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ESBIO

Development of a coherent approach to human biomonitoring in Europe

Coordination Action
Priority 8.1

Deliverable D8.1 – 8.8
Communication

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[Dr. Reinhard Joas]

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1. Background

WP 8 was dedicated to the communication related to the ESBIO project. Therefore several deliverables focusing on different work packages have been successfully realised and will be summarised in the following document. In particular the deliverables of work package 8 are the following:

- D8.1 Realisation of the Conference (WP1) including announcement, and conference report
- D8.2 Implementation and maintenance of Web site sections
- D8.3 Communication related to WP3 (translation of biomonitoring results into risk management and environmental and health policy programmes)
- D8.4 Realisation of workshop with major stakeholders concerning the topics of WP4 including workshop report
- D8.5 Realisation of workshops concerning the topics of WP6 including workshop report
- D8.6 Prepare form of communication of impact results for communication to various actors and Communicate results in meetings with the Commission and MS as well as in the Consultative Forum
- D8.7 Poster and Brochure for ESBIO
- D8.8 Conclusion and Consequences for ESBIO work from other meetings

2. Realisation of Deliverables

DELIVERABLE 8.1 – REALISATION OF WP1 CONFERENCE INCLUDING ANNOUNCEMENT AND CONFERENCE REPORT

On the 19th – 21 March 2006 the ESBIO consortium realised under the lead of the team of work package 1 a conference on the “State of the art concerning HBM in Europe”. The conference was announced via a specific website <http://conference.hbm-inventory.org> and more than 1000 people have been informed on the event via a mailing list and have been encouraged to participate and to contribute with oral or poster presentations.

The Conference brought together providers of HBM information in order to improve existing information on HBM, to identify expertise and institutions that are performing HBM research and surveillance activities, to provide a forum for discussion of problems in conducting HBM and to stimulate exchange of experiences.

About 100 HBM experts from all over Europe listened to more than 40 presentations and participated in a poster exhibition. The programme is attached in [Annex I](#). A lot of discussions took place during the conference days and the aim to provide a forum for exchange of information was completely achieved.

The contributions for the conference resulted in a special issue of the International Journal of Hygiene and Environmental Health (2007: Volume 210 (6)) on Human Biomonitoring in Europe which is available since May 2006 (Figure 1).

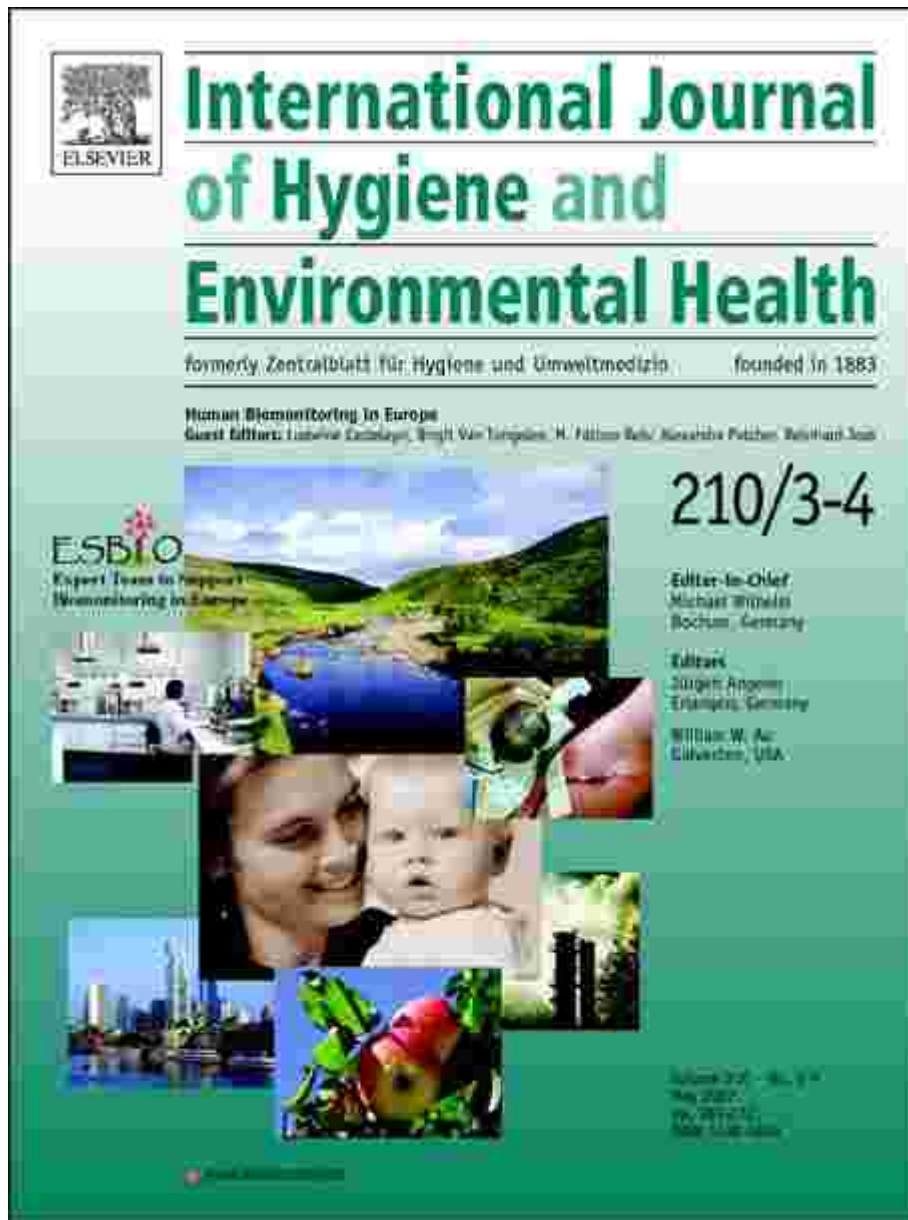


Figure 1 Cover page special issue

DELIVERABLE 8.2 – IMPLEMENTATION AND MAINTENANCE OF WEBSITE SECTION

The main aim of work package 1 was to establish an updated electronic inventory of human biomonitoring research and non research in an electronic format. In this regard a separate website has been set up with an interactive inventory tool (for further explanations see Deliverable 1.2 and 1.4). The website is available on www.hbm-inventory.org and has been updated continuously during the project running time. Figure 2 shows a screenshot of the website.



Figure 2 Screenshot Inventory website

In addition a project website (Figure 3) has been established in close cooperation with the implementation Group on HBM in Europe.

The website is part of the website www.eu-humanbiomonitoring.org and has been updated regularly. It provides background information on HBM in general as well as on the political developments over the last years. In addition it provides an overview on the work packages and the involved actors as well as the possibility to download deliverables and other relevant documents.



Figure 3 Screenshot project website

DELIVERABLE 8.3 – COMMUNICATION RELATED TO WP 3




Workpackage 3 as well as work package 2 represent core work packages of ESBIO and provide essential input to all discussion concerning a European human biomonitoring pilot project. The work carried out in WP 3 was presented at several meetings (see final plan for using and disseminating of knowledge) and led to the following papers/publications:

- Identifying opportunities and gaps for establishing an integrated EDR-triad at a European level (International Journal of Hygiene and Environmental Health 210 (3-4): 235-257)
- Translating biomonitoring data into risk management and policy implementation options for a European Network on Human Biomonitoring
- Human biomonitoring and the INSPIRE Directive: Spatial data as link for environment and health research
- Policy implementation options for Scenario 2 chemicals
- Defining synergism between HBM and REACH
- A proposal for (statistical) analysis and linkage of human biomonitoring data

DELIVERABLE 8.4 – REALISATION OF WORKSHOP WITH MAJOR STAKEHOLDERS ON THE TOPICS OF WP 4 INCLUDING WORKSHOP REPORT

A major achievement of WP 4 was the successful realisation of a workshop held in Copenhagen March 2007 with more than 50 attendants from industry, governments, science coming from the following European countries Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Italy, Luxembourg, Netherlands, Poland, Portugal, Romania, Slovakia, UK as well as the USA. The programme is given in [Annex II](#).

The conference was announced by means of a flyer as shown in Figure 4. The contributions and presentations resulted in a supplement of the journal Environmental Health, which will be published soon.

Members of the ESBIO Consortium	Practical information and Contacts
<p>> 11 Active Members with specific tasks</p> <ul style="list-style-type: none"> Reinhard Joas, BIPRO GmbH, Germany (Coordinator) Fátima Reis, Instituto de Medicina Preventiva, Faculdade de Medicina de Lisboa, Portugal Greet Schoeters, Flemish Institute of Environmental Technology (VITO), Belgium Lisbeth Knudsen, University of Copenhagen, Denmark Louis Bloemen, EXPONENT, The Netherlands Ludwine Casteloy, University of Louvain, Belgium Marek Jakubowski, Institute of Occupational Medicine, WHO collaborating Centre, Poland Marika Kolossa-Gehring, Federal Environmental Agency, Germany Maryse Lehnens-Arendt, Institut Liewensufank asbl, Luxembourg - International Baby Food Action Network Nadine Frère, National Institute of Public Health Surveillance (InVS), France Stella Canna Michaelidou, State General Laboratory, Ministry of Health, Cyprus <p>> 11 Ad Hoc Members</p> <ul style="list-style-type: none"> Aleksandra Fúčić, Institute for Medical Research and Occupational Health, Croatia Ari Hirvonen, Finnish Institute of Occupational Health, Finland Carlo Sala, ARPA Lombardia, Italy Eleonóra Fablánová, Regional Authority of Public Health Banská Bystrica, Slovakia Marika Berglund, Institute of Environmental Medicine, Karolinska Institute, Sweden Milena Černá, National Institute of Public Health, Czech Republic Ovnair Sepal, Health Protection Agency, United Kingdom Peter Boogaard, CONCAWE, Belgium Philipp Hohenblum, Federal Environmental Agency, Austria Soterios Kyrtopoulos, Maria Botivali, National Hellenic Research Foundation, Greece Toomas Veldebaum, National Institute for Health Development, Estonia 	<p>Deadlines</p> <p>01/1/2006 Oral presentations - Call for speakers Participants are encouraged to submit abstracts (300 words)</p> <p>01/03/07 Poster presentations - Call for abstracts Participants are encouraged to submit abstracts (300 words) being consistent with the theme</p> <p>Registration by mail to: L.Knudsen@pubhealth.ku.dk</p> <p>Meeting place: University of Copenhagen</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p style="text-align: center;">Contacts:</p> <p>Chairpersons of the workshop: Lisbeth E. Knudsen, PhD E-mail: Lisbeth.Knudsen@pubhealth.ku.dk</p> <p>Greet Schoeters, professor E-mail: Greet.schoeters@vito.be</p> <p>Coordinator of ESBIO: BIPRO Reinhard Joas E-mail: mail@bipro.de</p> <p>EC Project Officer: DG Research Tuomo Karjalainen E-mail: Tuomo.Karjalainen@cec.eu.int</p> <p>Policy DG Involved: DG Environment Birgit Van Tongelen E-mail: Birgit.Van-Tongelen@cec.eu.int</p> </div> <p>Further information on ESBIO is available at www.eu-humanbiomonitoring.org</p> <p>ESBIO has initiated an European Inventory on Human Biomonitoring Activities via: www.HBM-inventory.org</p> <p>PRIVREAL examined the implementation of the Data Protection Directive 95/46/EC in relation to medical research and the role of ethics committees: www.privreal.org</p> <p>Contract no.: SSPE-2005-022580</p> <div style="text-align: right;">  <p>Call for Speakers and Participants</p>  <p>Ethical practises and communication in human biomonitoring - ESBIO workshop Copenhagen March 11-13, 2007</p>  <p>ESBIO Expert team to Support BIoMonitoring in Europe</p> <p><small>ESBIO is funded by the European Commission (Directorate-General Research) under the 6th Framework Programme for Research and Technological Development in close cooperation with Directorate-General Environment</small></p> </div>





Workshop on Ethical Practices in Europe	Human Biomonitoring and ESBIO	Ethical Practises in Human Biomonitoring
<p>An overview on how ethical issues are already practiced in different countries and projects, current legislation and optimal harmonized procedures related to individualized biomonitoring identified and analyzed as an important part of the ESBIO project will be presented at the workshop.</p> <p>The workshop will provide two days of debate on identifying major items for guidelines for ethical issues in human biomonitoring. The workshop will focus on the following themes:</p> <ul style="list-style-type: none"> Justification of interventions <ul style="list-style-type: none"> Autonomy Beneficence Non-maleficence Transparency Recruitment <ul style="list-style-type: none"> Motives of participation Altruism, benefit, knowledge, citizenship, voluntary Information practices <ul style="list-style-type: none"> Situated informed consent Critical circumstances Decision-making capabilities Assent Right to know and not to know Target group specific communication Public understanding of human biomonitoring <ul style="list-style-type: none"> Public participation Communication of results Communicating uncertainties Translation into policies Risks communication Role of media Biobanking, data protection and dissemination Follow-up Intellectual property rights Ethics committees Current legislation and constraints <ul style="list-style-type: none"> Guidelines <p>A number of academics, policy makers and practitioners will address these themes by presenting of cases on individual, community, society level during sessions including:</p> <ul style="list-style-type: none"> Susanne Bauer, Medical Museion, University of Copenhagen Philippe Grandjean, Environmental Medicine, University of Southern Denmark Ludwine Casteloy, Ministry of the Flemish Community, Env., Nature, Land and Water Management Administration Belgium 	<p>Human biomonitoring is a scientific technique for assessing human exposure to and health effects from environmental pollutants. It is based on sampling and analysis of human tissues and fluids (e.g. blood, urine) and it is seen as a powerful tool to support environment policy as well as public health policy.</p> <div style="text-align: center;">  </div> <p>The figure illustrates the exposure-disease sequence in which biomarkers can be measured as indicators of environmental exposures, early predictors of adverse human health effects and susceptibility.</p> <p>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.</p> <p>The ESBIO project (Expert team to Support BIoMonitoring in Europe) was launched by the European Commission in October 2005 and consists of 22 European experts on human biomonitoring, coming from national governments, research institutes, industry and NGOs in 17 Member States and Croatia.</p> <div style="text-align: center;">  </div> <p>The overall objectives of ESBIO are:</p> <ul style="list-style-type: none"> • Development of a coordinated approach for biomonitoring based on existing expertise and experiences available in Member States surveillance programmes and results from research • Elaboration how biomonitoring results can be integrated most efficiently with environmental monitoring and registered health data • Development of strategies to communicate biomonitoring results to stakeholders (population affected, regulators, politicians) including the establishment of websites publicly available and with links to national and international activities resulting in full transparency for the stakeholder • Elaboration of scenarios for the use of biomonitoring results for policy making 	<p>Human biomonitoring studies are increasing in Europe, however no uniform guidelines on ethical issues such as how to inform the participants and how to protect personal data exist.</p> <div style="text-align: center;">  </div> <p>Research with and on human individuals is necessary and appropriated communication is needed.</p> <p>European practices in informing, consenting and managing ethical issues related to human biomonitoring studies gathered from the inventory by SCALE, the PRIVIREAL website and from interviews with stakeholders (e.g., study persons, nurses, technicians, researchers, regulators, etc.) will be identified and analyzed in ESBIO. Specific attention will be devoted to the use of biobanks and information obtained in common databases and adhering regulations in force and foreseen.</p> <p>In order to identifying major items for guidelines for ethical issues in European human biomonitoring, this workshop aims to invite a broad range of stakeholders.</p> <div style="text-align: center;">  </div> <p>The figure illustrates the various groups of stakeholders involved in the different steps of human biomonitoring.</p> <p>Two days of presentations by the various stakeholders allowing diverse views and understanding of the advantages and limits of human biomonitoring to be debated may improve to the current understanding of factors causing ethical conflicts by promoting exchange of experiences</p>

Figure 4 Flyer for WP 4 conference

DELIVERABLE 8.5 – REALISATION OF WORKSHOP WITH ON THE TOPICS OF WP6 INCLUDING WORKSHOP REPORT

The workshop on the utility and sensitivity of biomarker has been organized within WP 6 on the 30-31 March 2006 in Lodz, Poland. The discussions during the workshop were based on the report prepared by the team of WP 6. All contributions during the workshop days have been taken into consideration for the final WP 6 which is available as D 6.3.

DELIVERABLE 8.6 – PREPARE FORM OF COMMUNICATION OF IMPACT RESULTS FOR COMMUNICATION TO VARIOUS ACTORS AND COMMUNCIATE RESULTS IN MEETINGS WITH THE COMMISSION AND MS AS WELL AS IN THE CONSULTATIVE FORUM

During the whole project running time the project team assisted and supported the European Commission DG Environment and the Implementation group on Human biomonitoring in Europe in the discussions and negotiations with Member States and stakeholders in the Consultative Forum. Essential scientific input has been provided to the IG recommendations which are available on <http://www.eu-humanbiomonitoring.org/sub/implgroup/rec.htm>.

DELIVERABLE 8.7 – POSTER AND BROCHURE FOR ESBIO

The first drafts of the poster and the brochure were presented by BiPRO on 7th November during the working meeting in Lamaca, Cyprus. During the meeting the content and the lay out was discussed with the consortium members and BiPRO has taken all comments into account for the final version. Before publication the poster was also discussed with relevant persons at the Commission Directorate General Research and Environment.

The poster was printed in the format Din A1 and distributed to the consortium members. The brochure was designed as a folding map with 3 sections on each side. The total number of copies is 3,000. Most of the brochures were shared among the project team the rest has been distributed on conferences, workshops and other meetings.

Figure 5 shows a miniaturisation of the poster. In Figure 6 the front- and backside of the brochure is given.

Both – the poster and the brochure contain sections on objectives and background:

Objectives

- Development of a coordinated approach for biomonitoring based on existing expertise and experiences available in Member States surveillance programmes and results from research
- Elaboration how biomonitoring results can be integrated most efficiently with environmental monitoring and registered health data
- Development of strategies to communicate biomonitoring results to stakeholders (population affected, regulators, politicians) including the establishment of websites publicly available and with links to national and international activities resulting in full transparency for the stakeholder
- Elaboration of scenarios for the use of biomonitoring results for policy making

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.

For the implementation of Action 3 the Commission has set up a Technical Working Group on HBM (TWG), consisting of HBM experts from several 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:

The first step (2004-2006) consists of the technical preparation of the European Pilot Project. For this reason the EU Commission has launched the ESBIO project. The project team consists of nearly all members of the Implementation Group on Human Biomonitoring.

The second step (2006-...) is the EUROPEAN PILOT PROJECT, which is a "learning by doing tool". It aims to test out the developed coordinated approaches and to facilitate the establishment of collaboration networks and the sharing of methodologies.

In addition the different tasks of the workpackages are briefly introduced and the consortium members involved are named:

Implementation in 8 work packages (WPs):

- **WP1 - Updated inventory of biomonitoring research and non-research actions and databases**
Contact: mfreis@fm.ul.pt
 - ✓ Conference „State of the art“ to be held in Lisbon, Portugal
 - ✓ Updated inventory in electronic form
 - ✓ EU platform for exchange of experiences and expertise (www.HBM-inventory.org)

- **WP2 - Guidelines for best practice on coordinated approach for biomonitoring in EU to be tested out in a EU Pilot Project**
Contact: marike.kolossa@uba.de
 - ✓ Protocols for sampling; recruitment, collecting, analyses, organisation of laboratory work
 - ✓ Questionnaires for the Pilot Project

- **WP3 - Guidelines for integration scenarios and to integrate biomonitoring with environmental and health monitoring; use of biomonitoring results for policy making**
Contact: greet.schoeters@vito.be

- ✓ Links of HBM results to environmental monitoring, health monitoring and research
- ✓ Concept to establish biomonitoring as a
- **WP4 - Ethical issues and concept for communicating biomonitoring information to participants in the Pilot Project**
Contact: l.knudsen@pubhealth.ku.dk
 - ✓ Workshop with stakeholders
 - ✓ Justified concept for dissemination and communication of results within participants of HBM
- **WP5 - Socio-economic consequences, communication to stakeholders and follow up of the EU Pilot Project**
Contact: reinhard.joas@bipro.de
 - ✓ Assessment of alternatives for costs and benefits
 - ✓ Concept for follow up of the Pilot Project
- **WP6 - Utility and Sensitivity of Biomarkers**
Contact: majakub@imp.lodz.pl
 - ✓ workshops to be held in Lodz, Poland
- **WP7 - Coordination and management of the consortium including communication issues**
Contact: reinhard.joas@bipro.de
- **WP8 - Dissemination and overall Communication**
Contact: reinhard.joas@bipro.de
- 11 Active Members with specific tasks
 - Reinhard Joas, BiPRO GmbH, Germany (Coordinator)
 - Fátima Reis, Instituto de Medicina Preventiva, Faculdade de Medicina de Lisboa, Portugal
 - Greet Schoeters, Flemish Institute of Environmental Technology (VITO), Belgium
 - Lisbeth E. Knudsen, University of Copenhagen, Denmark
 - Louis Bloemen, ENVIRON, The Netherlands
 - Ludwine Casteleyn, University of Leuven, Belgium
 - Marek Jakubowski, Institute of Occupational Medicine, WHO collaborating Centre, Poland
 - Marike Kolossa-Gehring, Federal Environmental Agency, Germany
 - Maryse Lehnens-Arendt, Initiativ Liewensufank asbl, Luxembourg - International Baby Food Action Network
 - Nadine Fréry, National Institute of Public Health Surveillance (InVS), France
 - Stella Canna Michaelidou, State General Laboratory, Ministry of Health, Cyprus

➤ 11 Ad Hoc Members

- Aleksandra Fūcić, Institute for Medical Research and Occupational Health, Croatia
- Ari Hirvonen, Finnish Institute of Occupational Health, Finland
- Carlo Sala, ARPA Lombardia, Italy
- Eleonóra Fabiánová, Regional Authority of Public Health Banská Bystrica, Slovakia
- Marika Berglund, Institute of Environmental Medicine, Karolinska Institute, Sweden
- Milena Cema, National Institute of Public Health, Czech Republic
- Ovnair Sepai, Health Protection Agency, United Kingdom
- Peter Boogaard, CONCAWE, Belgium
- Philipp Hohenblum, Federal Environmental Agency, Austria
- Soterios Kyrtopoulos, Maria Botsivali, National Hellenic Research Foundation, Greece
- Toomas Veidebaum, National Institute for Health Development, Estonia

Finally links and contact data are given:

Links:

- http://europa.eu.int/comm/dgs/research/index_en.html
- http://europa.eu.int/comm/dgs/environment/index_en.htm
- www.eu-humanbiomonitoring.org
- www.HBM-inventory.org

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Policy DG involved:

DG Environment



Ms. Birgit Van Tongelen

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Dates of events and further information are available on
www.eu-humanbiomonitoring.org

Contract no.: 022580 (SSPE)

European Human Biomonitoring

funded by the European Commission (Directorate-General Research) under the 6th Framework Programme for Research and Technological Development in close cooperation with Directorate-General Environment

OBJECTIVES

- Development of a coordinated approach for biomonitoring based on existing expertise and experiences available in Member States surveillance programmes and results from research
- Elaboration how biomonitoring results can be integrated most efficiently with environmental monitoring and registered health data
- Develop strategies to communicate biomonitoring results to stakeholders (population affected, regulators, politicians) including the establishment of websites publicly available and with links to national and international activities resulting in full transparency for the stakeholder
- Elaboration of scenarios for the use of biomonitoring results for policy making

BACKGROUND

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The second step (2006-...) is the EUROPEAN PILOT PROJECT, which is a "learning by doing tool". It aims to test out the developed coordinated approaches and to facilitate the establishment of collaboration networks and the sharing of methodologies.

Members of the Consortium

11 Active Members with specific tasks

- Reinhard Joas, BiPRO GmbH, Germany (Coordinator)
- Fátima Reis, Instituto de Medicina Preventiva, Faculdade de Medicina de Lisboa, Portugal
- Greet Schoeters, Flemish Institute of Environmental Technology (VITO), Belgium
- Lisbeth E. Knudsen, University of Copenhagen, Denmark
- Louis Bloemen, ENVIRON, The Netherlands
- Ludwine Casteleyn, University of Leuven, Belgium
- Marek Jakubowski, Institute of Occupational Medicine, WHO collaborating Centre, Poland
- Marika Kolossa-Gehring, Federal Environmental Agency, Germany
- Maryse Lehnens-Arendt, Initiativ Liewensufank asbl, Luxembourg - International Baby Food Action Network
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- Ovnair Sepai, Health Protection Agency, United Kingdom
- Peter Boogaard, CONCAWE, Belgium
- Philipp Hohenblum, Federal Environmental Agency, Austria
- Soterios Kyrtopoulos, Maria Botsivali, National Hellenic Research Foundation, Greece
- Toomas Veidebaum, National Institute for Health Development, Estonia

Implementation in 8 Workpackages:


WP1 Updated inventory of biomonitoring research and non-research actions and databases

Contact: mfreis@fm.ul.pt

- ✓ Conference „State of the art“ to be held in Lisbon, Portugal
- ✓ Updated inventory in electronic form
- ✓ EU platform for exchange of experiences and expertise (www.HBM-inventory.org)

WP4 Ethical issues and concept for communicating biomonitoring information to participants in the Pilot Project


Contact: l.knudsen@pubhealth.ku.dk



- ✓ Workshop with stakeholders
- ✓ Justified concept for dissemination and communication of results within participants of HBM

WP2 Guidelines for best practice on coordinated approach for biomonitoring in EU to be tested out in a EU Pilot Project

Contact: marika.kolossa@uba.de



- ✓ Protocol for sampling; recruitment, collecting, analyses, organisation of laboratory work
- ✓ Questionnaires for the Pilot Project


WP5 Socio-economic consequences, communication to stakeholders and follow up of the EU Pilot Project

Contact: reinhard.joas@biopro.de

- ✓ Assessment of alternatives for costs and benefits
- ✓ Concept for follow up of the Pilot Project

WP3 Guidelines for integration scenarios and to integrate biomonitoring with environmental and health monitoring; use of biomonitoring results for policy making

Contact: greet.schoeters@vito.be



- ✓ Links of HBM results to environmental monitoring, health monitoring and research
- ✓ Concept to establish biomonitoring as a policy making tool on a European level

WP6 Utility and Sensitivity of Biomarkers

Contact: majakub@imp.lodz.pl

- ✓ Workshops to be held in Lodz

WP7 Coordination and management of the consortium including communication issues

Contact: reinhard.joas@biopro.de

WP8 Dissemination and overall Communication

Contact: reinhard.joas@biopro.de

Contacts

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Figure 5 Poster for ESBIO

Members of the Consortium

➤ 11 Active Members with specific tasks

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- Greet Schoeters, Flemish Institute of Environmental Technology (VITO), Belgium
- Lisbeth E. Knudsen, University of Copenhagen, Denmark
- Louis Bloemen, ENVIRON, The Netherlands
- Ludwine Casteleyn, University of Leuven, Belgium
- Marek Jakubowski, Institute of Occupational Medicine, WHO collaborating Centre, Poland
- Marike Kolossa-Gehring, Federal Environmental Agency, Germany
- Maryse Lehnens-Arendt, Initiativ Liewensufank asbl, Luxembourg - International Baby Food Action Network
- Nadine Fréry, National Institute of Public Health Surveillance (InVS), France
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- Marika Berglund, Institute of Environmental Medicine, Karolinska Institute, Sweden
- Milena Cerna, National Institute of Public Health, Czech Republic
- Ovnair Sepai, Health Protection Agency, United Kingdom
- Peter Boogaard, CONCAWE, Belgium
- Philipp Hohenblum, Federal Environmental Agency, Austria
- Soterios Kyrtopoulos, María Botsivali, National Hellenic Research Foundation, Greece
- Toomas Veidebaum, National Institute for Health Development, Estonia

Links and Contacts

- http://europa.eu.int/comm/dgs/research/index_en.html
- http://europa.eu.int/comm/dgs/environment/index_en.htm
- www.eu-humanbiomonitoring.org
- www.HBM-inventory.org

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DG Environment
Ms. Birgit Van Tongelen
Email: Birgit.Van-Tongelen@cec.eu.int

Dates of events and further information are available on
www.eu-humanbiomonitoring.org

Contract no.: 022580 (SSPE)



European Human Biomonitoring

ESBIO
Expert team to Support
BIOmonitoring in Europe

funded by the European Commission (Directorate-General Research) under the 6th Framework Programme for Research and Technological Development in close cooperation with Directorate-General Environment



Objectives

- Development of a coordinated approach for biomonitoring based on existing expertise and experiences available in Member States surveillance programmes and results from research
- Elaboration how biomonitoring results can be integrated most efficiently with environmental monitoring and registered health data
- Development of strategies to communicate biomonitoring results to stakeholders (population affected, regulators, politicians) including the establishment of websites publicly available and with links to national and international activities resulting in full transparency for the stakeholder
- Elaboration of scenarios for the use of biomonitoring results for policy making

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.

For the implementation of Action 3 the Commission has set up a Technical Working Group on HBM (TWG), consisting of HBM experts from several 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:

The first step (2004-2006) consists of the technical preparation of the European Pilot Project. For this reason the EU Commission has launched the ESBIO project. The project team consists of nearly all members of the Implementation Group on Human Biomonitoring.

The second step (2006-...) is the EUROPEAN PILOT PROJECT, which is a "learning by doing tool". It aims to test out the developed coordinated approaches and to facilitate the establishment of collaboration networks and the sharing of methodologies.

Implementation in 8 work packages (WPs):

• WP1 - Updated inventory of biomonitoring research and non-research actions and databases

Contact: mfreis@fm.ul.pt

- ✓ Conference „State of the art” to be held in Lisbon, Portugal
- ✓ Updated inventory in electronic form
- ✓ EU platform for exchange of experiences and expertise (www.HBM-inventory.org)

• WP2 - Guidelines for best practice on coordinated approach for biomonitoring in EU to be tested out in a EU Pilot Project

Contact: marike.kolossa@uba.de

- ✓ Protocols for sampling; recruitment, collecting, analyses, organisation of laboratory work
- ✓ Questionnaires for the Pilot Project



• WP3 - Guidelines for integration scenarios and to integrate biomonitoring with environmental and health monitoring; use of biomonitoring results for policy making

Contact: greet.schoeters@vito.be



- ✓ Links of HBM results to environmental monitoring, health monitoring and research
- ✓ Concept to establish biomonitoring as a policy making tool on a European level

• WP4 - Ethical issues and concept for communicating biomonitoring information to participants in the Pilot Project

Contact: l.knudsen@pubhealth.ku.dk



- ✓ Workshop with stakeholders
- ✓ Justified concept for dissemination and communication of results within participants of HBM

• WP5 - Socio-economic consequences, communication to stakeholders and follow up of the EU Pilot Project

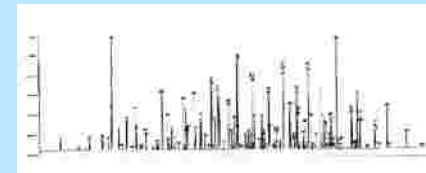
Contact: reinhard.joas@bipro.de

- ✓ Assessment of alternatives for costs and benefits
- ✓ Concept for follow up of the Pilot Project

• WP6 - Utility and Sensitivity of Biomarkers

Contact: majakub@imp.lodz.pl

- ✓ workshops to be held in Lodz, Poland



• WP7 - Coordination and management of the consortium including communication issues

Contact: reinhard.joas@bipro.de

• WP8 - Dissemination and overall Communication

Contact: reinhard.joas@bipro.de

Figure 6 Brochure for ESBIO

European Commission, DG RTD

Deliverable 5.2

Development of a coherent approach to human biomonitoring in Europe

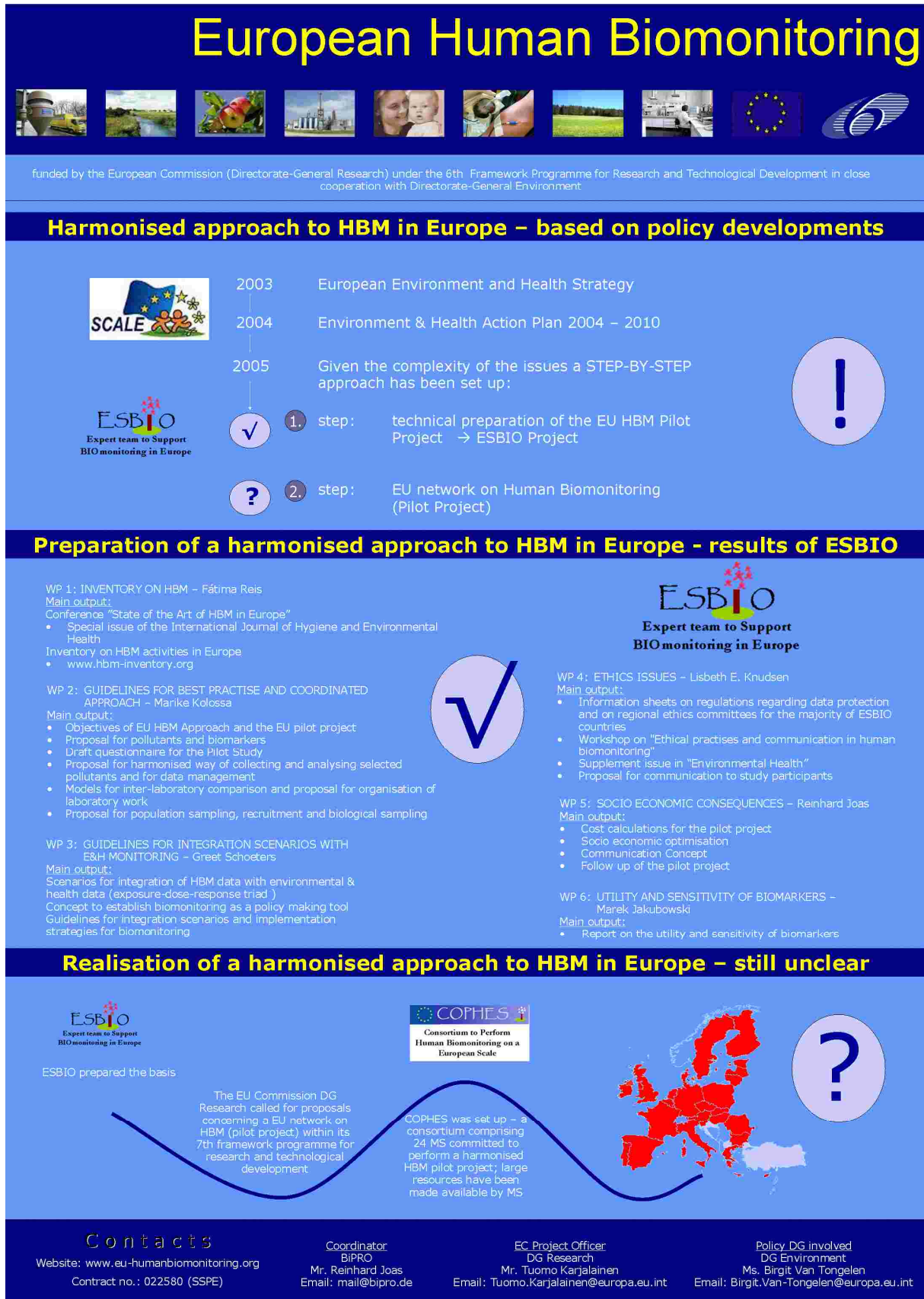


Figure 7 Second poster for ESBIO

DELIVERABLE 8.8 – CONCLUSIONS AND CONSEQUENCES FOR ESBIO WORK FROM OTHER MEETINGS

During the two years project running time nearly all members of the ESBIO team participated in important meetings on national, EU as well as international level.

Feedback from the meetings has been provided during the ESBIO working meetings and has been taken into account for the tasks carried out within the ESBIO project.

3. Conclusions

The communication within ESBIO has been carried out successfully with the aim to prepare a coherent approach to HBM in Europe. The European Commission as well as Member States and the scientific world have been informed regularly; the whole project was transparent for all interested people.

The project contributed to create a network of experts all over Europe, to increase the visibility of HBM and to find an agreed basis for an EU wide European HBM pilot project.

ANNEX I



Conference program





	March 19, 2006	March 20, 2006	March 21, 2006	
09:00-09:30		OPENING SESSION Conference welcome Plenary session 1 Plenary session 2	SESSION 2 – Part 3 Plenary session 11 Plenary session 12	
09:30-10:00				
10:00-10:30				
10:30-11:00		Coffee break - Posters visit	SESSION 1 Plenary session 3 Plenary session 4 Plenary session 5 Plenary session 6	Coffee break
11:00-11:30				
11:30-12:00				
12:00-12:30		Session 3 Plenary Session 13		
12:30-13:00		Closing Session		
13:00-13:30		Lunch		SESSION 2 – Part 1 Parallel sessions A Parallel sessions B Symposium
13:30-14:00				
14:00-14:30				
14:30-15:00				
15:00-15:30				
15:30-16:00				
16:00-16:30		Coffee break - Posters visit		
16:30-17:00		SESSION 2 – Part 2 Plenary session 7 Plenary session 8 Plenary session 9 Plenary session 10 Parallel Sessions Conclusions		
17:00-17:30				
17:30-18:00				
18:00-18:30	Registration Welcome Reception	Conference Dinner		
18:30-19:00				
19:00-23:00				



Introduction and objectives

The European Environment and Health Strategy adopted by the European Commission in 2003 (COM (2003) 338 final) presented a new vision on how to address environment and health in an integrated way and put health in the centre of environmental policy. Action 3 of the Environment and Health Action Plan 2004 – 2010 adopted by the Commission in 2004 (COM (2004) 416 final, volume I, COM (2004) 416 final, volume II), announced the development of a coherent approach to Human Biomonitoring (HBM) in Europe in close cooperation with the Member States.

For the implementation of Action 3 of the Environment and Health Action Plan 2004 – 2010, a step by step approach has been set up. The Expert team to Support BiOmonitoring (ESBIO) project is preparing the launch of an European Pilot Project.

The objective of ESBIO's Work Package I is to promote an European Inventory of Human Biomonitoring (EIHBM), an updated and extended data base of the existing HBM activities within Europe; to ensure integration of relevant activities and stakeholders in the development of a coordinated approach to Human Biomonitoring in Europe, and to initiate the creation of a platform for exchange on HBM experiences and expertise.

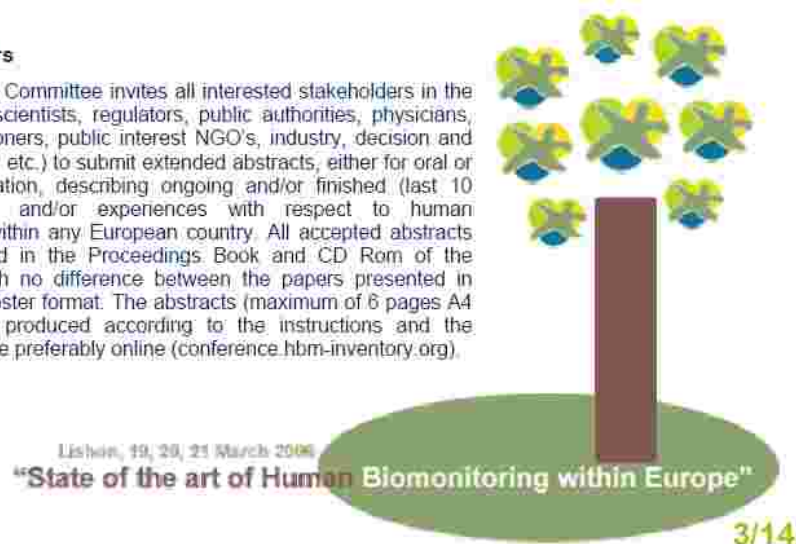
The aims of this Conference are: to get together providers of HBM information; to improve existing information on HBM; to identify expertise and institutions that are performing HBM research and surveillance activities; to provide a forum for discussion of problems in conducting HBM; and to stimulate exchange of experiences on human biomonitoring.

Announcement

As coordinator of the ESBIO's WP1, the Institute of Preventive Medicine, with the support of several national institutions, namely the Lisbon Faculty of Medicine, the High Commissioner's Office for Health; the General Direction of Health; the Environment Institute, and the Science and Technology Foundation at the Ministry of Science, Technology and Higher Education, announces the ESBIO Conference on **"State of the art of Human Biomonitoring within Europe"**, to be held in Lisbon, Portugal, on March 19-21, 2006, at the Lisbon Faculty of Medicine, Edifício Egas Moniz.

Call for Papers

The Organising Committee invites all interested stakeholders in the field of HBM (scientists, regulators, public authorities, physicians, general practitioners, public interest NGO's, industry, decision and opinion makers, etc.) to submit extended abstracts, either for oral or poster presentation, describing ongoing and/or finished (last 10 years) studies and/or experiences with respect to human biomonitoring within any European country. All accepted abstracts will be included in the Proceedings Book and CD Rom of the Conference with no difference between the papers presented in either oral or poster format. The abstracts (maximum of 6 pages A4 size) shall be produced according to the instructions and the submission done preferably online (conference.hbm-inventory.org).





Exhibitions

Companies/Organizations operating in any field of HBM area will have an opportunity to exhibit their latest technical developments.

Structure of the Conference and Program

The Conference, bridging a wide spectrum of topics in the thematic area of HBM, will run through "Oral plenary sessions", by invited speakers; "Oral and Poster presentations", by scientists and decision makers; and "Technical exhibition" incorporating accepted Companies, according to the following Program.

Honorary Committee

Fernandes e Fernandes, J.	Lisbon Faculty of Medicine (Portugal)
George, Francisco	General Direction of Health (Portugal)
Gonçalves, João	Environment Institute (Portugal)
Joas, Reinhard	ESBIO Coordination (Germany)
J. Pereira Miguel	High Commissioner's Office for Health (Portugal)
Sentieiro, João	Science and Technology Foundation (Portugal)
Haavisto, Kirsi	DG Research (European Commission)
Van Tongelen, Birgit	DG Environment (European Commission)

Scientific Committee

Casimiro, Elsa	D. Luís Institute, Lisbon Faculty of Sciences, Portugal
Casteleyn, Ludwine	University of Leuven, Government of Flanders, Belgium
Figueira, Rui	Botanic Garden, National Museum of Natural History, Lisbon University, Portugal
Jakubowski, Marek	Institute of Occupational Medicine, Poland
Joas, Reinhard	ESBIO Coordination, Germany
Kolossa, Marika	Federal Environmental Agency, Germany
Reis, M. Fátima	Institute of Preventive Medicine, Portugal
Schoeters, Greet	Flemish Institute of Environmental Technology, Belgium
Vilão, Regina	Institute for the Environment, Portugal
Weigert, Cláudia	Directorate General of Health, Portugal

Lisbon, 19, 20, 21 March 2006

"State of the art of Human Biomonitoring within Europe"

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Organizing Committees

Main Conference

Carrola, Cristina	Institute for the Environment, Ministry for Environment, Spatial Planning and Regional Development
Casimiro, Elsa	D. Luis Institute, Faculty of Sciences of the Lisbon University
Diegues, Paulo	Directorate General of Health, Ministry of Health
Lopes, Marta	Institute of Preventive Medicine, Lisbon Faculty of Medicine
Reis, M. Fatima	Institute of Preventive Medicine, Lisbon Faculty of Medicine
Tedim, João	Sensó Comum Lda
Vilão, Regina	Institute for the Environment, Ministry for Environment, Spatial Planning and Regional Development
Weigert, Cláudia	Directorate General of Health, Ministry of Health

Symposium

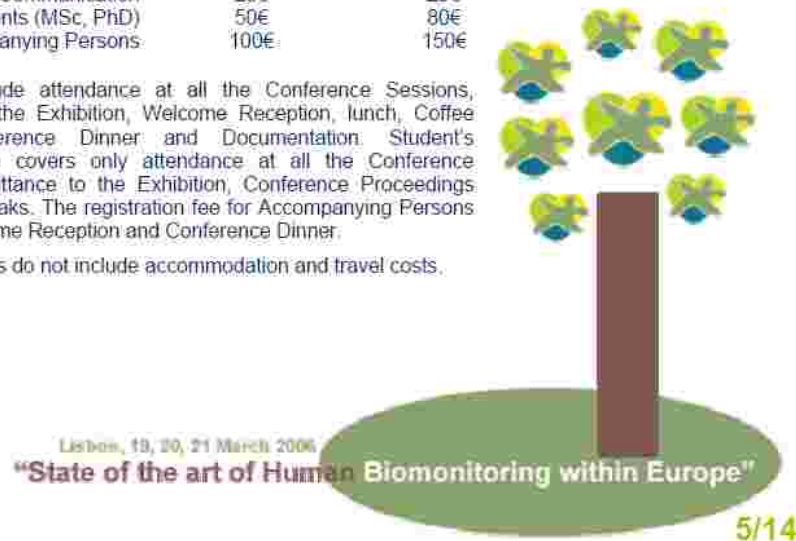
Figueira, Rui	Botanical Garden, National Natural History Museum, Lisbon University
Reis, M. Fatima	Institute of Preventive Medicine, Lisbon Faculty of Medicine
Sérgio, Cecilia	Botanical Garden, National Museum of Natural History, Lisbon University
Vilão, Regina	Institute for the Environment, Ministry for Environment, Spatial Planning and Regional Development
Weigert, Cláudia	Directorate General of Health, Ministry of Health

Registration fees

Type of Registration	Up to 01/03/2006	After 01/03/2006
ESBIO Members	-	-
Participants (full fee)	200€	250€
Participants (Symposium)	100€	100€
Authors (1 communication)	100€	150€
Additional Communication	20€	25€
Students (MSc, PhD)	50€	80€
Accompanying Persons	100€	150€

The fees include attendance at all the Conference Sessions, admittance to the Exhibition, Welcome Reception, lunch, Coffee Breaks, Conference Dinner and Documentation. Student's registration fee covers only attendance at all the Conference Sessions, admittance to the Exhibition, Conference Proceedings and Coffee Breaks. The registration fee for Accompanying Persons includes Welcome Reception and Conference Dinner.

Conference fees do not include accommodation and travel costs.





Conference venue

ESBIO Conference on "*State of the art of Human Biomonitoring within Europe*" will be held in Lisbon, Portugal, on March 19-21, 2006, at the Lisbon Faculty of Medicine, Edifício Egas Moniz. Venue for Opening Session is "Aula Magna" at the building of Hospital de Santa Maria.

Conference Language

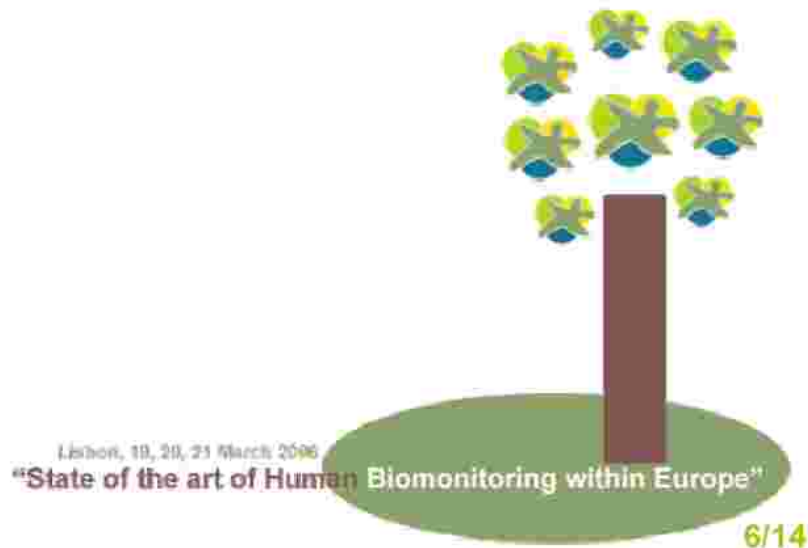
The official language of the Conference is English. No simultaneous translation will be provided for the Scientific and the Social Program.

Application and timetable

Please register using conference.hbm-inventory.org having into consideration the following important dates:

Abstract submission deadline	March 1, 2006
Notification of acceptance	March 8, 2006
Early registration deadline	March 1, 2006
Conference Days	March 19 – 21, 2006

Hotel details and other relevant information will be sent following registration confirmation.





PROGRAM

Monday, March 20, 2006

09:00 – 10:30 **OPENING SESSION**

CHAIR: *Ludwine Casteleyn, University of Leuven, Government of Flanders, Belgium*

Conference Welcome

*J. Fernandes e Fernandes, Lisbon Faculty of Medicine
F. George, Directorate General of Health, Portugal
João Gonçalves, Institute for the Environment, Portugal
M. Fátima Reis, Organising Committee*

Context and background of Action 3 of the EC Environment and Health Action Plan 2004-2010

Birgit Van Tongelen, DG Environment, European Commission

Introduction to ESBIO objectives and work

Reinhard Joas, BiPRO GmbH, Germany

10:30 – 11:00 **Coffee break / Posters visit**

11:00 – 13:00 **SESSION 1 – Introduction to HBM, objectives and key issues**

CHAIR: *Birgit Van Tongelen, DG Environment, European Commission*

HBM: what is it and why do we need it?

Ludwine Casteleyn, University of Leuven, Government of Flanders, Belgium

Biomonitoring – general requirements and situation in Germany

Juergen Angerer, Institute für Arbeits-, Sozial – und Umweltmedizin der Universität Erlangen-Nürnberg, Germany

Problems and deficits in conducting HBM

Marika Kolossa, Federal Environmental Agency, Germany

Overview on projects funded by DG Research, European Commission

Kirsi Haavisto, DG Research, European Commission

DISCUSSION

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13:00 – 14:00 Lunch

14:00 – 16:00 SESSION 2 – HBM activities within Europe (Part 1)

Country case studies

Overview of HBM activities – research, surveillance, regulation ... – executed or under development, reported by answering the following questions: why, what, where and how are we measuring?

✓ **Parallel session A: HBM addressing exposure**

CHAIR / Reporter: *Marika Kolossa, Federal Environmental Agency, Germany*

14:00-14:10

Better use of methods for biological monitoring of exposure to carcinogenic substances (BIOMONECS)

Paul Schrebiers, Radboud University Medical Centre, Nijmegen, The Netherlands

14:10-14:20

Human Biomonitoring in North Rhine Westphalia, Germany

Michael Wilhelm, Ruhr-University Bochum, Dept. of Hygiene, Social and Environmental Health, Germany

14:20-14:30

Biological monitoring of environmental exposure to lead: An example from Poland

Marek Jakubowski, Nofar Institute of Occupational Medicine, Poland

14:30-14:40

The new Italian web-site on biological monitoring

Gianna Nen, University of Brescia, Italy

14:40-14:50

German Environmental Survey (GerES): Human Biomonitoring as a Tool to Identify Exposure Pathways

Kerstin Becker, Federal Environmental Agency, Germany

14:50-15:00

Biomonitoring in the UK Health & Safety Laboratory

John Cocker, Health & Safety Laboratory, UK

15:00-15:10

Biomarkers of exposure, effect and susceptibility to carcinogenic PAHs in polluted air

Radim Srám, Institute of Experimental Medicine AS, CR

Lisbon, 19, 20, 21 March 2006

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State of the art of Human Biomonitoring within Europe

15:10-15:20

Sentinel Health Department Project in Baden-Wuerttemberg (Germany) - an useful tool for monitoring children's health and environment
Bernhard Link, Landesgesundheitsamt Baden-Wuerttemberg, Germany

15:20-15:30

Blood Concentrations of Long Chain n-3 PUFA and Methylmercury among French High Seafood Consumers (Study CALIPSO)
J. Leblanc

15:30-15:40

Polycyclic musk compounds in blood samples of young adults in Austria
Philipp Hohenblum, Umweltbundesamt Vienna, Austria

DISCUSSION

- ✓ **Parallel session B: HBM addressing adverse effects in health or quality of life**

CHAIR / Reporter: *Ludwine Casteleyn, University of Leuven, Government of Flanders, Belgium*

14:00-14:10

Styrene-oxide N-terminal valine haemoglobin adducts as biomarkers of occupational exposure to styrene
João Paulo Teixeira, National Institute of Health, Portugal

14:10-14:20

The assessment of the exposure of breast milk to persistent organic pollutants
Marite Anja Bawe, Institute of Occupational & Environmental Health of Riga Stradins University, Lithuania

14:20-14:30

Heavy metal content of forages, organs and primary products of a grazed sheep flock and its effect on human food safety
Akos Bodnar, Szent Istvan University, Hungary

14:30-14:40

Human Biomonitoring System in the Czech Republic
Milena Cerna, National Institute of Public Health, CR

14:40-14:50

Prospective study on incidence and environmental determinants of spontaneous abortion before clinically recognized pregnancy
M. Fátima Reis, Institute of Preventive Medicine, Lisbon Faculty of Medicine, Portugal

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State of the art of Human Biomonitoring
within Europe

14:50-15:00

Fast, low volume methods for human monitoring of anabolic agents and endocrine disrupting compounds

Abraham Brouwer, BioDetection Systems B.V., The Netherlands

15:00-15:10

Lead exposure of children and newborn in Porto, Portugal

Joana Roma Torres, National Institute of Health, Portugal

15:10-15:20

Who global environment monitoring system/food contamination monitoring programme in Europe – WHO/UNEP coordinated global survey of human milk for persistent organic pollutants and link with SCALE

Cristina Tirado, WHO

15:20-15:30

Biomonitoring of environmental estrogens in breast cancer. Experience in Southeast Spain

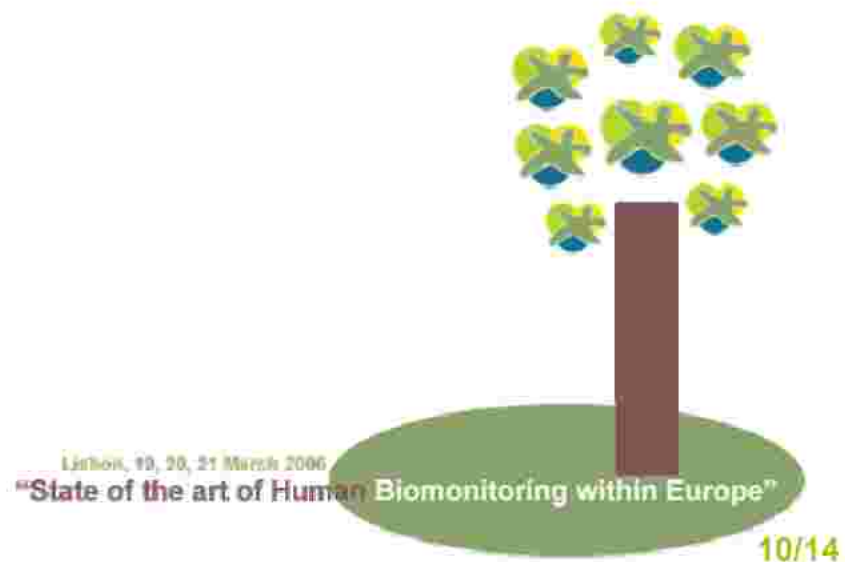
Nicolas Olea, University of Granada, Spain

15:30-15:40

Biomonitoring and communication

Maryse Leitner, Initiative Liewensufank, Luxemburg

DISCUSSION



14:00 – 16:00 **SESSION 2 – HBM activities within Europe (Part 1) (cont)**

Country case studies

Overview of HBM activities – research, surveillance, regulation ... – executed or under development, reported by answering the following questions: why, what, where and how are we measuring?

✓ **Symposium on Integration of Environment and Health Data: Use of HBM as a Tool for Policymaking**

CHAIR / Reporter: *Stella Michaelidou, Cyprus Committee on Children's Environment and Health*

14:00-14:10

Environmental monitoring, biomonitoring and health surveillance for developing tools for Integrated Assessment of Health risks from environmental stressors (INTARESE)

David Briggs, Department of Epidemiology and Public Health, Imperial College of Science, Technology and Medicine, UK

14:10-14:20

Integrating Environmental and Human Biomonitoring: advantages and problems

Greet Schoeters, VITO, Belgium

14:20-14:30

Biomonitoring as a tool to support Children's Environment and Health policies

Stella Michaelidou, Cyprus Committee on Children's Environment and Health, Greece

14:30-14:40

A Proposed Framework for the Interpretation of Biomonitoring Data

Chris Money, ExxonMobil Petroleum & Chemical, Belgium

14:40-14:50

Foetal exposure to lead as determined by human and environmental biomarkers – investigation of influence on human reproductive outcomes and autonomic nervous system in rats

Carla Sampaio, Institute of Preventive Medicine, Portugal

14:50-15:00

Identifying opportunities and gaps for establishing an integrated EDR-Triad at a European level

Roel Snijders, VITO, Belgium

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15:00-15:10

The Spanish Environment and Childhood Research Network («INMA» Study)

Marieta Fernandez, University Hospital San Cecilio, Granada, Spain

15:10-15:20

How biomonitoring with lichens will improve the knowledge on human biomonitoring

Cristina Branquinho, University of Lisbon, Sciences Faculty, Ecology and Vegetal Biology Center, Portugal

15:20-15:30

Ten years of biomonitoring atmospheric metal deposition assessment in Portugal, measured by mosses

Rui Figueira, IST, Lisbon, Portugal

15:30-15:40

Integrated Exposure Assessment Survey (INES) Exposure to persistent and bioaccumulative chemicals in Bavaria, Germany

Hermann Fromme, Bavarian Health and Food Safety Authority, Department of Environmental Health, Germany

DISCUSSION

16:00 – 16:30 Coffee break / Posters visit / Technical exhibition

16:30 – 19:00 SESSION 2 – HBM activities within Europe (Part 2)

CHAIR / Reporter: *Maria Botsivali, National Hellenic Research Foundation, Greece*

WHO activities in Europe: overview of HBM actions, finished and ongoing

Gerald Moy, WHO

WHO-coordinated exposure studies on levels of persistent organic pollutants in human milk

Part 1. Concept and results of previous rounds

Rainer Malisch, Gerald Moy and Rotaf van Leeuwen, WHO

Part 2. Ongoing and future work

Gerald Moy, Hae Jung Yoon and Rainer Malisch, WHO

Lisbon, 18, 20, 21 March 2006

“State of the art of Human Biomonitoring within Europe”

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16:30 – 19:00 SESSION 2 – HBM activities within Europe (Part 2) - cont

CHAIR / Reporter: *Maria Botsivali, National Hellenic Research Foundation, Greece*

Human Biomonitoring Activities – Programmes by Industry
Peter Boogaard, CONCAWE, Belgium

HBM Activities by NGOs
Genon Jensen, EPHA Environment Network (EEN), Belgium

Parallel sessions conclusions

Marika Kolossa, Federal Environmental Agency, Germany
Marek Jakubowski, Institute of Occupational Medicine, Poland
Ludwine Casteleyn, University of Leuven, Government of Flanders, Belgium
Louis Bloemen, Exponent, The Netherlands
Stella Michaelidou, Cyprus Committee on Children's Environment and Health
Nadine Fréry, National Institute of Public Health Surveillance, France

DISCUSSION

Tuesday, March 21, 2006

09:00 – 11:30 SESSION 2 – HBM activities within Europe (Part 3)

CHAIR: *Reinhard Joas, BiPRO GmbH, Germany*

Online integrated solution to collect data, generate information and manage events in the human biomonitoring field

M. Fátima Reis, Institute of Preventive Medicine, Portugal
João Tedim, Senso Comum Lda, Portugal
Pedro Aguiar, National School of Public Health, Lisbon, Portugal
Ludwine Casteleyn, University of Leuven, Government of Flanders, Belgium
Reinhard Joas, BiPRO GmbH, ESBIO Coordination, Germany
Birgit Van Tongelen, DG Environment, European Commission

A coordinated approach to HBM in Europe: the way forward / state of affairs of the Pilot Project

Alexandra Weiss, BiPRO GmbH, Germany
Birgit Van Tongelen, DG Environment, European Commission
Ludwine Casteleyn, University of Leuven, Government of Flanders, Belgium

DISCUSSION

Lisbon, 19, 20, 21 March 2006

"State of the art of Human Biomonitoring within Europe"

13/14



11:30 – 12:00 Coffee break / Posters visit / Technical exhibition

12:00 – 12:30 SESSION 3 – USA perspectives on HBM

CHAIR: Greet Schoeters, *Flemish Institute of Environmental Technology, Belgium*

The Human Biomonitoring Program at the Centers for Disease Control and Prevention

Eric Sampson, Centers for Disease Control and Prevention (CDC), USA

12:30 – 13:00 CLOSING SESSION

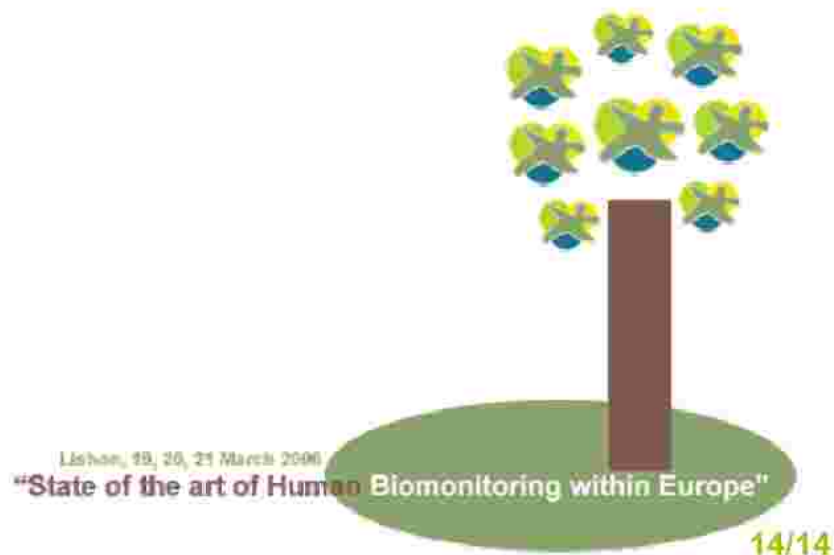
CHAIR: Birgit Van Tongelen, *DG Environment, European Commission*

Conference conclusions

Reinhard Joas, Birgit Van Tongelen, Maria Botsivali, Stella Michaelidou, Ludwine Casteleyn and WPs leaders (M. Fátima Reis, Marika Kolossa, Greet Schoeters, Marek Jakubowski)

Closing ceremony

*Birgit Van Tongelen, DG Environment
Maria Luisa Tamborra, DG Research, European Commission
Reinhard Joas, ESBIO
J. Pereira Miguel, High Commissioner's Office for Health
Henrique de Barros, High Commissioner's Office for Health
J. Sentieiro, Science and Technology Foundation
M. Fátima Reis, Organizing Committee*



ANNEX II

Program for ESBIO workshop on ethics and communication in Copenhagen 11-13.3.2007

An overview on how ethical issues are already practiced in different countries and projects, current legislation and optimal harmonized procedures related to individualized biomonitoring identified and analyzed as an important part of the ESBIO project will be presented at the workshop.

The workshop will provide two days of debate on identifying major items for guidelines for ethical issues and communication in human biomonitoring. The workshop will focus on the following themes:

Monday 12th March: Ethics workshop at the EEA building European Environment Agency, Kongens Nytorv 6. Please bring identification papers as you will only be allowed in according to list of participants.

Chairperson Lisbeth E. Knudsen, co-chairperson Uffe Lind University of Copenhagen

10.00-10.30 Welcome to EEA and presentation of EEA and biomonitoring by Dorota Jarosinska, EEA

10.30-11.00 Update on WP 4 and summary of workshop in Brussels, suggestions for common informed consent and information by Lisbeth E. Knudsen

11.00-11.30 Research on ethics in ECNIS and NewGeneris: A bottom up approach - Birgit Dumez/Ludwine Casteleyn University of Leuven

11.30-12.00 The seven deadly sins in environmental epidemiology and biomonitoring Philippe Grandjean University of Southern Denmark

12.00-13.0 Lunch

13.00-13.30 Susanne Bauer, Medical Museion, University of Copenhagen: Ethical issues in HBM –a view from science studies

13.30-14.00 Ulf Görman, University of Lund: Involving children in research - an ethical challenge

14.00-14.30 Myron Harrison. Applying Traditional Bioethical Principles to Human Biomonitoring

14.30-15.00 Lisbeth E. Knudsen: Issues of biobanking related to HBM

15.00-15.15 Break

15.15-15.40 Franco Merlo, Institute of Cancer Research Genoa: Special ethics issues in environmental health

15.40-16.00 Alexandra Fucic: Ethical and psychological aspects of sampling for biomonitoring: experiences in Central European countries

16.00-16.20 Uffe Lind Monitoring ethics – a case study

16.20-16.40 Lisbeth E. Knudsen - Recommendations for WP4

16.40-18.00 Groups with specific issues to be discussed

Evening free

Tuesday 13th March: Communication workshop at the EEA building

Chairperson Greet Schoeters, co-chairperson Roel Smoelders

9.00-9.15 Update on WP3 and summary of workshop in Brussels Roel Smoelders

9.15-9.40 Hans Keune Knowledge for action: joint reflection on environment & health-

9.40-10.00 Gudrun Koppen: The Flemish action plan used to deal with regionally elevated serum pp'-DDE in two Flemish areas

10.00-10.30 / Maryse Lehnert- Arendt / Communicating human biomonitoring results - interference with public health recommendations Analysing breastmilk- promoting, protecting and supporting breastfeeding?

10.30-11.00 Break

11.00-12.00 Recommendation for WP3

Contact person of the workshop (registration, booking of hotel etc):

Lisbeth E. Knudsen, PhD E-mail: L.Knudsen@pubhealth.ku.dk

Further information on ESBIO is available at:

www.eu-humanbiomonitoring.org Contract no.: SSPE-2005-022580

ESBIO has initiated a European Inventory on Human Biomonitoring Activities via:

www.HBM-inventory.org

Lisbeth E. Knudsen: The objectives and results from WP4 will be presented.

A summary of discussions in Brussels at stakeholder meeting will be given

Stakeholders in human biomonitoring from industry, government, research and NGOs gave opinions on organisation of biomonitoring studies including children. Enrolment could either be through direct approaches to parents or advertisements. Repeated measurements were fully acceptable by all and the majority accepted all samplings of blood, urine, scalp hair and questionnaire. Study persons should be informed about study results or request results. Data should be protected by coding and made available for governments and research after anonymisation. Reimbursement of expenses related to participation should be organised while different views were expressed regarding incentives as gifts and payment. National differences in regulation should be respected while harmonisation was considered a necessity for future HBM activities.

Ethical issues in human biomonitoring – a view from science studies

Susanne Bauer Medical Museion, University of Copenhagen

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Having moved from environmental science and epidemiology to STS (science and technology studies), my current research examines contemporary epidemiology as a historically situated biomedical practice. Following the practices of sampling, data collection and organisation, my current project “The Population as a Laboratory: Epistemic and Visual Cultures of Epidemiology” documents epidemiology’s “quasi-experimental” research systems: this documentation ranges from study designs, aetiological models, data gathering and sampling procedures, population registers, data organisation to biostatistical analysis and evidence-based public health recommendations.

In this paper I will reflect on human biomonitoring (HBM) as part of environmental epidemiology. My goal here is to explore how science studies can contribute to mapping out ethical issues in HBM. Biomarkers constitute a direct measure of multiple environmental exposures and are increasingly used in epidemiological studies. Monitored in large populations, they often add to or replace previous environmental indicators. Measuring environmental exposure within the human body shifts the site of monitoring from air, soil and water towards a screening study populations. What are the ethical and social implications of this shift?

Biomarkers can indicate exposure, susceptibility or disease and are interpreted within an array of risk factors including “genetic predisposition, lifestyle, culture, socio-economic factors, geographical location, climate and exposure to environmental stresses”. The linkage of biological samples together with the storage of individual data (biobanking) raises a host of ethical issues with regard to participation, consent, risk communication etc.. Epidemiological studies can be understood as complex assemblages that comprise extensive information networks and data flows stabilised for knowledge generation. Their products – population-based risk estimates – represent tools of governance; at the same time they enrol citizens into a mode of risk management, drawing on epidemiological assessments. What kind of biological citizenship do they enact - both as to the researchers, study participants and the general public? In what ways do sampling, data organisation practices, biomarkers and choices of indicators co-shape how we conceptualise the environment, health and disease?

Myron Harrison,

Addressing bioethical concerns is routinely identified as one of the challenges in the field of human biomonitoring. Any attempt to do that begs the question of whose or which bioethical framework is most germane. Without trying to answer that question this presentation is an attempt to apply “traditional bioethical principles” to the interpretation and use of human biomonitoring data. A key point is that there is not a single generic bioethical analysis applicable to the use of human biomonitoring data, but that each specific use requires a separate deliberation.

Uffe Lind, Institute of Public Health, University of Copenhagen

Abstract: Monitoring research – a sociological study of research subjects participation in HBM

Purpose: To gain sociological knowledge about why and how research subjects participate in the production of medical knowledge and technologies in relation to HBM.

Method: 20 in-depth semi-structured interviews with research subjects participating in placenta perfusion project at University of Copenhagen. Interviews are recorded and transcribed. Interviews are analysed according an interactions method.

Results: Results regarding the themes *trust in science*, *reasons for participation* and *ways informing* will be presented:

Trust in science: Research subjects have general trust in science as such and are pro-science

Reasons for participation: Research subjects feel obliged to participate but they are also genuinely interested in the project. They ask for the results. They stress the importance of being asked (informed consent) and the importance of proper information. They want to know what the research is about. The easiness of participating is important.

Ways of informing: Information must be short and precise. The purpose of the project is important. It should also be clear what the nature of the results is and what the participation involves.

Discussion: Results from the analysis may lead to different ways of understanding practices of medical ethics and the role of research subjects in the production of medical knowledge and technologies.

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Ethical and psychological aspects of sampling for biomonitoring: experiences in R Croatia

Due to differences in social systems, Western and Central Europe differed in the biomonitoring practice of populations occupationally or environmentally exposed to xenobiotics. The practice of ethics committees in socialist countries varied, as it started from different concepts and quality levels. Harmonization on the European level seen in the last decade has resulted in standardized procedures to obtain individual consent to participate in a biomonitoring study as well as in standardised ethics committee procedures. In Croatia, biomonitoring was a routine part of occupational medicine and was also often applied for the evaluation of environmental exposure, such as analyses of breast milk, urine or saliva. Genotoxicological methods have been used as a part biomonitoring studies for almost 30 years now.

Individual voluntary decisions (not) to participate in cytogenetic tests for occupational exposure to carcinogens involve a complex interaction of personal ethical and religious values and apprehension of test results. Traditionally, Croats have been taught to put common benefit before personal, even if it sometimes takes a wilful sacrifice, which has certainly been beneficial for collaboration with potential study participants. The critical requirement, however, is that the biomonitoring study interviewer is highly qualified and able to adjust to potential participants, whatever their education, social status or age.

Ethical issues experienced in HBM within Portuguese health surveillance and research projects

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Abstract

In keeping with the fundamental practice of transparency in the discussion and resolution of ethical conflicts raised by research, we present a summary of ethical issues raised during Portuguese biomonitoring in health surveillance and research and describe if and how they have been solved. Projects include the biomonitoring in the general population as well as in pregnant women and children, of dioxin-like compounds and heavy metals in tissues including blood and scalp and pubic hair; monitoring of blood lead and dioxin-like compounds and linkage to incidence of miscarriage; correlation of blood lead levels in pregnant women to sub-normal foetal development; and monitoring of persistent organic pollutants and dioxin-like compounds in breast-milk. The frequent involvement of both children and pregnant women, although intended to protect these particularly vulnerable sub-groups, raises important questions about autonomy – an individual's right to be fully informed and free to decide to participate – as children (born or unborn) are legally unable to provide informed consent. In an attempt to mitigate the harm-benefit ratio, current research efforts include alternative less invasive biomarkers. Recruitment has been successful, among eligible participants, in spite of rewards or incentives rarely being offered. The notable exception has been the difficulty in obtaining guardians' consent to children's participation, particularly for blood sampling. Surveys are currently conducted under contract as independent biomonitoring actions and as such, must be explicitly disclosed as a potential conflict of interests, relying on researchers' objectivity and impartiality and a supervisory committee's appraisal for its ethical resolution. Communication of results to participants is in general only practised when a health issue is present and corrective action possible. Communication of pollutants in breast-milk is especially carefully approached so mothers do not stop breast-feeding for fear of risks to children, thereby forgoing its proven greater benefits. No national legislation currently accounts for the surveillance component of biomonitoring as distinct from research, so ethical issues including those presented here are frequently left to involved professionals' or ethics committees' best judgement.

„Activity of Biomedical Ethics Committees and Data Protection issues in Poland” Danuta Ligocka, NIOM, Lodz, Poland

The detail regulations concerning functioning of Bioethical Commissions in Poland are on the basis of Ordinance of the Ministry of Health and Welfare on 11 May 1999. All regulations complain most important guidelines such as: the Helsinki Declaration, The Rules of Good Clinical Practice, EU Directives and legal regulations binding in Poland, mainly Act of medical doctor profession and the dentist profession on 5 December of 1996, as well as Act of Pharmaceutical Law on 6 October 2001.

Bioethical Committees are the collegial body independent in its opinion whose task is to guarantee the rights, safety and welfare of subjects of medical research. The Committee guards the respect for the dignity of human being as the superior value to scientific aims of research.

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In Poland there are 54 Bioethical Committees; where 20 are appointed at the Medical Universities, 19 at the R & D Medical Institutes and 24 are at the Regional Medical Councils.

At the Ministry of Health is one Bioethics Appeals Commission.

In the frame of the Human Biomonitoring Programme, the application for bioethical evaluation will be submitted to the Bioethical Committee at the Nofer Institute of Occupational in Lodz.

Data protection legislation in Poland according to the Act of the Protection of Personal Data on 29 August 1997, last amended in 2006 complies EU regulations. The Act contains also detailed provisions regarding the duties of the Inspector General for Data Protection. In presentation there are some data of activity of the Bureau of the Inspector General for Personal Data Protection in 2005 and 2006.

Interpreting and communicating HBM results

Roel Smolders, Greet Schoeters

Environmental health sciences focus on the link between the presence of contaminants in the environment and their relationship with possible adverse health effects. Human biomonitoring (HBM) has recently gained much attention as a tool to evaluate exposure to and effects of environmental pollution by measurements in human tissue or fluid samples. HBM directly measures the amount of a chemical substance in a person's body, taking into account often poorly understood processes such as bioaccumulation, excretion, metabolism and the integrative uptake variability through different pathways, rather than each individual exposure source. Hence, these data can be much more relevant for risk assessment than extrapolations from chemical concentrations in soil, air, and water.

However, important challenges remain in the field of interpreting and communicating the results of HBM studies to scientists, policy makers and the general audience. It is increasingly recognized that the chemical-analytical capacity to measure contaminants in human tissue often exceeds the ability to evaluate whether and how this may cause a health risk or to evaluate its sources and pathways of exposure. Putting HBM data into a relevant and scientifically sound context is a necessary requirement to fully exploit this powerful tool for environmental health research.

This presentation will in first instance outline the main questions that need to be addressed in a framework that aims at translating HBM data into risk management and policy making options. Secondly, we will report from last December's "Stakeholder Workshop on Data Interpretation and Ethics" in Brussels, where several of these questions and related issues were discussed in breakout sessions. Finally, we will briefly focus on the work that is taking place in WP3 of the ESBIO project on these matters.

Knowledge for action: joint reflection on environment & health-data

Hans Keune (Research Department for Technology, Energy & Environment (STEM), University of Antwerp), Gudrun Koppen (Flemish Institute for Technological Research (VITO)), Karen Van Campenhout (Environment & Health, Flemish Government, Department of Environment, Nature and Energy)

Key words:

Biomonitoring, policy interpretation, practice cycle, jury, multi criteria analysis

Abstract:

In Flanders (Belgium) the Centre for Health and Environment started a biomonitoring campaign end 2001. Main purpose of this project, funded by the Flemish government, is to investigate the relation between environmental pollution and human health by measuring pollutants and health effects in (more than 4000) Flemish inhabitants. The big question is: what should be done with this vast amount of information? Together

with medical and environmental scientific experts and policymakers, social scientists worked on the preparation of an action-plan for interpretation and policy measures. At first this was thought of as a merely scientific quest: with the right group of experts the interpretation with regard to policy priorities will follow automatically. While trying to build bridges towards policy interpretation though the limitations of an exclusively scientific endeavour clearly showed: no scientist or group of scientists dared claiming to possess the necessary and overarching knowledge for answering difficult questions, questions e.g. on policy priorities when also other than (medical and environmental) scientific factors had to be taken into account (economics, social preferences, feasibility of policy measures). The social scientists therefore introduced the formation of a jury that will judge relevant data and knowledge in order to give advice to the government. The jury will be made up of experts, stakeholders and (other) citizens. For the jury we developed a multi criteria analysis. The action-plan was accorded by both the Centre for health and Environment and policy representatives, and was adopted by the government.

The Flemish action plan used to deal with regionally elevated serum pp'-DDE in two Flemish areas

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Key words: Action plan, Biomonitoring, DDT, DDE, policy interpretation

P,p'-DDE is a metabolite of the pesticide DDT, which was banned in Belgium in 1974. However, in the Flemish Human Biomonitoring campaign, p,p'-DDE was found in measurable concentrations in all 4400 analysed samples of cord plasma or serum of youngsters, and elderly people. Each of the age groups was examined totally independently in three consecutive parts of the campaign running from 2002 tot 2006.

The levels in two Flemish regions (rural area in the W, and Albert canal area in the N-E of Flanders) appeared always significantly higher (30 to 80 %) than the Flemish reference value calculated based on all study participants across Flanders (i.e. reference mean of 110, 94 and 423 ng/g fat in cord plasma and serum of adolescents and elderly, respectively). However, the levels in all Flemish regions were comparable to recently measured values in other European countries. Furthermore, the estimated uptake of DDT was calculated to be 1000 to 100 times below the provisional tolerable daily intake (PTDI) suggested by JECFA (2001). Nevertheless, because of the high consistency of elevated DDE levels in the two regions among all age groups, and since DDT contamination should be eliminated according to the Stockholm Convention on Persistent Organic Pollutants (2001)⁵, it was considered a case to be coped with in the Flemish 'action plan'.

Further desk research of existing data, pointed out that, in both regions, more local and/or own cultivated products were consumed. For each of the age groups the mean p,p'-DDE concentration appeared to be 24 to 44% higher for people consuming local food (apart from the influence of the covariates: age, BMI and sex). DDT is rarely found in nutrition sold at the Belgian market. However, data from a limited random sampling of chicken eggs from private free ranged chicken, in the area under investigation (but also some other regions), indicated that at some places these eggs had concentrations far above the acceptable concentration for consumption (500 ng sum DDT/g fat). It was assumed that use of DDT could be more traditional in both regions. Also, the ratio of DDT/ pp'-DDE was significantly higher in adults of both regions compared to the reference value of Flanders, indicating more recent use, than in other regions. Furthermore, over the past years, higher concentrations of DDT were measured in the soil and sediment of rivers in the rural area (Leie and Boven-Schelde). High DDT levels were also observed in eels from this river basin. From the N-E of Flanders

⁵ Aiming reduction and eventual elimination of 12 particularly toxic POPs (www.pops.int).

(Albert canal area), there were no data (available) indicating environmental contamination with DDT. There was no known dump or any production of DDT or related compounds in none of the regions.

Maryse Lehnens- Arendt Lactation consultant IBCLC

Coordinator for Luxemburg of the 4th WHO coordinated survey of human milk for persistent organic pollutants Director Initiativ Liewensufank Luxemburg

Communicating human biomonitoring results – interference with public health recommendations

Analysing breastmilk- promoting, protecting and supporting breastfeeding?

Last year during the debate on REACH legislation a report was presented in the European parliament called toxic inheritance - more than 300 pollutants in breastmilk. This is a shocking reality and I will try to present the biomonitoring results of breastmilk in a wider context. The results presented are the mirror of the chemical substances accumulated over the lifespan in the bodies of both men and women.

These substances in our bodies may have an effect on male or female reproductive cells; they are present in the womb in the direct environment of the fragile developing foetus and are present in breastmilk. Repeated biomonitoring of breastmilk or other body fluids shows that effective legislation for phasing out or reduction of chemicals has had results.

Analyses of breastmilk show important components, active in building up the immune system, in gastro intestinal maturation, in immune defence and have anti viral and anti bacterial activity. Some of those are: secretory IgA, lactoferrin, lysozyme, cytokines, epithelial growth factors, antioxidants and leucocytes.

Through cohort studies researchers ended up with the conclusion that:

- Little if any adverse health effects have been associated with breast-feeding. (eeley) - There is evidence that breast feeding counteracts the adverse developmental effects of PCBs and dioxins (Boersma) (Vreugdenhil). - The effect of prenatal exposure to p,p'DDE causing delay in mental and psychomotor development was counterbalanced by long-term breastfeeding.(Ribas-Fito)

Breastfeeding strengthens the infant's developing immune system and decreases the incidence or the severity of infectious diseases. Breastfeeding is associated with slightly enhanced performance on test of cognitive development. These studies have been done in our western environment with the actual pollution levels.

Based on the strong scientific evidence of the benefits of breastfeeding the American Academy of Pediatrics, WHO and UNICEF and other organisations of health professionals recommend exclusive breastfeeding for the first 6 months of life and continued breastfeeding up to two years and beyond.

Therefore caution should be used when presenting the results of biomonitoring of breastmilk. The results should be an incitation to have strong legislation on chemicals and review the use of chemical substances turning up in breastmilk, but the results should not be used to undermine the confidence in breastmilk as the optimal food for infants and young children

Similar caution in communication should be used when communicating levels of chemicals in fish versus the positive health effects of fish, or about residues of pesticides in fruit and vegetables while promoting five portions of fruit or vegetables a day.