HBM4EU NEWSLETTER

Newsletter n°3- September 2018

HORIZON2020 Programme
Contract No. 733032 HBM4EU

Prioritising substances for monitoring and research under HBM4EU

HBM4EU is generating new knowledge on human exposure to chemicals in Europe and the resulting impacts on human health. This knowledge can support the efforts of policy makers to enhance chemical safety in Europe, as well as serving the needs of a range of stakeholders.

The selection of substances to be the subject of research activities under HBM4EU represents a critical step in the project. A 1st list of HBM4EU priority substances was identified, in collaboration with policy makers in 2016.

From 2017 to 2018, HBM4EU ran a second round of prioritisation, guided by the imperative to produce knowledge for policy making in Europe and based on scientific evidence. HBM4EU partners consulted policy makers and stakeholders on the prioritisation of substances, so broadening participation to ensure the legitimacy and credibility of our work.

> Prioritisation was guided by the imperative to produce knowledge for policy making in Europe and based on science.

The HBM4EU National Hubs, members of the EU Policy Board and members of the Stakeholder Forum nominated substances via an online survey. Participants submitted evidence on hazards, exposure, public concern, regulatory status and the availability of technical methods for human biomonitoring.

At a stakeholder workshop in November 2017, stakeholders, scientists and policy makers had an open discussion on their priorities and concerns regarding specific substances.

In parallel, Citizens outreach activities were employed to better understand public concerns regarding chemical safety and ensure the societal relevance of our work. These included an online survey and a focus group with citizens in Austria, described in the article on outreach to citizens in this newsletter.

These strands of input provided the basis for the prioritisation strategy, whereby evidence for nominated substances was systematically assessed against a set of prioritisation criteria. A ranked list of substances was discussed by the HBM4EU Management Board and the EU Policy Board, with agreement reached on nine groups of substances to be prioritised for monitoring and research.

In this issue:

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The 2nd list of HBM4EU priority substances is shown in the table below and was approved by the HBM4EU Governing Board in July 2018. Chemical Substance Group Leaders have been identified for the substances on the 2nd list and are working with the HBM4EU Management Board to develop targeted and realistic research proposals for these substances.

Regarding the substance group on pesticides, HBM4EU partners and the Chemical Substance Group Leader are working collaboratively with the EU Policy Board to develop research priorities. In terms of substances, the pesticides group is expected to include chlorpyrifos, dimethoate, pyrethroids, the permethrin group, glyphosate and POE-tallowamine, and fipronil.

The second round of prioritisation is fully documented on the HBM4EU website under HBM4EU Priority Substances – Prioritisation Strategy.

In 2019, HBM4EU partners will request feedback from participants with the aim of reviewing and refining the prioritisation process.

Dr. Catherine Ganzleben , European Environment Agency

European Environment Agency

The work package on prioritisation is led by the European Environment Agency. The principle partners involved in delivering this work include the French Agency for Food, Occupational Health and Safety, VITO and the German Environment Agency.

Chemical Group Leaders for the 2nd list of HBM4EU priority substances

Substance	Country	Affiliation and name
Arsenic	Poland	Wojciech Wasowicz Department of Environmental and Biological Monitoring Nofer Institute of Occupational Medicine
Acrylamide	Sweden	Federica Laguzzi Institute of Environmental Medicine, Karolinska Institute
Aprotic solvents	Latvia	Normunds Kadikis State Education Development Agency of the Republic of Latvia
Diisocyanates	Finland	Tiina Santonen Finnish Institute of Occupational Health
Lead & its compound	Hungary	Peter Rudnai National Public Health Institute
Mercury & its organic compounds	Cyprus	Andromachi Katsonouri-Sazeides Cyprus Ministry of Health
Mycotoxins	Portugal	Paula Alvito, Maria João Silva National Institute of Health Dr. Ricardo Jorge, and Susana Viegas Lisbon School of Health Technology
Pesticides	Denmark	Helle Raun Andersen University of Southern Denmark
UV filters - Benzophenones	Israel	Tamar Berman Israel Ministry of Health

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Human Biomonitoring in Portugal


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On 11 May 2018, more than 80 representatives of science, policy, industry and other stakeholders, gathered in Lisbon at the 1st Workshop on Human Biomonitoring in Portugal.

Speakers included Portuguese experts in the fields of public health, environmental and molecular toxicology and human biomonitoring, as well as HBM4EU partners.

Greet Schoeters from VITO, HBM4EU co-coordinator, introduced the HBM4EU project to the Portuguese community. The role of human biomonitoring in risk assessment for chemical mixtures was presented by Erik Lebret, Dutch National Institute of Public Health and the Environmental. Joana Lobo Vicente, European Environment Agency, presented the HBM4EU strategy for the prioritisation of substances for monitoring and research.

The workshop provided an opportunity to communicate the activities of the Portuguese National Hub under HBM4EU to the Portuguese community, as presented by the National Hub Contact Point for Portugal, Rita Cavaleiro from the Foundation for Science and Technology.

The national research community had the opportunity to disseminate their work on human biomonitoring and related fields through presentations and a poster session.

The meeting ended with a panel discussion, chaired by the Ambassador of the Portuguese National Hub, João Lavinha from the the National Institute of Health Dr. Ricardo Jorge (INSA) and attended by stakeholders from research, policy and industry. Participants debated the needs for human biomonitoring in Portugal. The Programme and Abstract Book and the summary of the meeting are available online.

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Feedback from the national and international participants was very positive. The majority felt the workshop increased their understanding of HBM4EU and of human biomonitoring and provided an excellent networking opportunity.

Several participants expressed their interest in collaborating with the Portuguese National Hub, as stakeholders, as members of its Advisory Board or as members of a broader community interested in human biomonitoring as a tool to improve chemical risk assessment and regulatory actions.

In summary, the 1st Workshop on Human Biomonitoring in Portugal was successful in fostering the involvement of the Portuguese community in the activities of the National Hub, with the aim of promoting and protecting environmental health.

Rita Cavaleiro, the Foundation for Science and Technology, FCT - National Hub Contact Point for Portugal

FCT Fundação para a Ciência e a Tecnologia

Contributors: Maria João Silva, the National Institute of Health Dr. Ricardo Jorge, INSA; Teresa Borges, the Directorate-General of Health, DGS; Isabel Moura, the Portuguese Environment Agency, APA; Marta Abrantes, the Foundation for Science and Technology, FCT

The workshop was hosted by the National Institute of Health Dr. Ricardo Jorge (INSA), and was co-organised by the HBM4EU Programme Owners and/or Managers from Portugal, the Foundation for Science and Technology (FCT), the Directorate-General of Health (DGS) and the Portuguese Environment Agency (APA). Together with the Portuguese Linked Third Parties, the Faculty of Medicine, University of Lisbon (FMUL), the Lisbon School of Health Technology, Polytechnic Institute of Lisbon (ESTeSL-IPL) and DGS, these are the core organisations of the Portuguese National Hub for Human Biomonitoring.

Outreach to the European Public

Citizens are consumers of products containing chemicals, voters with an influence on policy directions and individuals with body burdens of chemicals and environmental pollutants. They therefore have a personal interest in the scientific results produced under HBM4EU and may be affected by any policy measures based on these results. Indeed, HBM4EU results are co-produced with citizens who participate in sampling exercises and agree to the use of their data in research.

The involvement of citizens in the prioritisation of substances for research is therefore important in ensuring the legitimacy and credibility of the HBM4EU project. In addition to the scientific criteria used to assess evidence regarding chemical risks, it is also important to capture societal concerns regarding the safety of chemicals in everyday use, chemicals in the workplace and environmental pollutants.

With the explicit aim of understanding public concern regarding chemicals and capturing the perspectives of non-experts when prioritising chemicals for research, HBM4EU undertook two outreach activities with European citizens.

These included an online questionnaire and a focus group with members of the general public.

The online survey aimed to evaluate citizens' views on the substances nominated for research under HBM4EU and to capture the interests, needs, and questions of European citizens. It was not the aim to have a representative sample of the European general public, but rather to capture a flavour of the main concerns. During February and March 2018, a questionnaire was made available online, in English and German. We received responses from 341 participants, 214 English-speaking and 127 German-speaking.

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90% of the participants expressed concerns about chemicals in their daily life.

With regard to chemical exposure, chemicals in consumer products and pesticides in food were regarded as most important. 97% of respondants believe that products contain hazardous chemicals. Participants consider chemical compounds in drinking water and food to be extremely dangerous.

Three quarters of the participants requested further information about HBM4EU via channels such as websites, social media and scientific publications.

In February 2018, a focus group on chemicals was held in Vienna, Austria with members of the public, including 14 citizens of different social backgrounds.

The participants expressed their concerns regarding chemical safety and their views regarding the responsibilities of business and industry, politicians, scientists and consumers in preventing the emission of pollutants and in minimising exposure.

A central focus of the discussion was the range of options that consumers have for preventing their own exposure, as well as the limits they face in terms of access to information and options for changing their own consumption patterns.

Consumers face an overload of often contradictory and highly technical information on product safety that is difficult to evaluate in terms of trustworthiness and quality. Consumers also have to juggle different priorities in their busy lives and may face financial constraints that oblige them to purchase cheaper products, more likely to contain hazardous properties.

Therefore, as several participants emphasized, it is not enough to just inform consumers about chemical risks. It is also important that the political, business and scientific communities collaborate to foster conditions that prevent the exposure to dangerous substances.

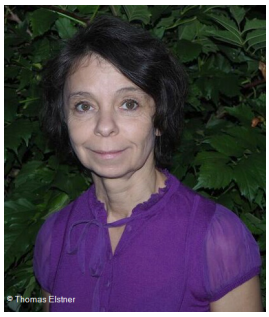
The scientific community has an important role in providing information that is trustworthy, clear and factual. Research should produce detailed knowledge about new substances and share data across European research and policy institutions. This should include information about alternative, less harmful substances.

Business and industry were seen by citizens as responsible for not using harmful substances in their production processes or products. They have a principle role in ensuring the safety of their employees and providing information regarding the occurrence of potentially harmful substances to consumers.

Regarding policies, participants called for bans of harmful substances, promoting less harmful alternatives and subsidising industry to minimise pollution. Citizens called for:

- Clarifying how scientific evidence feeds into the development of policy measures;
- Preventing the disproportionate influence of industry on the regulatory process;
- Enhancing public influence; and
- Implementing robust and transparent chemicals regulation at European Union level.

The citizens participating in the workshop expressed the view that a sustainable and harmonized European human biomonitoring network would help to better protect human health and the environment.



Maria Uhl, Toxicologist, Environment Agency Austria (EAA)

Derya Ay, European Environment Agency (EEA)

ENVIRONMENT AGENCY AUSTRIA umweltbundesamt

European Environment Agency

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Stakeholder workshop on the future of human biomonitoring in Europe

HBM4EU will span 5 years, from 2017 to 2021. Looking forward, HBM4EU partners are dedicated to exploring options for a sustainable HBM4EU beyond 2021. In support of this goal, HBM4EU is consulting a broad range of stakeholders regarding their priorities, to ensure the societal, scientific and policy relevance of a future initiative.

To this end, HBM4EU ran a short online survey from April 2018 to May 2018, asking a broad range of stakeholders about their expectations and suggestions for the scope and objectives of a possible future initiative, as well as ideas for which partners should be involved.

The survey was answered by 175 participants, representing industry, research, risk assessors and risk managers, trade unions and health and environmental non-governmental organisations. Results fed into a workshop on the long-term needs and expectations of stakeholders, held on 20 June 2018 in Brussels and involving participants from non-governmental organisation, industry, biobanks, policy and science.

The workshop explored stakeholder perspectives regarding the long-term objectives of a sustainable human biomonitoring initiative for Europe.

Participants reflected on options for establishing a future human biomonitoring initiative in Europe. These include a possible joint research programme under Article 185 of the Treaty on the Functioning of the European Union, establishing a European Strategy Forum on Research infrastructures (ESFRI), and exploring options for European institutions to host a future initiative, and well as possibilities for public private partnerships.


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Participants reflected on the survey results, which suggested that the objectives of a future initiative should be to:

- Support chemical risk assessment and risk management in the European Union;
- Increase knowledge regarding the health impacts of chemical exposure; and
- Identify emerging chemical risks.

All stakeholders agreed on the contribution that human biomonitoring can make to protecting human health in Europe from hazardous chemical exposures, by generating harmonised, robust exposure data for the European population as the basis for effective and targeted risk assessment and management.

The results of this workshop, together with the outcome of a survey with the National Hubs and work on available finance mechanisms will be captured in a deliverable, due for publication in December 2018.

Dr. Joana Lobo Vicente, European Environment Agency

European Environment Agency

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Assessing the risks of Chemical Mixtures - moving forward

How to conduct robust risk assessments of chemicals mixtures is a key question in chemicals policy today. With the aim of streamlining activities and exploring synergies, HBM4EU partners have teamed up with four other research projects funded by the European Commission to tackle gaps in our knowledge regarding exposure to and effects of chemical mixtures. The research projects are EDC-MixRisk, EuroMix, EU-ToxRisk and SOLUTIONS.

As a first step, project partners engaged in joint exchanges with the European Commission Services and relevant EU Agencies to identify remaining gaps in mixture research and policy. An outcome of this collaboration is a forthcoming publication by Bopp, S., et al. entitled "Current EU research activities on combined exposure to multiple chemicals".

Project representatives produced a position paper entitled "Preventing risks for people and environment from hazardous chemical mixtures". The paper was co-signed by 127 scientists and experts and was sent to Director-Generals of DG Environment, DG Research and Innovation and DG Health and Food Safety. The paper calls for the stepwise translation of the latest science into the development of new approaches, methodologies and tools. It proposes 12 key actions and recommendations to help better address combined effects.

To provide a forum for exchange, a joint workshop entitled "Advancing the Assessment of Chemical Mixtures and their Risks for Human Health and the Environment" was held at the European Commission's Joint Research Centre in Ispra on 29-30 May 2018. The workshop brought together around 60 experts working in the field of chemical mixtures to review the latest advancements in science and reflect on policy and research needs.

Topics included hazard and exposure assessment, data and tools, and risk analysis and risk management. Speakers from the United States, Japan and the Organization for Economic Cooperation and Development (OECD) brought an international perspective to discussions.

Although progress has been achieved in recent years, more work is required to better understand and manage combined exposure to multiple chemicals, both with regards to intentional mixtures such as pesticides and cosmetic products, and unintentional mixtures in our indoor and outdoor environment.

One of the major gaps continues to be the lack of robust datasets on exposure to mixtures. The Information Platform for Chemical Monitoring, IPCHEM, provides access to chemical monitoring data in order to foster an understanding of multiple exposures. However, access to robust data on the (eco)toxicological properties and the various uses of the large number of chemicals on the market remains a key challenge.

Workshop participants proposed options for how to enhance risk governance for hazardous chemical mixtures. These included exploring opportunities to establish clear legal mandates for mixture risk assessment under European Union (EU) chemicals legislation and broader environmental legislation, as well as across regulatory silos. It was also suggested that "protection goals" could be established for human health.

Such protection goals could be drawn from the Water Framework Directive 2000/60/EC, which requires that surface water be of good status, expressed as both good ecological status and good chemical status. Good chemical status requires that concentration of pollutants do not exceed environmental quality standards set at EU level. Similar protection goals could be set for good chemical status and good health status in the human population, with chemical status measures through human biomonitoring activities.

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Participants identified the need to develop uniform principles and harmonised approaches for mixture risk assessments. Procedures should be piloted, agreed and established across regulatory bodies and sectors, to enable more holistic and systematic mixture risk assessments. Due to the substantial complexity, uncertainty and ambiguity in the field of mixtures, interdisciplinary collaboration and multi-stakeholder dialogue are essential to developing tools and methods and fostering consensus. The workshop outcome and future research needs will be published later in 2018.

Elina Drakvik, Karolinska Institutet, Swetox (EDC-MixRisk)

SWETOX

Erik Lebret, Netherlands National Institute of Public Health and the Environment (RIVM)

National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

Recent developments in the field of mixtures:

A joint output from the mixtures collaboration is the article by Bopp, S., et al. "Current EU research activities on combined exposure to multiple chemicals", Env. Int. 120 (2018).

JRC has published recently a news item on chemical mixtures and safety of combined exposures, as well as a "Policy Brief entitlted "Something from nothing? Ensuring the safety of chemical mixtures". JRC has also published:

- Review of case studies on the human and environmental risk assessment of chemical mixtures (2016)
- Scientific methodologies for the combined effects of chemicals – a survey and literature review (2015)
- An assessment of Mixtures – Review of Regulatory Requirements and Guidance (2014)

EFSA has just concluded a public consultation on its draft guidance on harmonised methodologies for assessing combined exposure to multiple chemicals, as well as a consultation on how to address the genotoxicity of chemical mixtures. EFSA will hold a technical hearing on the genotoxicity assessment of chemical mixtures on 27 September in Brussels, Belgium. For more about EFSA's work on chemical mixtures, see: http://www.efsa.europa.eu/en/topics/topic/chemical-mixtures

GRANADA WORKSHOP on Biomarkers of Effect

HBM4EU work on biomarkers of effect aims to link the existing biomarkers of health effects relevant for the 1st set of priority substances to known or suspected adverse outcome pathways (AOPs). This includes identifying needs for the development of new biomarkers of effect and documenting the use of specific effect biomarkers in ongoing European cohort studies.

From the 19th to the 21st of March 2018, the University of Granada hosted the 1st Granada Workshop on Biomarkers of Effect. The aim of the workshop was to establish science-based procedures for selecting biomarkers of effect and to review and finalise the list of effect biomarkers for the 1st list of HBM4EU priority substances. An additional goal was to coordinate with work to establish exposure and health relationships.

At the workshop, participants agreed on a system of classification for effect biomarkers, including classical effect biomarkers, classical but understudied effect biomarkers, and novel effect biomarkers.

On the basis of this classification system, participants finalised the list of effect biomarkers for the 1st list of HBM4EU priority substances that are to be used in human biomonitoring studies undertaken in HBM4EU partner countries.

Preliminary results regarding biomarkers of combined effect that can be used to provide information on mixture effects were also reviewed by the participants.

Discussions at the workshop highlighted the importance of combining epidemiologic effect biomarkers with AOPs developed under the HBM4EU project, and plans were laid for future collaboration.

Nicolas Olea Serrano, University of Granada

UNIVERSIDAD DE GRANADA

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Linking human biomonitoring and health studies - opportunities and obstacles?

HBM4EU is working to link human biomonitoring results with health studies and registers to better understand the relationship between chemical exposure and health.

In 2017, HBM4EU ran a questionnaire with leaders of health surveys across our partner countries, to discover what kind of biological samples health surveys collect and store in biobanks and to explore whether these sample might be analysed using human biomonitoring techniques. The leaders of health studies were also asked to identify opportunities and obstacles associated with including human biomonitoring in their studies.

Responses were received from 58 studies in 19 countries. Most of the health studies were relatively large (>1000 participants) and had collected and stored biological samples for future use. The most commonly collected biological samples were blood, plasma, serum and DNA. In some studies urine was also collected.

65% of the studies that took biological samples had measured or were planning to measure chemicals. For studies without chemical analysis, the main reasons were a lack of funding, irrelevance to the study aim, and a lack of technical capacity for analysis. These were also the main challenges associated with combining human biomonitoring and health studies.

Many studies also anticipated problems with recruiting participants and implementing health surveys, were a human biomonitoring module to be incorporated.

The results of the questionnaire survey are captured in a report on the opportunities and obstacles of combining human biomonitoring and health studies.

The report provides an overview of available health studies with biological samples, and includes guidelines for combining studies.

In follow up, a workshop on linking human biomonitoring with health surveys was held in June 2018 in Brussels, Belgium. The workshop explored practical experiences to data with combining human biomonitoring and health studies and reflected on future challenges and opportunities.

Three countries, namely Germany, France and Canada, have combined their human biomonitoring surveys with their health examination surveys. At the workshop, each country provided a short description of their national survey and identified the benefits gained as well as the challenges they faced. The three countries identified very similar advantages and obstacles.

Advantages included the possibility to use common infrastructure, jointly recruit participants, and collect measurements and questionnaire information during one visit. Exploiting these synergies reduces the cost of data collection, while at the same time producing wider data sets that capture both exposure and health information.

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In terms of obstacles, combining two study types presents challenges in terms of study organization, as there may be different requirements for target populations, survey timing and content, and the number of blood samples required. Compromising between the needs of human biomonitoring researchers and health researchers can be challenging.

Looking forward, four countries presented their expectations regarding opportunities and obstacles, were they to combine human biomonitoring surveys with health surveys in their domestic context. These included Slovenia and Belgium, which currently have human biomonitoring surveys in place, and Denmark and the UK, which currently have health examination surveys in place. These countries anticipated the same advantages and obstacles outlined above. In additional, they expressed concern regarding the possible effect that an extended survey might have on participation rates.

Participants at the workshop reflected on other challenges when combining studies. These included complying with ethics requirements, the need for corss-disciplinary training and tackling the differences between human biomonitoring and health studies.

Key difference between study types include:

- Due to sample size requirements, it is often easier to incorporate a small human biomonitoring module into a national health examination survey with a sample size of at least 4,000 persons than vice versa.
- Questionnaires in human biomonitoring and health studies have common components such as socio-demographic background, smoking history and status, and use of medications. However, many components are different and combining studies would result in a very long questionnaire and interview time.
- The collection of biological samples, such as blood and urine, is foreseen under both human biomonitoring and health studies. However, they often have different pre-analytic requirements, such as the requirement for survey participants to fast when sampling for glucose measurements. This may in turn influence some human biomonitoring measurements.
- Objective anthropometric measurements, such as height and weight, are generic to human biomonitoring and health studies and in many studies blood pressure is also measured. However, health surveys may require many additional objective health measurements.

A report of the workshop is in production and will be published on the HBM4EU website, together with all the presentations.

At European level, HBM4EU has also investigated how results from Bridge Health, the EU project on BRidging Information and Data Generation for Evidence-based Health policy and research, might be incorporated into HBM4EU work.

Dr. Hanna Tolonen, National Institute for Health and Welfare (THL)

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Recent and future events in 2018

Month	Events
29 - 30 May	Joint H2020 Workshop - Advancing the Assessment of Chemical Mixtures and their Risks for Human Health and the Environment, Joint Research Centre, Ispra, IT
27 - 30 May	HBM4EU was presented at the PPTOX VI Conference, Faroe Islands, Denmark
14 - 15 June	Workshop: Linking HBM and health studies. What are possible opportunities and obstacles? Brussels, Belgium
20 June	Stakeholder workshop on priorities for a future HBM4EU initiative, Brussels, Belgium
18 - 22 June	1st HBM4EU Training Event, Ljubljana, Slovenia
9 - 14 July	HBM4EU was presented at the ESOF - EuroScience Open Forum, Toulouse, France
26 - 30 August	HBM4EU was presented at the ISES - ISEE 2018 - The Joint Annual Meeting of the International Society of Exposure Science and the International Society for Environmental Epidemiology, Ottawa, Canada
13 September	National Hub Contact Point and Stakeholder Meeting, Netherlands
24 September	Workpackage meetings, Vienna, Austria
25 September	Consortium Meeting, Vienna, Austria
26 September	Meeting of the Stakeholder Forum, Vienna, Austria
26 September	Meeting of the Advisory Board, Vienna, Austria
27 September	Meeting of the Governing Board, Vienna, Austria
28 September	Conference under the auspices of the Austrian Presidency of the Council of the European Union "Human Biomonitoring in Europe – science and policy for healthy citizens", Vienna, Austria
8 - 9 November	EU Case Study Workshop - workshop with EU policy makers on the interpretation of HBM results
15 - 16 November	Meeting of the Management Board, Berlin, Germany
19 - 23 November	2nd HBM4EU Training School, in Nijmegen, The Netherlands
3 December	HBM4EU French National Hub Meeting, Paris, France

HBM4EU events External events Annual meetings of key HBM4EU Bodies

Project contact & coordination

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Editor: HBM4EU EEA Team
Cover photo: © HBM4EU
Layout: HBM4EU