoring Activities (DPA/EHBA)", completed for every published paper selected during the search.

Registration of an activity or a published paper must be preceded by registration as a user, which is a simple and quick process involving the completion of a form, where the user's work institution is a required field, acting to a degree to validate introduced data.

The form-completion interface through floating windows allow fast access to each group of questions and means the form can be filled in gradually, over as long a time interval as the user requires, and saved between sessions.

It was agreed that limited access to available information should be provided to anyone visiting the site, in order to draw in new users by providing a glimpse of the inventory's scope and usefulness. As such, "reference books" providing ready-to-use specific overviews of general interest are available to any user, whether registered or not, through a direct link. "Who is who in the EU HBM field?" provides a list of all registered users, with a summary of the registered activities they are involved in; whereas "EU HBM activities: all or by country" lists registered activities, with start and finish dates and contact person's details, and allows filtering by country.

These overviews, formatted as printable "reference books", have the advantage of being a comprehensive and cheap way to disseminate information on what is going on related to human biomonitoring within Europe, from the double perspective of "who is doing what" in the field.

If further filtering or cross-referencing of data is required, to address, for example, specific biomarkers (of exposure, effect or susceptibility) or parameters like duration, budget, population group, etc, a querying functionality can be employed, adding to "who is doing what" information on "how", "where" and "when". These user-defined searches can only be performed by registered users and include basic overviews (resulting from a single search criterion) and more complex searches which allow the user to select an unlimited number of question/answer options from the form and link them with logical operators (AND | OR | NOT | IN), producing frequencies along with the search results. The real time data management system means that the system's response time to complex user queries is short and the results are up-to-date as the search is performed on all data entered until that specific moment.

Furthermore, if the queries specifically address the analytical laboratories used by at least one user in the development of human biomonitoring, a Reference Book on HBM analytical capacity within Europe is available listing all the registered laboratories, contact persons, address and, potentially, relevant Laboratory information for potential users. This advertisement tool for the laboratories can be discussed as a complementary means of financing the continuation of the inventory.

A message board is also available to registered users. Besides being posted on the message board web-page and saved to its history list, the content of the message is also sent by e-mail to all registered users. In addition to its use by users to post questions on a specific topic and obtain answers from the registered community, the message can also be used for administrative functions, informing users about events and issuing reminders to register new activities and maintain data on existing activities up-to-date.

c) Concept for an EU web platform and for the continuation of the inventory

A concept for an EU Platform on HBM (EP-HBM) was defined and its potentialities demonstrated through a number of functionalities already implemented. The concept developed will embody a dynamic system for the management and integration of HBM interests, supported by a web-based structure. It aims to assemble the state-of the-art of scientific knowledge in the HBM field and, by promoting an active exchange of information and expertise between all interested parties, act to bridge the gap between science and policy-making. Specifically, it will enable the systematization and organization of disperse data on HBM activities and the exchange of ensuing information and experience between all interested parties, open to extension at international level beyond European borders and with international institutions.

Management functions will include online organization of HBM-related events and of data, based on implemented functionalities, open to further developments but already used by the forms and websites to update the inventory, search the databases and post and send messages to other users.

Once the system is created, the responsibility for its upkeep is attributable not only to its promoters but specially to all those who will benefit from the promising platform outcomes: a) timely information generated by the analysis of input data; b) advantages offered by a common forum for exchange of knowledge and experiences between teams and countries, including international institutions; c) high potential for better co-operation among scientific, societal and political sides. As such, the platform's usefulness depends on all players' participation, suggesting that the identification of sources and invitation to provide material should be regular automatic tasks ensured by the system.

Given the necessary conditions, implementation steps will include a number of actions such as: identification, motivation and mobilization of all relevant players for continuous participation; development of additional information dissemination and deployment strategies; definition of user access profile, implementing a practice for openness and transparency, under respect of data contributors' permission; development of platform use indicators, for example by monitoring user access and information delivery, in order to shape the proposed solution for present and future challenges in the HBM field.

1.4.2. WP 2 – COORDINATED APPROACH - GUIDELINES

The main objective of work package 2 was translated to six deliverables which covered all key aspects to set up a harmonized EU Human Biomonitoring Pilot-Study. That entailed the defining of potential objectives of the Pilot Study, a proposal on pollutants and biomarkers required, the general Pilot Study design and the development of the questionnaires on exposure and socio-demography to be used in the Pilot Study. Furthermore it comprises the elaboration of concepts for a harmonised way of

sampling, analysis and data treatment, and lastly guidelines on organisation and comparison of laboratory work.

The work programme was characterized by close cooperation within ESBIO and with members of the Implementation Group on Biomonitoring (IG), respectively. Only such an approach enabled the pooling of different existing knowledge and various ideas/expectations.

a) ESBIO Objectives

The first and basic task of work package 2 was to define the objective of the EU Human Biomonitoring Pilot Study. Working on this subject the political background on which ESBIO was built had to be considered.

In June 2004 the Commission launched the Environment and Health Action Plan, covering the period of 2004-2010. The «E&H Action Plan 2004-2010» proposes an integrated approach involving closer co-operation between the health and environment research areas. Its added value shall be the development of a European System, integrating information on the state of the environment, the ecosystem and human health to render the assessment of the environmental impact on human health more efficient. To this end, the «E&H Action Plan 2004-2010» outlines three key elements, whereby the first element reads: "improving the information chain by developing integrated environment and health information".

In order "to understand the links between sources of pollution and health effects", Action 3 of the Plan reads: "Develop a coherent approach to biomonitoring in Europe". Therefore, the overall objective of the pilot project was finally outlined as:

To test the hypothesis that HBM can be performed in a coherent and harmonised approach throughout Europe by means of commonly developed protocols, strategies and scientific tools ensuring reliable and comparable data, whilst also leading to a more effective use of resources involved.

Thus, the pilot project focuses mainly on the organisational, technical, logistic and infrastructural feasibility of a pan-European biomonitoring, in place of immediately utilizable scientific research or survey results, generated from a large-scale experiment. However, the unique opportunity of a coordinated HBM-activity of Member States with all sorts of capacities and experience was regarded an extra-added value.

In addition the following particular objectives of an EU-Pilot Study on human biomonitoring were defined:

- To gain practical knowledge of access to study populations, recruitment procedures and response rates
- To test the developed guidelines, protocols and technical procedures for field work, chemical analyses, data handling and processing and the questionnaires
- To test ethical guidelines and gain experience on ethical rules, within the frame of social and legal aspects of the different Member States
- To receive practical information on overall performance of participating MS units including the laboratories involved via an inter-laboratory comparison
- To collect biomonitoring data from different European countries
- To obtain preliminary reference values of selected biomarkers from all participating MS
- To obtain basic data on the distribution of biomarkers among the proposed study populations
- To assess the costs of the applied HBM-programme, preferably including a concept to improve time and cost efficiency
- To collect basic data for the development of initial scenarios for the translation of biomonitoring results into risk management and environment and health policy

However, the first attempt of an EU-wide biomonitoring programme would be characterized mainly by the scrutiny of the technical and operational feasibility, aiming at the development of a European framework for surveillance. Such development should be seen as a research effort in itself.

b) Biomarkers

The proposed biomarkers have been divided into two scenarios, whereby Scenario 1 forms the obligatory element and Scenario 2 the facultative part of the pilot project. A lengthy review and discussion of currently known biomarkers revealed that for both scenarios only biomarkers of exposure which are covered by sufficient analytical experience in terms of validated analytical methods of adequate sensitivity, specificity and precision are at this moment regarded as suitable to develop and test a harmonized approach for HBM at the European level. The availability of appropriate reference materials guarantees the required internal and recommended external quality assurance like round-robin-tests.

As a general rule, with regard to the type of specimen material, urine is regarded superior in ranking to blood (invasive, more critical to collect, ethical concerns) and to hair (limited to only a few -widely accepted- biomarkers).

Scenario 1: lead in blood, cadmium and cotinine in urine and methyl-mercury in hair

Scenario 1 contains three heavy metal pollutants and one biomarker of ETS-exposure, all of which are of public health concern due to their largely recognized toxicity and for which toxicological assessments are available (e.g. threshold/HBM-values, PTWI). On top of this, validated analytical methods for sufficiently sensitive determination are readily available and assumed to be established in the Member States. Cost efficiency of the chemical analyses has been considered as well.

Scenario 2: a number of organic (emerging) pollutants

Scenario 2 does comprise additional biomarkers of exposure which do not fulfil all of the criteria defined for Scenario 1. However, Scenario 2 offers the eligible opportunity to include current pollutants of concern into the framework of the pilot project at Member State level. A list of potential pollutants including phthalates, PAH, pyrethroids, organophosphate-insecticides, as well as per-fluorinated and poly-brominated chemicals has been compiled.

c) Study design

The study design depends on the objectives and questions to be answered. The assessment of an operational structure for a harmonized EU-HBM-Project needs a different study design than the assessment of hot-spots within the EU. Within ESBIO all possible options were discussed with regard to their advantages and disadvantages.

Since the Environment and Health Action Plan 2004-2010 threw a focus on children the study population of the pilot project should reflect this emphasis. In that regard, children were foreseen to represent the prime target group. In order to arouse public interest, to gain access to and acceptability for future surveys on children and to cope with the preference of several European Member States for a broader view and an approach addressing the whole population, it is recommended to include the children's mothers into the scope of the pilot project. Though the proposed biomarkers of Scenario 1 are of lesser concern regarding a pre-natal mother to child transfer, the facultative pollutants of Scenario 2 bear health relevance for the future offspring.

Table 2 Suggested study design

Topic	Option of choice
Country	Only MS providing financial resources
Population segment	General population (urban/rural/industrial)
Age group	Children aged 6 to 11 years and their mothers, aged 22-45 years
Type of study	Cross-sectional
Sample size	240 participants (120 mother-child-pairs)

Management	National Study Centre
Choice of sampling locations	Performed by MS

Table 2: Continuation

Topic	Option of choice
Selection of participants	Embedded in already existing health care systems, such as medical examinations at schools or children's health monitoring programmes

Children and their mothers should be recruited in a way to be as representative as possible for the general population under study or subgroup of interest of the country or region. Random sampling would be the ideal manner. However, with regard to the pilot project such an approach is not feasible and a less sophisticated sampling scheme is recommended as a start. In regard to the pilot project a trifocal recruitment in each area -urban, rural and industrial- is suggested as a minimum, but should be extended as much as existing structures and capacities of participating Member States allow for. Table 1 gives on overview on the basic options concerning the study design.

Within the work of work package 2 strategies to perform field work were successfully discussed with all advantages and disadvantages. The most important and basic strategies concerning field work that were finally recommended are briefly shown in Table 3.

Table 3 Recommended options for field work

Topic	Option of choice
Information/invitation	Written invitation/information
Consent	By parents and children
Compensation	Depending on MS legislation
Personnel	Trained medical personnel
Seasonal Bias	Same season in all MS
Place of examination	Visit at an examination centre (blood sampling)
Way of contact	By phone or a personal letter
Subcontractors	Possible, decision by MS
Reporting results	Essential

Duration	Max. 2h
Questionnaires	To be filled out by the parents

The most important prerequisite to perform field work is written consent signed by the participants.

The legal imperative to obtain an informed consent of the participant and practical implications and recommendations concerning parent's consent and/or minors assent for the EU Pilot Study were elaborated by ESBIO work package 4.

d) Questionnaires for the Pilot-Study

Under the leadership of work package 2 a questionnaire was developed and reached a ready to use status. The ESBIO group proposes a self-explanatory auto-questionnaire which shall be completed by the participants/parents within 45 minutes. The questionnaire is divided into four sections.

1. The In-/Exclusion Section is aiming at the (pre-selected) mothers and addresses eligibility criteria and willingness to participate.
2. The Socio-Demography Section shall be filled by participants only and addresses social determinants.
3. The Environment and Food Frequency Section shall be filled by the participating mothers and is supposed to facilitate the individual and overall exposure assessments by elucidating the parents and children participants' association with known (or suspected) exposure sources of various domains (indoor/ambient, food, lifestyle habits).
4. The Admission and Sampling Section addresses very basic health-related matters and the guided documentation of specimen collection. This section shall be managed by health officials only.

e) Proposal on organisation of laboratory work

Among several options to organize laboratory work the option shown in Figure 3 has been chosen. To illustrate the figure the task of the different players have been defined and listed in Table 4.

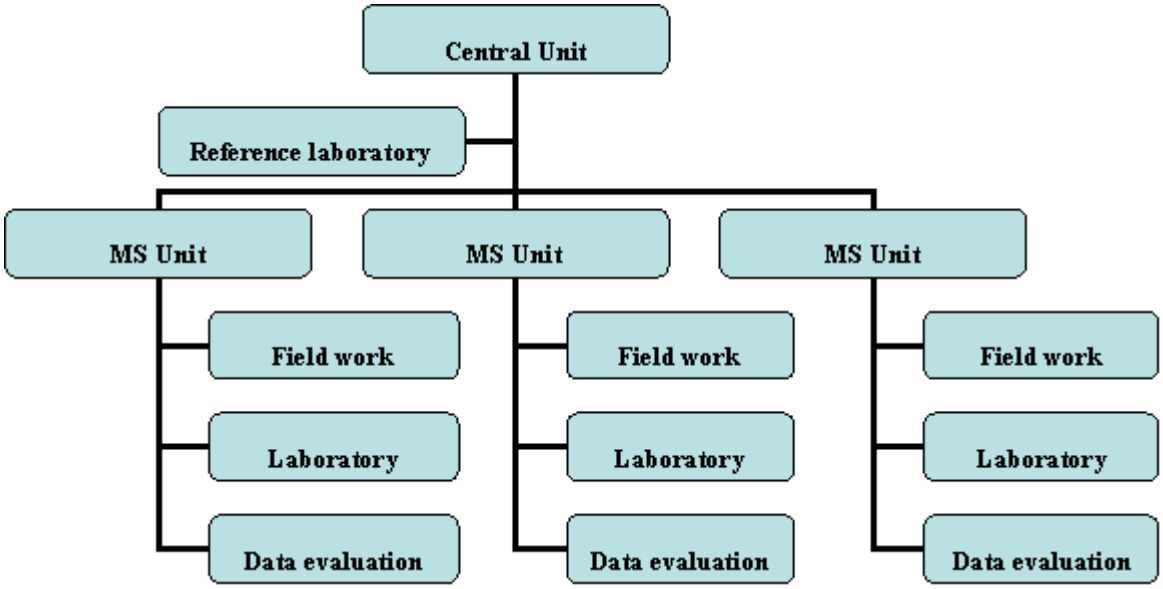

Figure 3 **Concept to share laboratory tasks**

Table 4 **Description of tasks regarding chemical analyses**

Unit	Task
Central Unit	To distribute ESBIO guidelines for • invitation of laboratories to participate • selection of laboratories • quality control measures • the data check among the MS units. To publish terms of reference for a reference laboratory on the EU level To select the reference laboratory To organize training activities or exchange of scientists among MS Coordinate the evaluation of results in MS, preparation of an overall report
Reference laboratory	To facilitate data comparison by implementing EU round robin tests To specify quality criteria for the methods applied in the MS To re-analyse samples from the different countries To assist Central Unit and MS in capacity building in the MS To identify needs for training

Table 4: Continuation

Unit	Task
MS Unit	To publish terms of reference on the country level To select a laboratory To supervise sampling and organize sample transport To organize and supervise quality control measures To provide samples to the reference laboratory To check incoming data To evaluate data To prepare a report
Laboratory	To analyse incoming samples in short term To conduct quality measures To participate in the EU round robin tests To provide data (samples and quality control) in short term
Note	This concept offers the possibility for capacity building in the MS under the guidance of the reference laboratory in case the relevant expertise and capacities are not available.

f) Guidelines for sampling, chemical and statistical analysis

To conduct a human biomonitoring study on a European scale is a challenging task. Beside clarification on the study design emphasis must be laid on a harmonised way of collecting and analysing the samples and on data management. Data management and handling is part of the post-analytical phase which also requires closer attention. The transfer of data from the lab to the data analysing unit is a critical step and should be performed following strict rules.

This background makes it quite clear that guidelines for all critical steps in conducting human biomonitoring are essential for the successful implementation of a European wide human biomonitoring approach. The guidelines listed in Table 5 were developed in work package 2 addressing the additionally mentioned details. The guidelines reached a ready to use status.

Table 5 Guidelines to perform an EU-wide human biomonitoring developed in ESBIO

Guideline	Issues considered
Sampling	Types of specimen, partition, transport, storage, quality control
Chemical analysis	Sample preparation, analytical methods, quality control
Data management	Laboratory and questionnaire data, generating a data base
Data Treatment	Description of samples at large, statistical analysis, reporting
Laboratory selection	Development of selection criteria

Table 5: Continuation

Guideline	Issues considered
Invitation to tender	Descriptions for scenario 1 and scenario 2
Evaluation of proposals	General procedure and special considerations

In order to work out guidelines for conducting the Pilot Study the work package leader (the Department of Environmental Hygiene of the German Federal Environment Agency) could draw on experience gathered by conducting representative population studies. The most relevant is the German Environmental Survey (GerES). GerES is a large scale population study which has repeatedly been carried out on adults in 1985/86, 1990/92 and 1998 and on children aged 6 to 14 years in 1990/92 (GerES IV). The Department of Environmental Hygiene has conducted several additional national studies in human biomonitoring focussing on children and was collaborating partner in multicentric studies like the ISAAC (International Study on Asthma and Allergies in Childhood) and the PEACE (Pollution Effects of Asthmatic Children in Europe) studies.

Current scientific methods like literature research, internet research and discussions with external and internal experts, inter alia, with members of the German Human Biomonitoring Commission, were used as well. Last but not least the close cooperation with core work packages of ESBIO should be mentioned.

1.4.3. WP 3 – INTEGRATION

Work Package 3 (WP3) focused on two specific items, on the one hand the possibilities to integrate human biomonitoring (HBM) with other sources of information such as environment and health data, and on the other hand outlining how HBM data could be used for policy makers and risk managers. Mainly based on literature research, identification of relevant databases, and previous experiences in large-scale HBM survey programs, such as the Flemish or German HBM projects, an overview of the current knowledge regarding these two items was developed. Through discussion with the other partners in the ESBIO working group, ideas were further developed, illustrated and expanded. Because of the sensitive and innovative nature of the topics handled in WP3, often lengthy discussions and extensive rewriting or reformulating of draft documents was necessary to reflect the viewpoints of all ESBIO Members. The work finally resulted in the completion of a number of guidelines or concepts on (1) the possibilities to link HBM with environment and health data, (2) how HBM data may be translated into advice for policy makers and risk managers, and (3) the identification of other research projects and policy development areas with which a European pilot project on HBM could interact and benefit from.

The work of WP3 has cumulated in the finalization of three deliverables that provide an extensive overview of the work done and reflects the many discussions had by the entire ESBIO group.
Deliverable D3.1 (Scenario's for integration of human biomonitoring with environmental monitoring, health monitoring and with research) aimed at identifying opportunities for integration HBM with environment and health data. This document provided an overview of:

- The available data on pollutant concentrations in air, water, food (quality and quantity) and other relevant environmental compartment as sources of exposure;
- The past and current projects dealing with health data for the 4 key health issues within the European Environment and Health Action Plan:
    - (Childhood) Cancer
    - Neurodevelopmental disorders
    - Asthma and respiratory diseases
    - Endocrine disruption
- Possible ways to link human biomonitoring data with both environmental and health data through either Physiologically-based pharmacokinetic (PBPK) modelling or spatial epidemiological statistics methods (e.g. Geographic information systems (GIS) and Bayesian Statistics)

The document identified available data, but also highlighted where no immediate information was available. In the overall assessment, 5 criteria were taken into account to identify data availability and quality on different sources of information on environmental exposure and health responses:

- Availability (is data available for all Member States?)
- Harmonization (are all Member States measuring and reporting the same data?)
- Geographical context (Is the data covering all Member States, and the whole Member State?)
- Quality control (is there a central controlling agency/institute that guards the quality of the data, and are specific quality control measures in action?)
- Policy developments (what are the current and foreseen policy evolutions for the selected sources of pollution and health outcomes?)

An overview of the findings of Deliverable D3.1 is schematically presented in Figure 4.

Deliverable D3.2 (Concepts to establish biomonitoring as a policy making tool on a European level including description of advantages and consequences) aimed at the development of a concept on how HBM could be used as a policy making tool. Therefore, a "Multistep Approach" was developed that outlines which steps need to be undertaken to translate HBM data into policy action, trying as much as possible to prioritize among different pollutants measured and different Member States. The Multistep approach will eventually lead to:

1. Aggregation of individual data based on geographical entities;
2. Determine whether there is a deviation (increase/decrease) at the aggregated level in one or more biomarkers measured;
3. Determine the seriousness of the deviation, based on a variety of expert opinions;
4. Set priorities in order to deal with these deviations;
5. Track the causes of these deviations, retrace pollutant loads to potential local, external sources, and identify the different actors that may contribute to the pollutant body burden;
6. To suggest appropriate risk reduction strategies, taking into account the relevant knowledge, actors and opinions;
7. To communicate with the general public and policy makers in a transparent and objective way, proposing and motivating different policy options.

This "Multistep Approach" has particularly been developed for chemicals proposed by the Implementation Group on HBM in Europe as Scenario I chemicals in their 3rd recommendations[6], as they are generally considered 'data-rich' substances and a full-chain assessment of their environment and health relevance is relatively straightforward. Additionally, it was highlighted how chemicals listed as Scenario 2 chemicals offer opportunities for policy making, despite the obvious fact that they do not necessarily fulfill all criteria for Scenario 1 biomarkers (largely recognized toxicity, available risk assessment, validated analytical methodologies and sufficiently sensitive determination, cost efficiency), but have raised the attention of different Member States for a number of reasons (e.g. phthalates, brominated flame retardants, perfluor compounds,…). While the general options for policy interpretation of Scenario 1 chemicals also stand for Scenario 2 chemicals, some additional considerations need to be taken into account. Hence, an additional chapter was dedicated to provide guidance on how Scenario 2 biomarkers could offer optimal information for policy makers and risk assessors, which could be narrowed down to two distinct, yet complementary directions:

1. If not all requirements are met to be classified as a Scenario 1 biomarker, can data still be used for policy implementation?
2. What information is needed and which steps need to be taken to "upgrade" biomarkers from Scenario 2 to Scenario 1?

Part of this work resulted in the development of a publication "Translating biomonitoring data into risk management and policy implementation options for a European Network on Human Biomonitoring", which will be published in the proceedings of the ESBIO Workshop on Ethics and Communication, organized in Copenhagen by ESBIO WP4.

Deliverable D3.3 (Guidelines for integration scenarios and implementation strategies for biomonitoring results to be tested in the pilot study) again brings together a number of key aspects

6 http://www.eu-humanbiomonitoring.org/doc/ig_rec3.pdf

and recent policy developments which the future European Network on Human Biomonitoring needs to take into account:

- HBM and REACH: it was briefly outlined how HBM data may assist in the REACH assessment scheme, and also how HBM will benefit from REACH, mainly due to the generation of more and better toxicity data;
- HBM and health examination surveys: In many countries, large-scale HBM survey projects are linked to health examination surveys. Also for the European pilot project on Human Biomonitoring such a liaison would be possible in terms of the FEHES[7] project, which studies the feasibility of a pan-European Health Examination Survey;
- HBM and INSPIRE: Geographical information systems may offer an excellent opportunity to combine environment, HBM and health data under one currency, being the spatial location of the data. In order to optimally integrate HBM data with other sources of information, a geographically representative sampling scheme for the European pilot project on Human Biomonitoring is advisable, although it remains until now uncertain what this sampling scheme could look like.

Again, some of the work for Deliverable D3.3 has been rewritten in the form of a publication (Human biomonitoring and the INSPIRE Directive: Spatial data as link for environment and health research) which will be submitted for publication soon.

Overall, no obvious departures from the objectives of WP3 were made. Generally, the objectives identified in the Description of Work of the ESBIO project were attained. The interpretation and policy implementation of HBM data is one of the hottest topics in environment and health research at this moment, and at this moment, no gold standards exist against which to evaluate the different procedures and concepts. Integrating HBM data with environment and health data and their subsequent translation into policy making is a highly innovative area, and will remain one of the key objectives of large scale HBM survey projects for many more years to come.

[7] Feasibility of a European Health Examination Survey; http://www.ktl.fi/fehes/

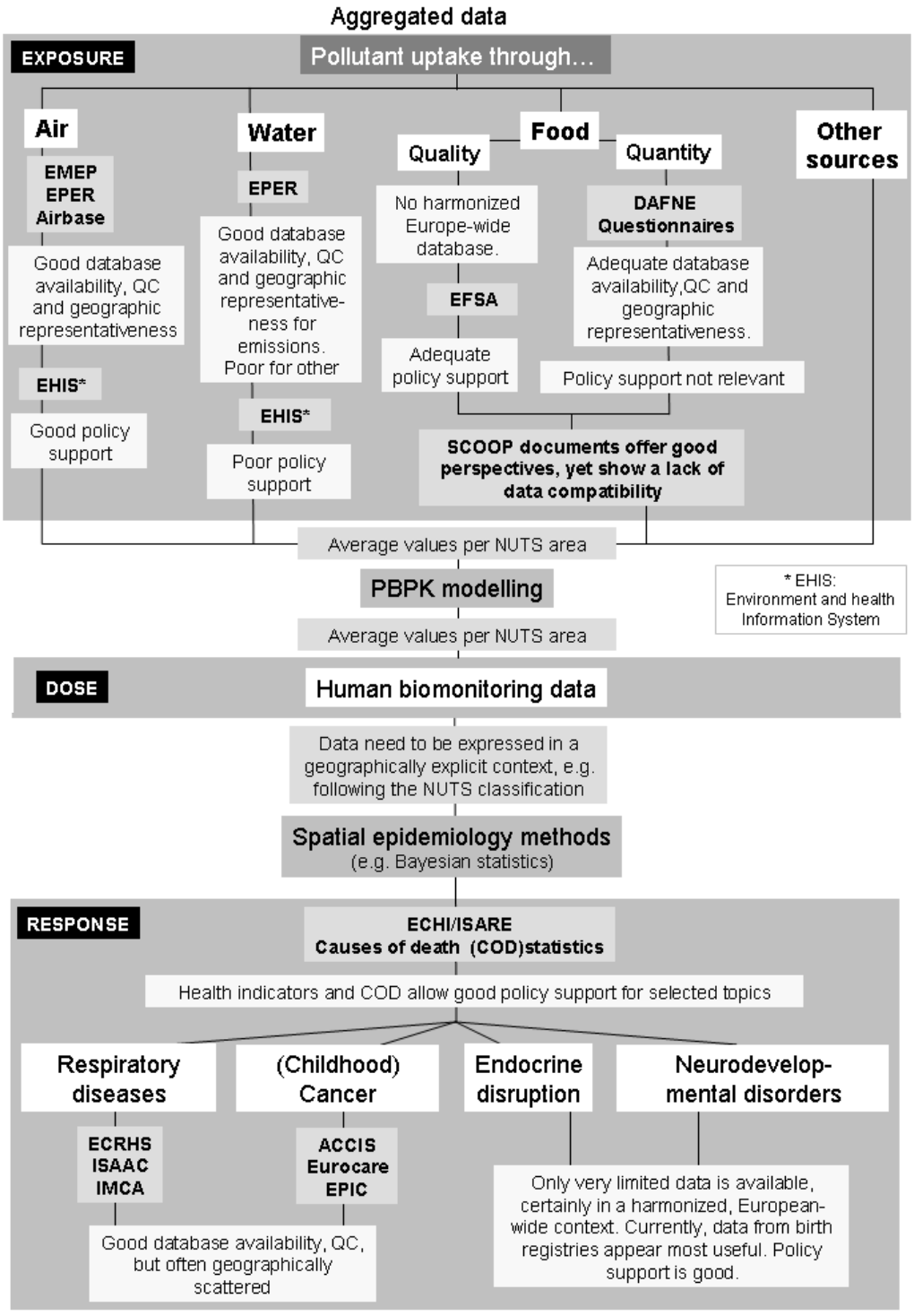

Figure 4 **A schematic representation of the Exposure-Dose-Response-triad identifying challenges and opportunities for Europe**

1.4.4. WP 4 – ETHICS

This work package implies knowledge on how ethical issues are already practiced in the different countries and projects, current legalisation and optimal harmonised procedures. The first step consisted in analysing existing information from the inventory already established, at the PRIVIREAL webpage. The second step was to update information about national practices through the partners of ESBIO and selected national key persons by use of a structured questionnaire. WP4 of the Expert team to Support BIOmonitoring in Europe (ESBIO) organised a 2 day workshop 11-13th March 2007 at the EEA and organised by University of Copenhagen to exchange experiences and comment on guidelines for dissemination and communication of results within participants of human biomonitoring. Stakeholders were invited. The program consisted of keynote lectures, discussions and poster presentations. Proceedings of the meeting with contributions from most speakers are edited by Lisbeth E. Knudsen for a special volume of Environmental Health

Conclusions and recommendations

For the pilot project it is recommended to develop protocols covering common issues

- Hypotheses to be tested regarding HBM exposures in populations and differences related to environmental exposures – background levels, spot exposures, vulnerable populations
- Methods to be used
- Selection and recruitment of study persons (special issue with children – directly via family or through schools), sampling (which media and how much) and processing and storage of samples, analysis
- Results and results interpretation
- Information strategy prior, while and after study
- Informed consent
    - Information about study
    - Procedures (sampling, questionnaire, monitoring, follow-up, data protection)
    - Sign to participation in separate parts
    - Agree to store samples and biobanking/future uses
    - Agree to use samples for purposes of environmental health studies
    - Agree to share results with other researchers, policy makers
- Biobanking
- Reporting
- Data protection
- Data sharing
- Follow-up

From the ESBIO WP4 a number of research questions have been developed related to exploration of biological citizenship, empowerment of participants, concepts of environmental health and biomonitoring, expectations towards policy makers.

Work package 4 entitled “ethical rules and practise, social and legal aspects” implies knowledge on how ethical issues are already practiced in the different countries and projects, current legalisation and optimal harmonised procedures.

An overview on available practices regarding data protection and ethics committees has been developed in the form of information sheets on regulations regarding data protection and on regional ethics committees.

The sheets are available within Deliverable 4.1/4.3 of ethics and data protection in the following countries: Denmark, Estonia, France, Germany, Ireland, Lithuania, Netherlands, Poland, Portugal, Slovak Republic, Spain, Sweden and UK.

Feed back from a number of ESBIO members to ethics questionnaire has been received from Germany, France, Italy, UK, Belgium, Czech Republic, Cyprus, Estonia, Luxembourg, and Slovakia.

The successful workshop held in Copenhagen March 2007 with more than 50 attendants from industry, governments, science and European countries of Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Italy, Luxembourg, Netherlands, Poland, Portugal, Romania, Slovakia, UK and USA will result in proceedings to be published in Environmental Health.

A survey of the European practices in informing, consenting and managing studies of children in pregnancy, prenatal and postnatal made within the ChildrenGenoNetwork stated that: “there are no uniformity and agreement in Europe about the procedures and contents of the process of informed consent.” It was recommended that the following elements should be taken into consideration in human biomonitoring studies:

Competence- the person(s) giving consent must be deemed mentally competent to do so. In the case of research on children, the researcher has responsibility for deter-mining whether or not the parent/legal representatives is in a fit state of mind to give consent.

Information -sufficient information must be given for the person to make an informed choice. It is through communication and the information sheet that the level of information provided is determined. The information sheet, prepared by the researcher, is assessed by the Research Ethics Committee (REC) although there are few guidelines as to a minimum standard of content.

Understanding - the person giving consent must be considered capable of making a reasoned choice. The researcher obtaining consent must judge the level of under-standing of the participants(s).

Voluntariness - the person giving the consent must do so voluntarily and must recognise that withdrawal from the study is possible at anytime without this affecting care.

One of the major problems and deficits in conducting biomonitoring in children, identified by SCALE: “For many biomarkers the link to health risk, especially at the individual level, is not well defined. Reporting of these results to the individual may therefore be problematic. Ethical questions on

communication and access to own data (right to know, right not to know) are therefore raised: e.g. is it acceptable not to report on the individual results? Also communication with the public was reported to raise difficulties and to need careful consideration and preparation. An active involvement of professionals in the field of communication and sociology may contribute to resolving these constraints."

Work package 4 implies knowledge on how ethical issues are already practiced in the different countries and projects, current legalisation and optimal harmonised procedures. The information from the questionnaires provided valuable information. The first step consisted in analysing existing information from the inventory already established and interviews of stakeholders (study persons, researchers, paediatricians, regulators, politicians, patient's organisations, ethical boards etc.) Opinions of a number of different stakeholders (see figure below) were collected during the project time in order to further investigate the processes of information of study persons as diverse views and understanding of the advantages and limits of human biomonitoring may cause ethical conflicts.

Study planning	Researchers, Statistician, Communities, Participants representatives
Funding	Regulators, Politicians, Industry
Study approval	Ethics boards (regional and/or institutional)
Sampling of biological material	Study persons, Parents or other relatives, School teachers, Patients organisations, Nurses, Technicians, Paediatricians, Researchers
Analyses of biological samples	Researchers, Technicians, Statistician
Communications of results	Researchers, Paediatricians, Nurses, Technicians, Media
Follow up	Regulators, Communities, Industry, Participants representatives

1.4.5. WP 5 – SOCIO ECONOMIC CONSEQUENCES, COORDINATION & COMMUNICATION

Work package 5 focused on several different aspects: the assessment of socio economic consequences of different study approaches, a model for the coordination, a communication concept and follow up possibilities of an HBM pilot project.

a) Socio Economic Consequences

In order to perform a socio economic optimisation for a future EU HBM pilot project first of all tasks necessary for a HBM pilot project have been identified. For the assessment of socio economic consequences an Excel based tool has been developed which enabled the project team to see at one glace the consequences due to changes in individual cost items.

For different approaches cost calculations have been prepared showing in detail the necessary resources on MS as well as on EU side.

Taking into account the advantages and disadvantages of each approach elaborated it could clearly be shown which approach provides the best cost-value ratio.

For all calculation a cost share of roughly 50:50 for MS and Commission has been assumed.

For the favoured approach which consists of an EU Central Unit, individual Member State Units, reference laboratory as well as stakeholder and MS boards, an average budget of about 480.000€ per MS for a three years project has been shown as necessary. During the project time DG Research published a call for the EU HBM pilot project and a team comprising institutes from 24 MS applied for it. Within this proposal it can clearly be seen that the majority of the MS calculated between 300,000 and 600,000€ for the project which is in line with the above mentioned average. Almost only countries with a low income level calculated less than 300,000.

As regards the impacts on jobs, an average of about 50 PM necessary to perform the study could be identified allocated to the following different groups of workers:

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

b) Coordination

As a second aspect the project team worked on a concept for coordination of a HBM pilot project proposing different work levels, i.e. performance of the pilot study should be done in each country by a national team; the harmonisation, support and evaluation of the study and its results should be done on EU level by multinational teams. In order to take into account the different levels of existing experiences a research-component should be established.

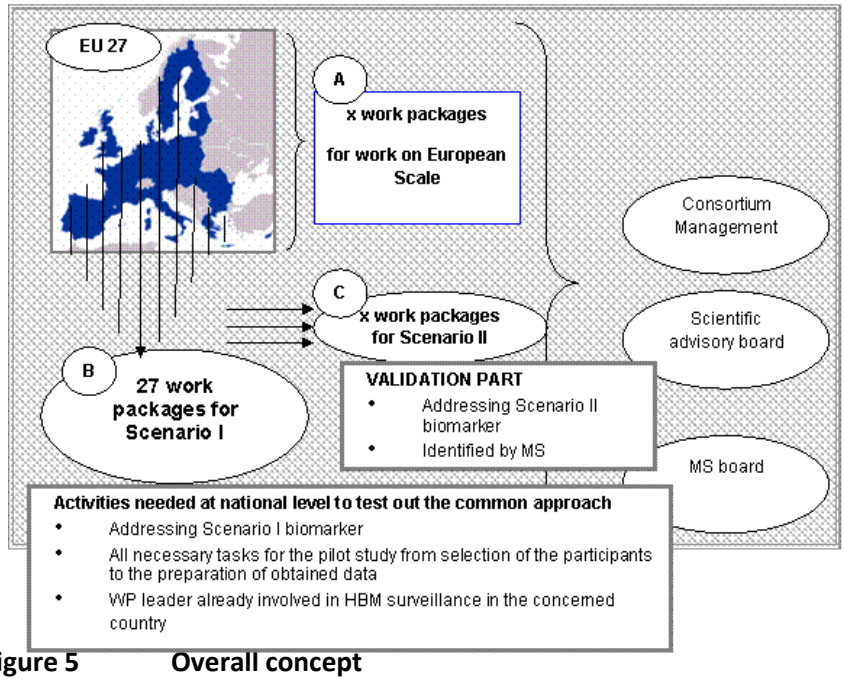

Figure 5 Overall concept

In order to find the most appropriate approach for each MS and the overall project a Central Unit on EU level as well as a MS Unit in each MS have been proposed and the different necessary tasks have been described in the associated deliverable. In addition different modules have been elaborated (e.g. Reference Laboratory, Member States Board, etc.) showing advantages and disadvantages of each which might be helpful and necessary for an EU wide HBM project.

c) Communication Concept

In the preparation as well as during the performance of the EU pilot project on Human Biomonitoring several important issues have to be organised and developed. A project established on a European Scale involving Member States requires a maximum of transparency as well as an active involvement of concerned actors. In addition to technical, political and financial preparation the elaboration of a communication concept is one very important issue. It ensures awareness raising and elucidates the objectives of the pilot project. Moreover the concept should be prepared in a way which enables to inform the general public and stakeholders about the aim of the pilot project, the individual and collective results and their significance for public health.

For the development of a concept for a successful communication strategy it is essential to define in an early stage clear aims, target groups, tools to be used as well as the content to be communicated.

In addition to the concept four principles have been identified within WP 5 which should be followed to keep the communication efficient and effective:

1. There should be no double work between the involved actors (like EU communication and Member States).

2. There should be a close coordination with other EU activities in the field of E&H.
3. The red thread and the core statements have to match in all communication activities.
4. The campaign should be flexible and adaptable according to different needs and requirements.

Against this background the main objectives of an appropriate communication strategy have been identified as:

- ensure awareness raising,
- elucidate the objectives of the EU network on HBM,
- inform the general public and stakeholders about the aim of the EU network on HBM,
- promote active participation of the general public and stakeholders,
- inform about individual and collective results and their significance for public health
- act as a tool to actively involve people

Within WP 5 a modular conception has been developed to ensure an efficient and effective communication strategy taking into account several different aspects. The proposed modules are:

1. Module: Target group
2. Module: Aim
3. Module: Content to communicate
4. Module: Tools to be used
5. Module: Actors to realize the communication campaign

Within each module a lot of different aspects have to be considered; in order to find the most appropriate way for a communication strategy the modules have to be combined and appropriately connected. In

Figure **6** the overall principle is shown.

d) Follow Up

As a fourth task within work package 5 considerations for a follow up of the pilot project have been elaborated.

During the project running time a special focus was laid on the expectations and needs of Member States, policy representatives as well as scientists. Form 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 Figure 7.

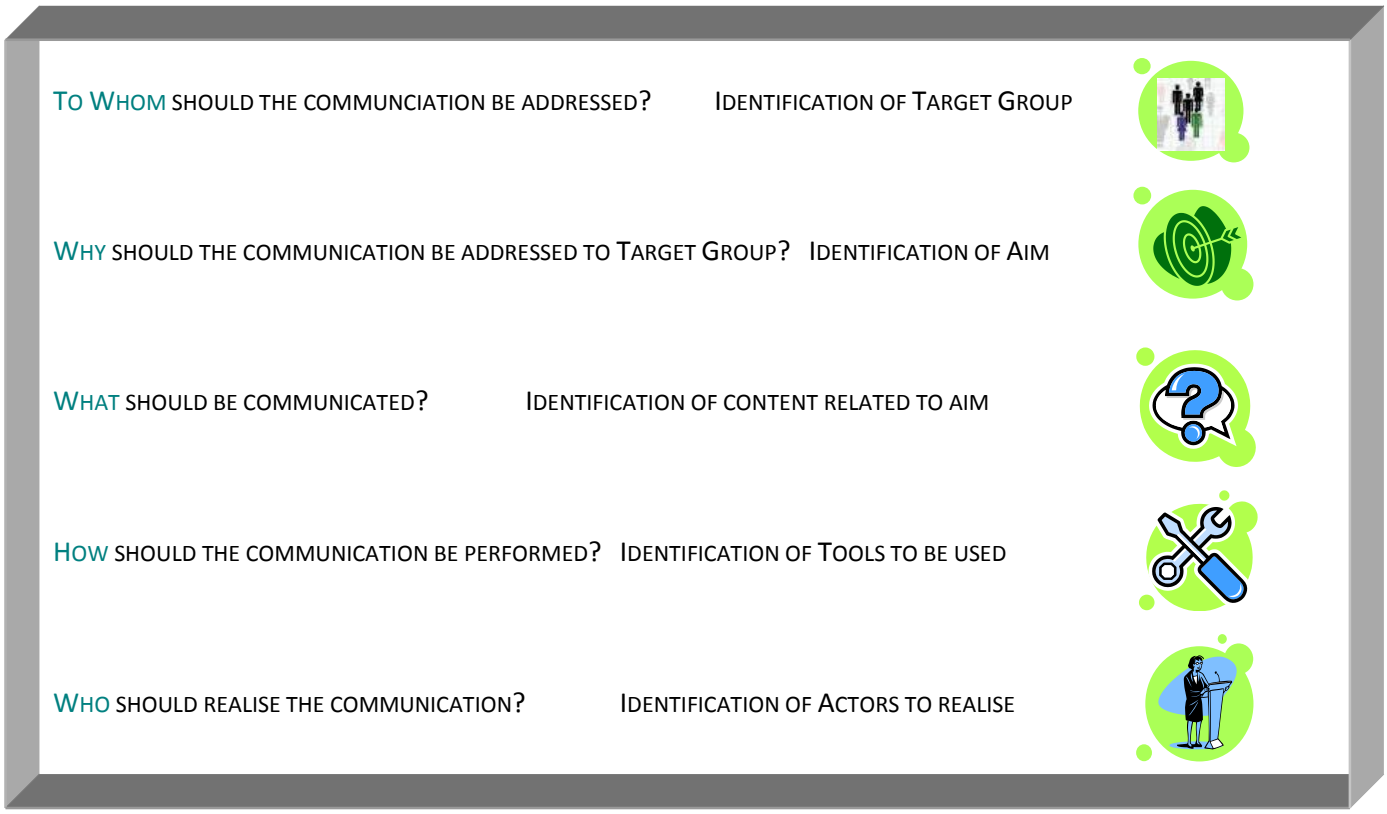

Figure 6 Communication strategy

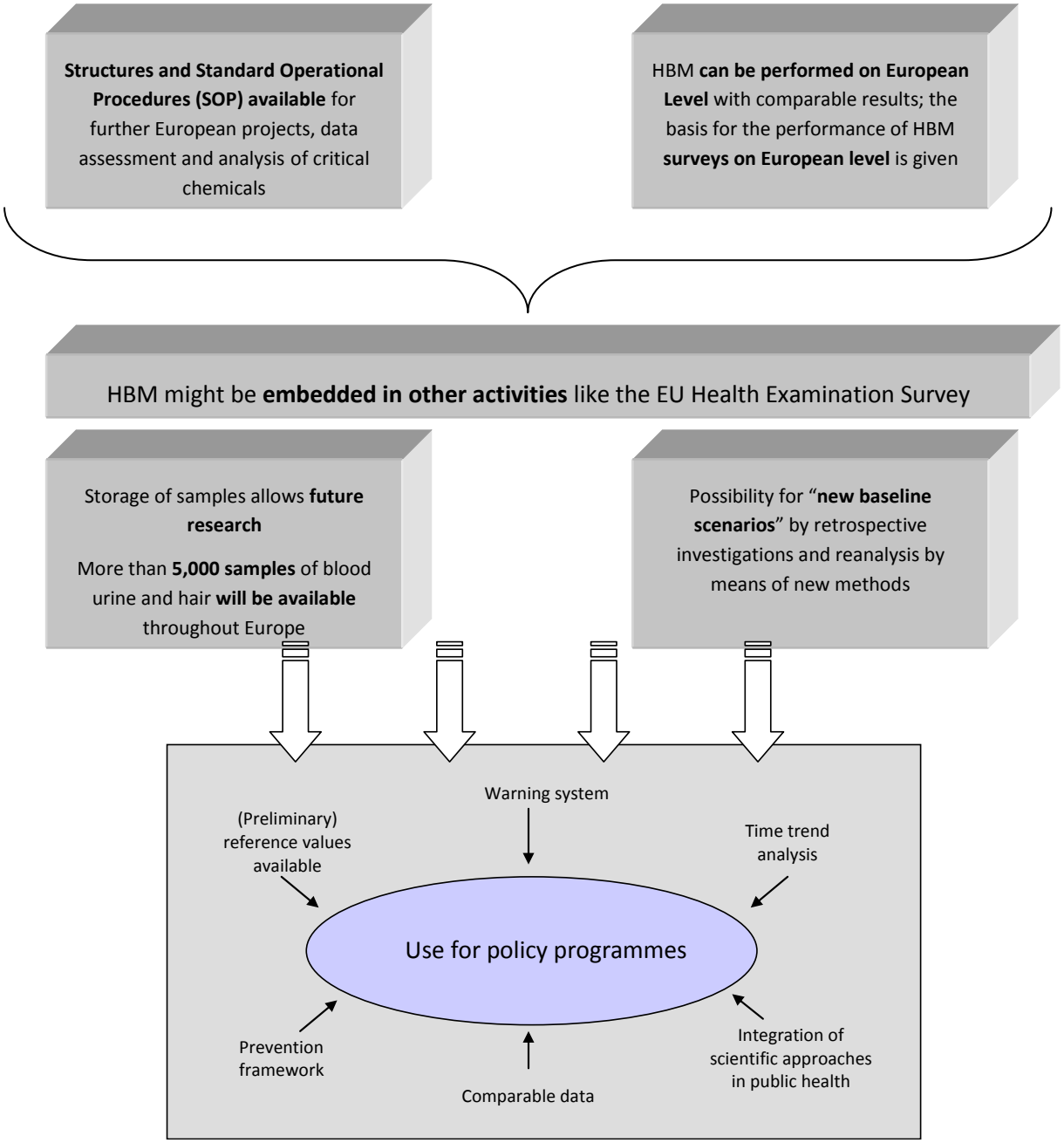

Figure 7 Follow up concept

1.4.6. WP 6 – UTILITY AND SENSITIVITY OF BIOMARKERS

Work package 6 aimed to provide information on the utility and sensitivity of biomarkers in the perspective of the EU HBM pilot project. The first step – an analysis of the literature data aiming at:

- Evaluation and comparison of the data published in different countries and critical analysis of their applicability at the present levels of environmental exposure.
- Identification of possible new biomarkers.
- Search for possible new health-based action levels.

Furthermore a workshop concerning WP 6 was organised in Lodz, Poland (March, 2006), aiming at the evaluation of the first draft of the work package report. For the final version of report all suggestions made during the meetings in Lodz, Berlin and Paris were taken into account.

The prepared document contains current information concerning the possible application of different biomarkers of exposure.

The first part contains data on the existing human biomonitoring (HBM) systems and reference values as well as information on the interlaboratory quality assurance systems and reference materials for internal daily quality control programs.

The second part includes background information on the biomarkers of exposure to substances considered as priority for a HBM system in Europe (cadmium, lead, methyl mercury, cotinine), other biomarkers used on routine basis to evaluate magnitude of exposure against the reference values or to compare the levels and trends of exposure in different regions or countries (PAH's, phthalates, volatile organic compounds, pesticides, arsenic, PCDD/PCDF, PCB's), and biomarkers used at present for research purposes.

According to the recently published data, in spite of the downward trend in emission to the environment, the substances considered as priority (cadmium, lead, methyl mercury, nicotine) can still be regarded as the possible cause of early health effects in fetuses and children.

Cadmium: The population groups at risk include elderly, diabetics and smokers. Women may be at increased risk because they absorb more cadmium than men due to the lower iron stores.

In spite of the decreasing cadmium emissions and deposition, the recently published data do not show any decrement in cadmium body burdens in non-smokers over the last decade. The margin of safety between the present dietary daily intake of cadmium and the level of intake which can bring about health effects is very narrow. For highly exposed subpopulations, this margin may even be non-existing. Therefore, monitoring cadmium levels in urine is highly recommended.

Lead: Impairment of the neurodevelopment in children is the most critical health effect. Contrary to previous opinions that cognitive effects in children are associated with Pb levels in blood of about 100-150 µg/l the recently published data provide strong evidence that effects can occur at blood

concentration below 100 µg/l. And there may be no threshold for these effects. Therefore it has been recently postulated that current exposure standards urgently need to be reduced. It was suggested that for children and female industrial workers of reproductive age the action level should be reduced to a Pb-B concentration of 50 µg/l.

In general, a decrease in lead levels has been noted over the last decades, mainly due to elimination of leaded petrol. The geometric mean values published recently in different countries suggest that in women and children the Pb-B levels are approaching the range of 10-30 µg/ l. However elevated exposures can occur due to local sources and the reliable information on Pb-B levels in some part of Europe is lacking.

Methyl mercury: Methyl mercury is a potent neurotoxic chemical. Unborn children are the most susceptible population group. The exposure is through fish in maternal diet. Methyl mercury bio-accumulates and the Hg concentrations in fish are likely to increase further during several centuries and to reach levels much higher than the current ones. The recently published results show that not only on the islands such as Faroe Islands or Madeira but also in the continental Europe, high fish consumption can result in hair mercury levels exceeding current recommendations.

External tobacco smoke (ETS): ETS has been shown to increase the risks for a variety of health effects in nonsmokers exposed at typical environmental levels. Acute and chronic respiratory health effects on children have been demonstrated at the homes where smokers dwell. There is no evidence for a safe exposure level. Cotinine is a major metabolite of nicotine and its levels in biological material are used to track exposure to ETS among non-smokers. Children particularly need protection from ETS at home. At the same level of ETS exposure, young children have nearly twice as high urine cotinine levels as adults. Non-smoking children exposed to parental tobacco smoke at home compared with the non-exposed ones showed higher cotinine concentration (geometric mean 8.1 µg/l vs. 2.7 µg/l) on average.

Therefore, the implementation of biomonitoring of exposure to these substances seems to be fully justified. For all the substances discussed in the report, validated analytical methods, external quality assurance systems and reference materials are available.

1.5. ARCHIEVEMENTS OF THE PROJECT TO THE STATE-OF-THE-ART AND IMPACT ON INDUSTRY OR RESEARCH SECTOR

Human Biological Monitoring (HBM) has long been used in occupational health as part of a preventive strategy in the medical surveillance of workers. Currently it is increasingly used as a tool in environmental research and in health policy development. HBM is an effective tool to assess human exposure to environmental pollutants and potential health effects of such pollutants. It therefore is seen as an essential element in a strategy aiming to integrate health and environment. HBM results integrate the contribution of the different routes of exposure and take into consideration the differences between individuals with regards to exposure and uptake (which are due to differences in e.g. physical activities, life-style factors, and genetic factors, etc). In children the potential for greater exposure and unique routes of exposure such as in utero and pica are of concern. HBM can identify new chemical exposures, trends and changes in exposure, establish distribution of exposure among the general population, identify vulnerable groups and populations with higher exposures and identify environmental risks at specific contaminated sites with relatively low expenditure. The sensitivity of some HBM methods enables the elucidation of human metabolism and toxic mechanisms of the pollutants. Therefore well designed HBM programmes are scientific tools that can provide the evidence base to drive policy relevant recommendations[8].

HBM data need to be integrated with toxicological, eco-toxicological, environmental and health monitoring data in a multidisciplinary setting for an efficient translation of biomarker results into intervention strategies or early warning tools aiming at minimizing the effects of environmental pollution on human health. More than the classical environmental measurements, HBM gets pollution personal[9] and therefore not only provides valuable information on exposure and its possible effects on health but also has great impact in raising awareness for possibilities of prevention. Activities intended to raise awareness by NGOs have demonstrated that HBM is a sensitive political and societal issue.

The European Environment and Health Strategy[10], launched in June 2003 by the European Commission as the SCALE initiative (based on Science, focused on Children, aiming at raising Awareness, using Legal instruments, and including Evaluation) paid particular attention to the potential of HBM. Activities within the Technical Working Group on Biomonitoring of Children, one of

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8 Angerer J, Ewers U, Wilhelm M. *Human biomonitoring: State of the art.* Int J Hyg Environ Health, 210: Issues 3-4*: 201-228, 2007*

9 Stokstad E.*, Pollution gets personal, Science, 304:1892-93, 2004*

10 Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee on a European Environment and Health Strategy (COM(2003)338 final) adopted by the Commission on 11 June 2003

the 9 working groups established under SCALE to prepare options for actions in preparation of the Action Plan, showed that within the EU significant resources are spent and efforts are made to collect biomarker data in environmental health. However, the studies are generally not using the same methodological approach making it very difficult to compare the results[11]. More harmonised HBM programmes are needed to (i) improve data comparability and accessibility within and between countries, leading to generation of broader information on the nature and extent of body burdens, or the response of the human body to chemical, physical or biological environmental agents, (ii) allow for better detection of spatial and - if studies are carried out repeatedly - temporal differences in exposure of the European population, (iii) deliver additional -integrated- data regarding the contributions of different environmental compartments and emission sources to body burden, and (iv) provide policy makers with better information on precaution, prevention and control measures to be taken. A harmonised approach can make integration of results of national HBM programmes more meaningful as the data can be analysed in the light of a much larger number of samples for the whole of Europe as long as comparability is not compromised. A pan European database may allow identification of high exposure groups and generation of hypotheses as to associations and possible causal relationships between environmental exposure trends and health outcomes[12].

ESBIO aimed to develop a coherent approach to HBM in Europe based on existing expertise and studies in the Member States. The state of the art in 2005 on which the project was built can be summarised as the following:

- numerous ongoing activities are often country specific surveillance activities and sometimes specific biomonitoring research activities and thus not easily comparable.
- there was no overall inventory of ongoing activities within Europe or even the registration of specific key data for such an inventory of monitoring activities.
- important surveillance or research projects (e.g. children cancer registers and miscarriage registers) do not cover all regions of Member States
- an updated inventory and consequently improved and additional data and databases were missing for functional biomonitoring and optimised surveillance programmes for children (e.g. in the field of geno-toxicological biomarkers it is necessary to establish baseline values for children as at present adult values are used)
- there was no or insufficient coordination between research and surveillance projects; a European approach with standardisation of monitoring strategies, communication of results, etc. is

[11] Baseline report on "Biomonitoring of Children" in the framework of the European Environment and Health Strategy (COM(2003)338 final) produced by the Technical Working Group on Integrated Monitoring subgroup Biomonitoring of Children - 09 January 2004 http://europa.eu.int/comm/environment/health/pdf/children_biomonitoring.pdf

[12] Options for Action for "Biomonitoring of Children" in the framework of the European Environment and Health Strategy (COM(2003)338 final) produced by the Technical Working Group on Integrated Monitoring subgroup Biomonitoring of Children - 30 March 2004 http://europa.eu.int/comm/environment/health/pdf/040330biomonitoring.pdf

completely lacking. Furthermore internationally available information is not sufficiently taken into account due to lack of common forum for exchange of knowledge, practice, etc

- as a consequence synergies concerning financial aspects and standards for optimal biomonitoring could not be realised and available information was not adequately exploited
- usually results are either considered in the frame of environmental or health aspects respectively; integration of environment and health was missing
- only in singular cases the outcomes of surveillance or research projects have an impact on policy making (e.g. dioxins in human breast milk)

Coordination of the ongoing biomonitoring activities in Europe will generally promote to achieve the objectives of the EU Environment and Health Action Plan. In particular it will improve data comparability between countries and will allow a better integration of information by bringing together available knowledge and by actively promoting exchange of experiences between teams and countries. It will also enable a more effective use of resources through shared development of tools and strategies. In particular, efficient networking will significantly enhance the current state of the art due to the following reasons:

- harmonised protocols and guidelines on a European scale will result in comparable criteria and procedures for biomonitoring and evaluation of results
- improved communication between all stakeholders will lead to synergies and increased know-how share within the scientific community
- harmonised approaches will lead to increased cost-efficiency as they can serve as support for the realisation of each single project; these synergies lead to financial savings and make sure that the information generated has full significance under a European scope
- biomonitoring on regional level will enable regional differentiation of environmental and health issues, comparisons between regions and regional policy approaches
- improved communication of results and establishment of links between research, surveillance and policy will lead to a better use of results, increased know how share and a better co-operation between the scientific and the political community
- a relation between research and surveillance and policy development will provide policy makers with (early) warning tools and enable the orientation of environment and health policies at an early stage (e.g. if a biomarker for exposure or for effect increases corresponding measures can be envisaged in policy); continued monitoring allows in the follow up to control the efficiency of policy measures
- availability of harmonised ethical standards will facilitate the implementation of each individual biomonitoring activity

The ESBIO project successfully contributed to enhance the situation concerning HBM in Europe. All work packages have achieved its aims and objectives and enabled the formation of an effective network on HBM on a European level.

In particular the work packages contributed to enhance the state of the art as follows:

- WP 1 Conference State of the art on HBM in Europe held in Lisbon contributes to improve the communication between all stakeholders to increased know-how share within the scientific community and created already at the beginning of the project a basis for an EU network on HBM.
- WP1 benefited to the current state of the art with the creation of an electronic HBM inventory as basis for the share of know how and coordinated approaches. The harmonised approaches will lead to increased cost-efficiency as they can serve as support for the realisation of each single project; these synergies lead to financial savings and make sure that the information generated has full significance under a European scope.
- WP 2 created the basis for a common approach. All elements needed for the performance of a HBM study have been taken into consideration and have been elaborated for an EU wide harmonised approach. Beside the definition of objectives for an EU HBM approach and the EU pilot project a proposal for pollutants and biomarkers, a draft questionnaire for the pilot study, a proposal for harmonised way of collecting and analysing selected pollutants and for data management, models for inter-laboratory comparison and a proposal for organisation of laboratory work as well as a proposal for population sampling, recruitment and biological sampling have been provided and are available for use in the future. By using the results of WP 2 a coordinated approach can be realised and the obtained biomonitoring data will be comparable and a harmonized way for procedures for biomonitoring and evaluation of results will benefit to the efficient use of resources.
- WP 3 worked on the linkage of environment and health data, prepared a concept to establish biomonitoring as a policy making tool and provided guidelines for integration scenarios and implementation strategies for biomonitoring. The results shows possibilities how especially policy makers can use the outcomes of biomonitoring projects as impact for policy making.
- Work package 4's current relation to the state-of-the-art consisted first of analysing existing information gathered from the inventory of 97 European biomonitoring studies by SCALE "Draft Baseline Report on Biomonitoring of Children under the framework of the European Environment and Health Strategy (COM 2003)338 final" and from the survey of European practices in informing, consenting and managing studies of children in pregnancy, prenatally and postnatally" made by ChildrenGenoNetwork. According to the reported consent procedures in the questionnaires used by SCALE written informed consents from the participants are used in more than half of the studies. Oral informed consents were reported in a few studies. There are no uniformity and agreement in Europe about the procedures and contents of the process of informed consent. The majority of the studies covered by SCALE protected the individual data in

regards to data protection and privacy legislation. Several studies referred to the 1995 EC Data Protection Directive or the local data protection legislation. Hence, samples and questionnaires were maintained by the responsible medical doctor and subsequently anonymised in order to maintain confidentiality under secure conditions in accordance with the legislation. Measures are taken to ensure confidentiality and security of the data. Ethical advice has been taken to determine the maximum volume of blood samples that may be taken in order to minimize distress to the participant. No patents or other copyright issues were reported. 38 studies have or have foreseen long term storage of biological samples and 36 studies have or have foreseen no long term bio banking. WP 4 working on the aspect of ethics also benefits the harmonisation of different approaches in the individual Member States. Therefore resources can be saved by using standards for optimal biomonitoring can be realised and available information can be is exploited adequately.

- WP 5 benefits by assessing different study approaches for their cost-value ration to identify the most effective and economic way to perform a HBM pilot project taking into account on the one hand side needs and expectation and on the other hand restricted resources. Additionally a communication concept has been set up to guarantee a effective and efficient communication among all involved actors as well as stakeholders and other interest groups. This will ensure awareness raising, transparency and appropriate communication of results. Improved communication of results and establishment of links between research, surveillance and policy will lead to a better use of results, increased know how share and a better co-operation between the scientific and the political community.
- WP 6 provided an extensive scientific basis for the utility and sensitivity of biomarkers. It shows the link of the biomarker to health consequences and can be used by all groups performing biomonitoring and will contribute to an efficient use of resources.
- All WPs especially WP 8 worked successfully on the improvement of the communication and the involvement of MS representatives, the scientific world as well as several other involved actors. With the enormous input of ESBIO to the recommendations prepared by the Implementation Group on HBM in Europe a huge step forward in the realisation of an EU wide biomonitoring could be achieved.

ESBIO showed clearly the way towards a harmonised approach and worked continuously on the establishment on a functional network on HBM in Europe. For all aspects which have to be considered for a future HBM pilot project like the selection of biomarkers or the general study approach ESBIO could provide a common ground - solutions and compromises accepted by all involved MS, industry as well as NGOs are a key outcome of ESBIO which offers the possibility to enhance the state of the art by starting the next step – the realisation of the EU HBM pilot project.

To underline the dimension of the results of ESBIO it should be mentioned that during the project phase a enlarged network has been set up to answer the call for an EU HBM network of DG Research

in the 7th framework programme based on ESBIO results. 24 Member States committed to contribute significantly to this project and there is clear evidence of increasing cooperation between E&H institutes and enthusiasm in MS with respect to HBM as a result of ESBIO and the consecutive formation of a new consortium. During the preparation of this report the evaluation and therewith the future of HBM in Europe was still ongoing.

ESBIO provided the basis – now in a second step – the pilot project can be realised.

2 DISSEMINATION AND USE

A major task of ESBIO was the continuous communication with MS, involved stakeholders and the scientific world. During the project time several workshops and one conference has been organised. The conference led to a publication of a special issue of the International Journal of Hygiene and Environmental Health on Human biomonitoring in Europe. Amongst others the following article are included:

- Human biomonitoring: Towards more integrated approaches in Europe
  Ludwine Casteleyn, Birgit Van Tongelen, M. Fátima Reis, Alexandra Polcher and Reinhard Joas
  199-200
- Identifying opportunities and gaps for establishing an integrated EDR-triad at a European level
  R. Smolders and G. Schoeters
  253-257
- Online integrated solution to collect data, generate information and manage events in the human biomonitoring field
  Reis M. Fátima, João Tedim, Pedro Aguiar, J. Pereira Miguel, Ludwine Casteleyn, Reinhard Joas and Birgit Van Tongelen
  403-406
- Ethical issues related to biomonitoring studies on children
  Marie Pedersen, Domenico Franco Merlo and Lisbeth E. Knudsen
  479-482

A second special issue on ethics and communication will be published after the project running time in the online based Environmental Health.

Beside a project website www.eu-humanbiomonitoring.org which provided all prepared deliverables and information on background, new developments and meetings a project brochure and two information posters have been prepared and can be obtained via the co-ordinator.

Nearly all project members were involved in the communication activities and presented ESBIO and the way forward on manifold meetings, conferences and workshops on national and international level.

In the following the main results of the work packages are shown:

Part 1 Project and results overview

2.1 PROJECT SUMMARY

EC PROGRAMME:	**FP6-POLICIES**
PROJECT TITLE:	**Development of a coherent approach to human biomonitoring in Europe**
PROJECT ACRONYM:	**ESBIO (Expert team to Support BIOmonitoring)**
CONTRACT NUMBER :	**SSPE-CT-2005-022580**
PROJECT WEB SITE (if any) :	www.eu-humanbiomonitoring.org www.hbm-inventory.org
COORDINATOR:	
Coordinator's name	**Dr. Reinhard Joas**
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Coordinator telephone	**+49-89-18979050**
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	Federal Environment Agency, Austria Finnish Institute of occupational Health, Finland Health Protection Agency, United Kingdom National Institute for Health Development, Estonia
EC PROJECT OFFICER:	
EC PO name	**Dr. Tuomo Karjalainen**
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EC Directorate General	Research Directorate-General Directorate I (Environment) Unit I.5 (Climate Change and Environmental Risks)

2.2 OVERVIEW ON ALL PROJECT RESULTS

No.	Self-descriptive title of the result		Partner(s) owning the result(s) (referring in particular to specific patents, copyrights, etc.) & involved in their further use
1	Concept for communication to stakeholders accompanying a HBM pilot project		BiPRO
2	Socio economic optimisation and concept for coordination for a harmonised approach to HBM in Europe		BiPRO
3	Ethical issues related to present and future biomonitoring programs in EU countries by describing rules and practices in a number of countries and by organising a workshop from which proceedings will result.		UCPH
4	Updated European inventory of biomonitoring and concept for a platform for exchange of expertise and experience		IMP
5	Questionnaire to be used in a EU Human Biomonitoring Pilot Study		UBA
6	Guideline for data collection (sampling, chemical analysis and data management) in the framework of a EU Human Biomonitoring Pilot Study		UBA
7	Guideline for laboratory selection (invitation to tender and evaluation of proposals) in the framework of a EU Human Biomonitoring Pilot Study		UBA
8	Proposal for pollutants/biomarkers in regard to a EU Human Biomonitoring Project		UBA
9	Guideline on the possibilities to link HBM with environment and health data		VITO
10	Concept to establish biomonitoring as a policy making tool		VITO
11	Guidelines for integration scenarios and implementation strategies for biomonitoring results to be tested in a pilot study		VITO
12	Report on the utility and sensitivity of biomarker		NIOM

[*] A: results usable outside the consortium / B: results usable within the consortium / C: non usable results

Part 2 Description of each result

2.3 DESCRIPTION OF THE RESULT 1

NO. & TITLE OF RESULT

No.	Self-descriptive title of the result
1	Concept for communication accompanying a HBM pilot project

CONTACT PERSON FOR THIS RESULT

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Specific Result URL	http://www.eu-humanbiomonitoring.org/sub/esbio.htm

SUMMARY* *(200 words maximum)*

In order to accompany a European human biomonitoring pilot project a communication strategy has to follow four main principles:

- There should be no double work between the involved actors
- There should be a close coordination with other EU activities in the field of E&H
- The red thread and the core statements have to match in all communication activities
- The campaign should be flexible and adaptable according to different needs

In order to meet these principles BiPRO has developed a modular concept which provides a tool to establish an effective and efficient communication.

Starting point are the five modules target groups, aims, content to be communicated, actors to realise and tools to be used, which are elaborated in terms of their use for a HBM project supporting communication.

To establish a communication strategy the individual modules are linked appropriately in a way to follow the causal chain "to whom – why – what – how – who?"

The concept provides a common ground for communication activities within one project even if they differ greatly from each other e.g. due to different needs and expectations.

The concept is ready to be used in a future HBM pilot project by the responsible communication unit.

CURRENT STAGE OF DEVELOPMENT

Scientific and/or Technical knowledge (Basic research)	
Guidelines, methodologies, technical drawings	X
Software code	
Experimental development stage (laboratory prototype)	
Prototype/demonstrator available for testing	
Results of demonstration trials available	
Other (please specify.):	

INTELLECTUAL PROPERTY RIGHTS

Type of IPR	
Patent applied for	
Patent granted	
Patent search carried out	
Licence agreement(s) reached	

Partnership / other contractual agreement(s)	
Exclusive rights	
Registered design	
Trademark applications	
Copyrights registered	
Secret know-how	
Other - please specify : No IPR	X

MARKET APPLICATION SECTORS ***According to NACE classification***

Market application sectors	74	93	80	85	

2.4 FURTHER COLLABORATION, DISSEMINATION AND USE OF THE RESULT 1

COLLABORATIONS SOUGHT

R&D	Further research or development	X	**FIN**	Financial support	X
LIC	Licence agreement		**VC**	Venture capital/spin-off funding	
MAN	Manufacturing agreement		**PPP**	Private-public partnership	X
MKT	Marketing agreement/Franchising		**INFO**	Information exchange	X
JV	Joint venture		**CONS**	Available for consultancy	X
			Other	(please specify)	

POTENTIAL OFFERED FOR FURTHER DISSEMINATION AND USE

The concept is ready for use and has to be applied according to the framework in which an HBM pilot project will be performed. With the concept it can be ensured that all concerned actors as well as the general public are involved and will be kept informed on the project performance. As HBM and the link between environment and health is a topic of increasing public awareness it is seen as essential to ensure a maximum of transparency.

Actors to realise the communication and therefore to use the concept should be experts for communication on an international level together with experts in the field of HBM. A close cooperation with the institutions performing the project has to be guaranteed.

Investments involved depend on several factors like the level of involvement of the Commission or the tools to be used (e.g. brochures, videos, etc.). In main costs will incur within the cost category personnel costs.

PROFILE OF ADDITIONAL PARTNER(S) FOR FURTHER DISSEMINATION AND USE

Not applicable

2.5 DESCRIPTION OF THE RESULT 2

NO. & TITLE OF RESULT

No.	Self-descriptive title of the result
2	Socio economic optimisation and concept for coordination for an harmonised approach to HBM in Europe

CONTACT PERSON FOR THIS RESULT

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Specific Result URL	http://www.eu-humanbiomonitoring.org/sub/esbio.htm

SUMMARY* *(200 words maximum)*

In order to perform a socio economic optimisation for a future EU HBM pilot project first of all tasks necessary for a HBM pilot project have been identified. Subsequently an EXCEL tool has been developed in which different parameters are variable to be filled in by the user and which calculates with the inserted figures the total necessary budget for several different study approaches.

In order to achieve the optimal approach several contradictions had to overcome, this means to maximise the number of participating Member States, the biomarkers to be measured, the number of samples, the synergies effects and to maximise the scientific progress while keeping costs as low as possible.

In addition a coordination concept has been elaborated proposing different work levels, i.e. performance of the pilot study should be done in each country by a national team; the harmonisation, support and evaluation of the study and its results should be done on EU level by multinational teams. In order to take into account the different levels of existing experiences a research-component should be established.

The results have been discussed with all Member States and can be used for a future HBM pilot project.

CURRENT STAGE OF DEVELOPMENT

Scientific and/or Technical knowledge (Basic research)	
Guidelines, methodologies, technical drawings	X
Software code	
Experimental development stage (laboratory prototype)	
Prototype/demonstrator available for testing	
Results of demonstration trials available	
Other (please specify.):	

INTELLECTUAL PROPERTY RIGHTS

Type of IPR	
Patent applied for	
Patent granted	
Patent search carried out	
Licence agreement(s) reached	
Partnership / other contractual agreement(s)	
Exclusive rights	
Registered design	
Trademark applications	
Copyrights registered	

Secret know-how	
Other - please specify : No IPR	X

MARKET APPLICATION SECTORS ***According to NACE classification***

Market application sectors	74	93	80	85	

2.6 FURTHER COLLABORATION, DISSEMINATION AND USE OF THE RESULT 2

COLLABORATIONS SOUGHT

R&D	Further research or development	X	**FIN**	Financial support	X
LIC	Licence agreement		**VC**	Venture capital/spin-off funding	
MAN	Manufacturing agreement		**PPP**	Private-public partnership	X
MKT	Marketing agreement/Franchising		**INFO**	Information exchange	X
JV	Joint venture		**CONS**	Available for consultancy	X
			Other	(please specify)	

POTENTIAL OFFERED FOR FURTHER DISSEMINATION AND USE

The results offer an excellent basis for the establishment of an EU wider HMB network performing a harmonised pilot project.

The results are usable for a unit setting up an EU network on HBM in Europe. To use the results a high rate of coordination and communication skills is necessary. A team of HBM experts, laboratories, national authorities as well as coordination and communication experts should be formed to use the full range of results.

Investments involved only incur in case the HBM pilot project will be realised using the results obtained.

PROFILE OF ADDITIONAL PARTNER(S) FOR FURTHER DISSEMINATION AND USE

Not applicable

2.7 DESCRIPTION OF THE RESULT 3

No. & TITLE OF RESULT (same as in table 1.2)

No.	Self-descriptive title of the result
3	Ethical issues related to present and future biomonitoring programs in EU countries by describing rules and practices in a number of countries and by organising a workshop from which proceedings will result.

CONTACT PERSON FOR THIS RESULT

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Specific Result URL	http://www.eu-humanbiomonitoring.org/sub/esbio.htm

SUMMARY* (200 words maximum)

Workpackage 4 concentrated on ethical issues related to present and future biomonitoring programs in EU countries by describing rules and practices in a number of countries and by organising a workshop.

Special supplementary issue of the web based journal Environmental Health reporting from the workshop on ethical issues and communication within biomonitoring in Copenhagen March 2007 will be issued and a number of reports are available on the ESBIO web site and in open literature.

The recommendations are:

A protocol must be developed at an early stage describing rationale, justification of study, calculation of minimum number of study persons needed for sufficient power of study, recruitment of study persons, informed consent and information of ethics committees before initiation of studies

Biobanking issues needs to be solved prior to study initiation to ensure legal uses of data and samples

Incentives for participation must be considered to avoid economic pressure for participants and special concerns have to be made regarding children

Information to study persons about study results must be described and ensure respect of the right not to know

Harmonised approaches to steps of recruitment, information, consent, data protection, biobanking, dissemination and data/sample transfer between countries and institutions should be considered e.g. in future directives/guidelines for human environmental biomonitoring in Europe (and worldwide).

CURRENT STAGE OF DEVELOPMENT

Scientific and/or Technical knowledge (Basic research)	X
Guidelines, methodologies, technical drawings	
Software code	
Experimental development stage (laboratory prototype)	
Prototype/demonstrator available for testing	
Results of demonstration trials available	
Other (please specify.):	

INTELLECTUAL PROPERTY RIGHTS

Type of IPR	
Patent applied for	
Patent granted	

Patent search carried out	
Licence agreement(s) reached	
Partnership / other contractual agreement(s)	
Exclusive rights	
Registered design	
Trademark applications	
Copyrights registered	
Secret know-how	
Other - please specify : Scientific publications with authorships	X

MARKET APPLICATION SECTORS ***According to NACE classification***

Market application sectors	85				

2.8 FURTHER COLLABORATION, DISSEMINATION AND USE OF THE RESULT 3

COLLABORATION SOUGHT

R&D	Further research or development	X	FIN	Financial support	X
LIC	Licence agreement		VC	Venture capital/spin-off funding	
MAN	Manufacturing agreement		PPP	Private-public partnership	X
MKT	Marketing agreement/Franchising		INFO	Information exchange	X
JV	Joint venture		CONS	Available for consultancy	X
			Other	(please specify)	

POTENTIAL OFFERED FOR FURTHER DISSEMINATION AND USE

The knowledge assembled about legal conditions and practice within EU is of interest to many other research projects and surveillance programs.

PROFILE OF ADDITIONAL PARTNER(S) FOR FURTHER DISSEMINATION AND USE

Researchers and consortia planning studies with biological sample

2.9 DESCRIPTION OF THE RESULT 4

NO. & TITLE OF RESULT

No.	Self-descriptive title of the result
4	Updated European inventory of biomonitoring and concept for a platform for exchange of expertise and experience

CONTACT PERSON FOR THIS RESULT

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URL	
Specific Result URL	**http://www.hbm-inventory.org**

SUMMARY* *(200 words maximum)*

The result is an online inventory of European human research and non-research biomonitoring actions, either ongoing or having been carried out in the last ten years. The online structure and the procedure for self registration of activities provide the optimum strategy for maintaining the available information both accurate and up-to-date. Additional functionalities such as user-defined searches of the activities and the message-board are also favoured by the web environment, and move the inventory closer to the concept developed for a platform for exchange of expertise and experience between human biomonitoring (HBM) stakeholders.

The inventory holds potential for impacting all research, industry or policy sectors in any way related to HBM, in that it provides information on what is being done in the field, who is carrying out the actions, what methodologies are being applied and which laboratories have analytical experience in the area. Developments planned for the platform, such as discussion forums and web-pages dedicated to specific issues within HBM, including the organization of events, will expand this potential further through greater user involvement and a larger target public, ensuring the platform self-fulfils its potential, as a larger amount of information is registered and its usefulness consequently increases.

CURRENT STAGE OF DEVELOPMENT

Scientific and/or Technical knowledge (Basic research)	
Guidelines, methodologies, technical drawings	
Software code	
Experimental development stage (laboratory prototype)	
Prototype/demonstrator available for testing	
Results of demonstration trials available	
Other (please specify.): Scientific publications with authorships	X

INTELLECTUAL PROPERTY RIGHTS

Type of IPR	
Patent applied for	
Patent granted	
Patent search carried out	
Licence agreement(s) reached	
Partnership / other contractual agreement(s)	X
Exclusive rights	X
Registered design	
Trademark applications	

Copyrights registered	
Secret know-how	
Other - please specify :	

MARKET APPLICATION SECTORS ***According to NACE classification***

Market application sectors	85	73			

2.10 FURTHER COLLABORATION, DISSEMINATION AND USE OF THE RESULT 4

COLLABORATIONS SOUGHT

R&D	Further research or development	X	**FIN**	Financial support	
LIC	Licence agreement		**VC**	Venture capital/spin-off funding	
MAN	Manufacturing agreement		**PPP**	Private-public partnership	X
MKT	Marketing agreement/Franchising		**INFO**	Information exchange	X
JV	Joint venture		**CONS**	Available for consultancy	
			Other	(please specify)	

POTENTIAL OFFERED FOR FURTHER DISSEMINATION AND USE

The opportunity for the dissemination of human biomonitoring activities conducted by private or public entities or institutes around Europe is of interest to parties wishing to establish a partnership or exchange information on procedures and practices. This already includes the publicizing of specialized analytical services offered by laboratories and intends to include in the future the widespread dissemination of periodic events such as conferences or workshops among a targeted audience with a stated interest in the field.

Free and practically unrestricted usage is suggested to be complemented by the charging of e.g. commercial laboratories with an 'advertising' fee for the dissemination of biomonitoring analyses conducted, as a means of funding the upkeep of the online inventory.

PROFILE OF ADDITIONAL PARTNER(S) FOR FURTHER DISSEMINATION AND USE

Additional partners' participation required would primarily involve the registering of human biomonitoring activities and events or of analytical services offered, and the participation in exchanges and discussions on various topics related to HBM.

2.11 DESCRIPTION OF THE RESULT 5

NO. & TITLE OF RESULT

No.	Self-descriptive title of the result
5	Questionnaire to be used in a EU Human Biomonitoring Pilot Study

CONTACT PERSON FOR THIS RESULT

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Specific Result URL	http://www.eu-humanbiomonitoring.org/sub/esbio.htm

SUMMARY* *(200 words maximum)*

Conducting a human biomonitoring study it is essential to gather additional information on potential exposure pathways, behaviour and socio-demography. In the framework of ESBIO a suitable questionnaire was developed and reached a ready to use status. The questionnaire was divided into four sections.

5. The **In-/Exclusion Section** is aiming at the (pre-selected) mothers and addresses eligibility criteria and willingness to participate.
6. The **Socio-Demography Section** shall be filled by participants only and addresses socio-economic determinants of exposure.
7. The **Environment and Food Frequency Section** shall be filled by the participating mothers and is supposed to facilitate the individual and overall exposure assessments by elucidating the parents and children's participants' association with known (or suspected) exposure sources of various domains (indoor/ambient, food, lifestyle habits).
8. The **Admission and Sampling Section** addresses very basic health-related matters and the guided documentation of specimen collection. This section shall be managed by health officials only.

The questionnaire is available to the public via the ESBIO internet page. It might be used by other scientific groups or a guideline and serve as a standard, respectively.

CURRENT STAGE OF DEVELOPMENT

Scientific and/or Technical knowledge (Basic research)	
Guidelines, methodologies, technical drawings	X
Software code	
Experimental development stage (laboratory prototype)	
Prototype/demonstrator available for testing	
Results of demonstration trials available	
Other (please specify.): Scientific publications with authorships	

INTELLECTUAL PROPERTY RIGHTS

Type of IPR	
Patent applied for	
Patent granted	
Patent search carried out	
Licence agreement(s) reached	
Partnership / other contractual agreement(s)	

Exclusive rights	
Registered design	
Trademark applications	
Copyrights registered	
Secret know-how	
Other - please specify :	X

MARKET APPLICATION SECTORS ***According to NACE classification***

Market application sectors	85				

2.12 FURTHER COLLABORATION, DISSEMINATION AND USE OF THE RESULT 5

COLLABORATIONS SOUGHT

R&D	Further research or development	X	**FIN**	Financial support	
LIC	Licence agreement		**VC**	Venture capital/spin-off funding	
MAN	Manufacturing agreement		**PPP**	Private-public partnership	
MKT	Marketing agreement/Franchising		**INFO**	Information exchange	X
JV	Joint venture		**CONS**	Available for consultancy	
			Other	(please specify)	

POTENTIAL OFFERED FOR FURTHER DISSEMINATION AND USE

The questionnaire is available for free at the ESBIO-internet pages

(http://www.eu-humanbiomonitoring.org/sub/esbio.htm).

PROFILE OF ADDITIONAL PARTNER(S) FOR FURTHER DISSEMINATION AND USE

Not applicable.

2.13 DESCRIPTION OF THE RESULT 6

NO. & TITLE OF RESULT

No.	Self-descriptive title of the result
6	Guideline for data collection (sampling, chemical analysis and data management) in the framework of a EU Human Biomonitoring Pilot Study

CONTACT PERSON FOR THIS RESULT

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URL	www.umweltbundesamt.de
Specific Result URL	http://www.eu-humanbiomonitoring.org/sub/esbio.htm

SUMMARY* *(200 words maximum)*

Conducting a human biomonitoring study is a challenging. Guidelines for all critical steps might be helpful for the successful implementation of a human biomonitoring approach. Beside clarification on the study design emphasis must be laid on a harmonised way of collecting, of analysing the samples and on data management.

In this guideline three steps (sampling, analysing and data management) have been clustered. The guideline might be used by institutions or organisations conducting human biomonitoring studies to develop Standard Operating Procedures (SOPs) for each step described.

CURRENT STAGE OF DEVELOPMENT

Scientific and/or Technical knowledge (Basic research)	
Guidelines, methodologies, technical drawings	X
Software code	
Experimental development stage (laboratory prototype)	
Prototype/demonstrator available for testing	
Results of demonstration trials available	
Other (please specify.): Scientific publications with authorships	

INTELLECTUAL PROPERTY RIGHTS

Type of IPR	
Patent applied for	
Patent granted	
Patent search carried out	
Licence agreement(s) reached	
Partnership / other contractual agreement(s)	
Exclusive rights	
Registered design	
Trademark applications	
Copyrights registered	
Secret know-how	
Other - please specify :	X

MARKET APPLICATION SECTORS ***According to NACE classification***

Market application sectors	85				

2.14 FURTHER COLLABORATION, DISSEMINATION AND USE OF THE RESULT 6

COLLABORATIONS SOUGHT

R&D	Further research or development		**FIN**	Financial support	
LIC	Licence agreement		**VC**	Venture capital/spin-off funding	
MAN	Manufacturing agreement		**PPP**	Private-public partnership	
MKT	Marketing agreement/Franchising		**INFO**	Information exchange	X
JV	Joint venture		**CONS**	Available for consultancy	
			Other	(please specify)	

POTENTIAL OFFERED FOR FURTHER DISSEMINATION AND USE

The guideline is available for free at the ESBIO-internet pages

(http://www.eu-humanbiomonitoring.org/sub/esbio.htm).

PROFILE OF ADDITIONAL PARTNER(S) FOR FURTHER DISSEMINATION AND USE

Not applicable.

2.15 DESCRIPTION OF THE RESULT 7

NO. & TITLE OF RESULT

No.	Self-descriptive title of the result
7	Guideline for laboratory selection (invitation to tender and evaluation of proposals) in the framework of a EU Human Biomonitoring Pilot Study

CONTACT PERSON FOR THIS RESULT

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Specific Result URL	http://www.eu-humanbiomonitoring.org/sub/esbio.htm

SUMMARY* *(200 words maximum)*

Conducting a human biomonitoring study is a challenging task. Guidelines for all critical steps might be helpful for the successful implementation of a human biomonitoring approach.

Beside clarification on the study design emphasis must be laid on a harmonised way of collecting, of analysing the samples and on data management. A guideline for laboratory selection (invitation to tender and evaluation of proposals) for human biomonitoring studies has been evaluated. The guideline might be helpful for institutions or organisations conducting human biomonitoring studies.

CURRENT STAGE OF DEVELOPMENT

Scientific and/or Technical knowledge (Basic research)	
Guidelines, methodologies, technical drawings	X
Software code	
Experimental development stage (laboratory prototype)	
Prototype/demonstrator available for testing	
Results of demonstration trials available	
Other (please specify.): Scientific publications with authorships	

INTELLECTUAL PROPERTY RIGHTS

Type of IPR	
Patent applied for	
Patent granted	
Patent search carried out	
Licence agreement(s) reached	
Partnership / other contractual agreement(s)	
Exclusive rights	
Registered design	
Trademark applications	
Copyrights registered	
Secret know-how	
Other - please specify : Public use	X

MARKET APPLICATION SECTORS ***According to NACE classification***

Market application sectors	85				

2.16 FURTHER COLLABORATION, DISSEMINATION AND USE OF THE RESULT 7

COLLABORATIONS SOUGHT

R&D	Further research or development		**FIN**	Financial support	
LIC	Licence agreement		**VC**	Venture capital/spin-off funding	
MAN	Manufacturing agreement		**PPP**	Private-public partnership	
MKT	Marketing agreement/Franchising		**INFO**	Information exchange	X
JV	Joint venture		**CONS**	Available for consultancy	
			Other	(please specify)	

POTENTIAL OFFERED FOR FURTHER DISSEMINATION AND USE

The guideline is available for free at the ESBIO-internet pages

(http://www.eu-humanbiomonitoring.org/sub/esbio.htm).

PROFILE OF ADDITIONAL PARTNER(S) FOR FURTHER DISSEMINATION AND USE

Not applicable.

2.17 DESCRIPTION OF THE RESULT 8

NO. & TITLE OF RESULT

No.	Self-descriptive title of the result
8	Proposal for pollutants/biomarkers in regard to a EU Human Biomonitoring Project

CONTACT PERSON FOR THIS RESULT

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Specific Result URL	http://www.eu-humanbiomonitoring.org/sub/esbio.htm

SUMMARY* *(200 words maximum)*

In the framework of this proposal the current knowledge regarding biomarkers of exposure proposed for an EU Human Biomonitoring Project are presented. They are arranged in two groups, representing two scenarios of basic/obligate and extended/facultative biomarkers. Beside health related aspects of the individual pollutant, a brief rationale for the selected type of specimen and proposed biomarkers is provided.

The pollutants are: lead, cadmium, mercury, cotinine, perfluorinated chemicals, polybrominated flame retardants and metabolites of phthalates, polycyclic aromatic hydrocarbons, organophosphate insecticides and pyrethroids.

CURRENT STAGE OF DEVELOPMENT

Scientific and/or Technical knowledge (Basic research)	
Guidelines, methodologies, technical drawings	X
Software code	
Experimental development stage (laboratory prototype)	
Prototype/demonstrator available for testing	
Results of demonstration trials available	
Other (please specify.): Scientific publications with authorships	

INTELLECTUAL PROPERTY RIGHTS

Type of IPR	
Patent applied for	
Patent granted	
Patent search carried out	
Licence agreement(s) reached	
Partnership / other contractual agreement(s)	
Exclusive rights	
Registered design	
Trademark applications	
Copyrights registered	
Secret know-how	
Other - please specify :	X

MARKET APPLICATION SECTORS ***According to NACE classification***

Market application sectors	85				

2.18 FURTHER COLLABORATION, DISSEMINATION AND USE OF THE RESULT 8

COLLABORATIONS SOUGHT

R&D	Further research or development		**FIN**	Financial support	
LIC	Licence agreement		**VC**	Venture capital/spin-off funding	
MAN	Manufacturing agreement		**PPP**	Private-public partnership	
MKT	Marketing agreement/Franchising		**INFO**	Information exchange	X
JV	Joint venture		**CONS**	Available for consultancy	
			Other	(please specify)	

POTENTIAL OFFERED FOR FURTHER DISSEMINATION AND USE

The guideline is available for free at the ESBIO-internet pages

(http://www.eu-humanbiomonitoring.org/sub/esbio.htm).

PROFILE OF ADDITIONAL PARTNER(S) FOR FURTHER DISSEMINATION AND USE

Not applicable.

2.19 DESCRIPTION OF THE RESULT 9

NO. & TITLE OF RESULT

No.	Self-descriptive title of the result
9	Guideline on the possibilities to link HBM with environment and health data

CONTACT PERSON FOR THIS RESULT

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Specific Result URL	http://www.eu-humanbiomonitoring.org/sub/esbio.htm

SUMMARY* *(200 words maximum)*

This result provides an overview of:

- The available data on pollutant concentrations in air, water, food (quality and quantity) and other relevant environmental compartment as sources of exposure;
- The past and current projects dealing with health data for the 4 key health issues within the European Environment and Health Action Plan
- Possible ways to link human biomonitoring data with both environmental and health data through either physiologically-based pharmacokinetic (PBPK) modelling or spatial epidemiological statistics methods (e.g. Geographic information systems (GIS) and Bayesian Statistics)

The document identified available data, but also highlighted where no immediate information was available. In the overall assessment, 5 criteria (availability, harmonisation, geographical context, quality control and policy developments) were taken into account to identify data availability and quality on different sources of information on environmental exposure and health responses.

CURRENT STAGE OF DEVELOPMENT

Scientific and/or Technical knowledge (Basic research)	
Guidelines, methodologies, technical drawings	X
Software code	
Experimental development stage (laboratory prototype)	
Prototype/demonstrator available for testing	
Results of demonstration trials available	
Other (please specify.): Scientific publications with authorships	

INTELLECTUAL PROPERTY RIGHTS

Type of IPR	
Patent applied for	
Patent granted	
Patent search carried out	
Licence agreement(s) reached	
Partnership / other contractual agreement(s)	
Exclusive rights	

Registered design	
Trademark applications	
Copyrights registered	
Secret know-how	
Other - please specify : Public use	X

MARKET APPLICATION SECTORS ***According to NACE classification***

Market application sectors	85				

2.20 FURTHER COLLABORATION, DISSEMINATION AND USE OF THE RESULT 9

COLLABORATIONS SOUGHT

R&D	Further research or development		**FIN**	Financial support	
LIC	Licence agreement		**VC**	Venture capital/spin-off funding	
MAN	Manufacturing agreement		**PPP**	Private-public partnership	
MKT	Marketing agreement/Franchising		**INFO**	Information exchange	X
JV	Joint venture		**CONS**	Available for consultancy	
			Other	(please specify)	

POTENTIAL OFFERED FOR FURTHER DISSEMINATION AND USE

The related document is available for free at the ESBIO-internet pages

(http://www.eu-humanbiomonitoring.org/sub/esbio.htm).

PROFILE OF ADDITIONAL PARTNER(S) FOR FURTHER DISSEMINATION AND USE

Not applicable.

2.21 DESCRIPTION OF THE RESULT 10

NO. & TITLE OF RESULT

No.	Self-descriptive title of the result
10	Concept to establish biomonitoring as a policy making tool

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URL	www.vito.be
Specific Result URL	http://www.eu-humanbiomonitoring.org/sub/esbio.htm

SUMMARY* *(200 words maximum)*

As a result of ESBIO WP 3 a "Multistep Approach" was developed that outlines which steps need to be undertaken to translate HBM data into policy action, trying as much as possible to prioritize among different pollutants measured and different Member States. The Multistep approach will eventually lead to:

1. Aggregation of individual data based on geographical entities;
2. Determine whether there is a deviation (increase/decrease) at the aggregated level in one or more biomarkers measured;
3. Determine the seriousness of the deviation, based on a variety of expert opinions;
4. Set priorities in order to deal with these deviations;
5. Track the causes of these deviations, retrace pollutant loads to potential local, external sources, and identify the different actors that may contribute to the pollutant body burden;
6. To suggest appropriate risk reduction strategies, taking into account the relevant knowledge, actors and opinions;
7. To communicate with the general public and policy makers in a transparent and objective way, proposing and motivating different policy options.

CURRENT STAGE OF DEVELOPMENT

Scientific and/or Technical knowledge (Basic research)	
Guidelines, methodologies, technical drawings	X
Software code	
Experimental development stage (laboratory prototype)	
Prototype/demonstrator available for testing	
Results of demonstration trials available	
Other (please specify.): Scientific publications with authorships	

INTELLECTUAL PROPERTY RIGHTS

Type of IPR	
Patent applied for	
Patent granted	
Patent search carried out	
Licence agreement(s) reached	
Partnership / other contractual agreement(s)	
Exclusive rights	

Registered design	
Trademark applications	
Copyrights registered	
Secret know-how	
Other - please specify :	X

MARKET APPLICATION SECTORS ***According to NACE classification***

Market application sectors	85				

2.22 FURTHER COLLABORATION, DISSEMINATION AND USE OF THE RESULT 10

COLLABORATIONS SOUGHT

R&D	Further research or development		**FIN**	Financial support	
LIC	Licence agreement		**VC**	Venture capital/spin-off funding	
MAN	Manufacturing agreement		**PPP**	Private-public partnership	
MKT	Marketing agreement/Franchising		**INFO**	Information exchange	X
JV	Joint venture		**CONS**	Available for consultancy	
			Other	(please specify)	

POTENTIAL OFFERED FOR FURTHER DISSEMINATION AND USE

The related document is available for free at the ESBIO-internet pages

(http://www.eu-humanbiomonitoring.org/sub/esbio.htm).

PROFILE OF ADDITIONAL PARTNER(S) FOR FURTHER DISSEMINATION AND USE

Not applicable.

2.23 DESCRIPTION OF THE RESULT 11

NO. & TITLE OF RESULT

No.	Self-descriptive title of the result
11	Guidelines for integration scenarios and implementation strategies for biomonitoring results to be tested in a pilot study

CONTACT PERSON FOR THIS RESULT

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URL	www.vito.be
Specific Result URL	http://www.eu-humanbiomonitoring.org/sub/esbio.htm

SUMMARY* *(200 words maximum)*

A number of key aspects and recent policy developments were brought together which the future European Network on Human Biomonitoring needs to take into account:

- HBM and REACH: it was briefly outlined how HBM data may assist in the REACH assessment scheme, and also how HBM will benefit from REACH, mainly due to the generation of more and better toxicity data;
- HBM and health examination surveys: In many countries, large-scale HBM survey projects are linked to health examination surveys. Also for the European pilot project on Human Biomonitoring such a liaison would be possible in terms of the FEHES[13] project, which studies the feasibility of a pan-European Health Examination Survey;
- HBM and INSPIRE: Geographical information systems may offer an excellent opportunity to combine environment, HBM and health data under one currency, being the spatial location of the data. In order to optimally integrate HBM data with other sources of information, a geographically representative sampling scheme for the European pilot project on Human Biomonitoring is advisable, although it remains until now uncertain what this sampling scheme could look like.

CURRENT STAGE OF DEVELOPMENT

Scientific and/or Technical knowledge (Basic research)	
Guidelines, methodologies, technical drawings	X
Software code	
Experimental development stage (laboratory prototype)	
Prototype/demonstrator available for testing	
Results of demonstration trials available	
Other (please specify.): Scientific publications with authorships	

INTELLECTUAL PROPERTY RIGHTS

Type of IPR	
Patent applied for	
Patent granted	
Patent search carried out	

[13] Feasibility of a European Health Examination Survey; http://www.ktl.fi/fehes/

Licence agreement(s) reached	
Partnership / other contractual agreement(s)	
Exclusive rights	
Registered design	
Trademark applications	
Copyrights registered	
Secret know-how	
Other - please specify : Public use	X

MARKET APPLICATION SECTORS ***According to NACE classification***

Market application sectors	85				

2.24 FURTHER COLLABORATION, DISSEMINATION AND USE OF THE RESULT 11

COLLABORATIONS SOUGHT

R&D	Further research or development		**FIN**	Financial support	
LIC	Licence agreement		**VC**	Venture capital/spin-off funding	
MAN	Manufacturing agreement		**PPP**	Private-public partnership	
MKT	Marketing agreement/Franchising		**INFO**	Information exchange	X
JV	Joint venture		**CONS**	Available for consultancy	
			Other	(please specify)	

POTENTIAL OFFERED FOR FURTHER DISSEMINATION AND USE

The related document is available for free at the ESBIO-internet pages

(http://www.eu-humanbiomonitoring.org/sub/esbio.htm).

PROFILE OF ADDITIONAL PARTNER(S) FOR FURTHER DISSEMINATION AND USE

Not applicable.

2.25 DESCRIPTION OF THE RESULT 12

NO. & TITLE OF RESULT

No.	Self-descriptive title of the result
12	Report on the utility and sensitivity of biomarker

CONTACT PERSON FOR THIS RESULT

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URL	www.imp.lodz.pl
Specific Result URL	http://www.eu-humanbiomonitoring.org/sub/esbio.htm

SUMMARY* *(200 words maximum)*

The first part contains data on the existing human biomonitoring (HBM) systems and reference values as well as information on the interlaboratory quality assurance systems and reference materials for internal daily quality control programs.

The second part includes background information on the biomarkers of exposure to substances considered priority for HBM system in Europe (cadmium, lead, mercury, cotinine), other biomarkers used on routine basis to evaluate magnitude of exposure against the reference values or to compare the levels and trends of exposure in different regions or countries (PAHs, phthalates, volatile organic compounds, pesticides, arsenic, PCDD/PCDF, PCB's), and biomarkers used at present for research purposes.

According to the recently published data, in spite of the downward trend in emission to the environment, the substances considered the priority (cadmium, lead, methylmercury and nicotine) can still be regarded as the possible cause of early health effects in fetuses and children. Therefore, the implementation of biomonitoring of exposure to these substances seems to be fully justified.

For all the substances discussed in the present report, validated analytical methods, external quality assurance systems and reference materials are available.

CURRENT STAGE OF DEVELOPMENT

Scientific and/or Technical knowledge (Basic research)	
Guidelines, methodologies, technical drawings	X
Software code	
Experimental development stage (laboratory prototype)	
Prototype/demonstrator available for testing	
Results of demonstration trials available	
Other (please specify.): Scientific publications with authorships	

INTELLECTUAL PROPERTY RIGHTS

Type of IPR	
Patent applied for	
Patent granted	
Patent search carried out	
Licence agreement(s) reached	
Partnership / other contractual agreement(s)	

Exclusive rights	
Registered design	
Trademark applications	
Copyrights registered	
Secret know-how	
Other - please specify :	X

MARKET APPLICATION SECTORS ***According to NACE classification***

Market application sectors	85				

2.26 FURTHER COLLABORATION, DISSEMINATION AND USE OF THE RESULT 12

COLLABORATIONS SOUGHT

R&D	Further research or development		**FIN**	Financial support	
LIC	Licence agreement		**VC**	Venture capital/spin-off funding	
MAN	Manufacturing agreement		**PPP**	Private-public partnership	
MKT	Marketing agreement/Franchising		**INFO**	Information exchange	X
JV	Joint venture		**CONS**	Available for consultancy	
			Other	(please specify)	

POTENTIAL OFFERED FOR FURTHER DISSEMINATION AND USE

The related document is available for free at the ESBIO-internet pages

(http://www.eu-humanbiomonitoring.org/sub/esbio.htm).

PROFILE OF ADDITIONAL PARTNER(S) FOR FURTHER DISSEMINATION AND USE

Not applicable.