



science and policy
for a healthy future

HORIZON2020 Programme
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Annex 6

Corner stone paper for a study on children

WP7

Task 7.2

D 7.6

Authors and Acknowledgement


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Background	<ul style="list-style-type: none"> HBM4EU is a joint effort of 28 countries, co-funded by the European Commission under Horizon 2020, to coordinate and advance human biomonitoring (HBM) activities in Europe, in support of policy making. The main aim of the initiative is to harmonise HBM across Europe in order to produce comparable data. HBM4EU will build on existing knowledge and will generate comparable data on internal exposure of European citizens to chemicals of high concern to both politicians as well as the public. The project should facilitate the identification of geographical and temporal trends in exposure and important factors that influence exposure levels. To this end, existing studies from the participating countries including children of ages 6 to 11 are aligned to allow harmonisation of procedures and data. Harmonisation is needed to facilitate pooling of data from individual studies for joint statistical analysis.
Involved countries	11 sampling points from different European regions with different degree of representativity for the country (for the North: Norway, Denmark; for the West: France, Germany, the Netherlands; for the South: Slovenia, Greece, Italy; for the East: Hungary; Slovakia, Poland)
Project Funders	<ul style="list-style-type: none"> HBM4EU: The HBM4EU project is receiving funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032. Participating countries are providing 50% co-funding for the alignment of studies.
Objectives	<ul style="list-style-type: none"> To describe the internal exposure to chemicals in the European population as described by different metrics (different percentiles including the P95 as European reference value). Chemicals of interest in a first round: Phthalates, DINCH and Flame retardants. To obtain better data comparability with this aligned approach. To provide targeted training and support capacity building for involved countries.
Key words	Human biomonitoring; Children; Environment; Health; Chemicals; Exposure in Europe
Further information	<p>www.HBM4EU.eu is the website of the overarching project; Supporting information can be found in the result section (Deliverables, e.g. of WP1 (Ethics), WP7 (study protocol, fieldwork), WP 9 (sample analysis, QA/QC) and WP 10 (data management) and on the Online library section.</p> <p>Email: helpdesk-HBM4EU@phe.gov.uk: Email of WP8 Helpdesk</p>

The ideal study	Characteristics of an ideal study within HBM4EU alignment:
Study design	Cross-sectional study
Study population	Children between 6 to 11 years old. Only one child per family can participate. 300 children (150 male, 150 female) in a selected country with different SES, from different levels of urbanization (urban, suburban and rural). Having been living in the same catchment area for five or more years. Being able to fill out a questionnaire on personal characteristics of the child. Exclusion criteria: hospitalised; citizens living near industrial hot spot areas.
Sampling frame	Potential participants shall be obtained from the best available sampling frame, preferably population registries or list of students from randomly selected schools of the selected areas. Preferentially nationally representative sample using stratified multi-stage sampling. The catching area should be representative for the country.
Study methods – investigation	The study involves: <ul style="list-style-type: none"> • Interview of the parent or guardian of the child by questionnaire concerning personal data and living conditions especially pertaining the substances of interest (residential environment and housing conditions, exposure relevant behaviour incl. diet, smoking, hobbies and occupation; of child or family member respectively). • The collection of first morning urine and blood samples from the child. • Urine and blood collection is accompanied by special matrix specific questionnaires giving details about the collected samples and some exposure habits few days before sampling. • Urine and blood samples are newly collected or in case they have been collected earlier were stored in a biobank (preferably at -80°C) before analyses. • For all invitees who decided not to participate, a non-responder-questionnaire is applied. • Fieldwork and sampling/transfer/storage/treatment of samples follows well elaborated SOPs and are quality assured several times during the conduct.
Duration of the study	Preferably, fieldwork should cover all four seasons.
Communication	The study is accompanied by different measures of communication, especially to safeguard a good participation rate of invitees which is necessary to receive statistically valid (unbiased) results. Providing incentives should be considered.
Analytics	All samples will be analysed by labs that successfully passed the Quality Assurance program run by HBM4EU.
Results	Participants will be sent their individual results, if they wish to receive them as stated in the informed consent. Individual results will be used to derive European Reference Values and therefore will be shared with HBM4EU researchers fully respecting ethical and privacy consents. Pseudonymous data will be transferred and participating individuals will never be identifiable in the HBM4EU database. Collated results will be published on the project website and in peer reviewed manuscripts.
Ethics and data protection	The study follows the ethics and data protection regulations (national and GDPR). Participation in the study is voluntary; to withdraw is possible at any time. A written informed consent from all participants is required to allow collection and use of data for specified purposes. Personal identifiers such as

	<p align="center">HBM4EU: Studies on children aged 6-11 years Measuring environmental exposure of children living in Europe</p>
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	<p>name, address etc. will be removed from the study data and samples as soon as possible after collection. Data or samples provided to researchers will be pseudonymised by removing all direct personal identifiers.</p>
Sharing of data and samples	<p>Sharing samples and data for analyses is necessary within HBM4EU. To be in line with EU regulations, data and material transfer agreements have to be signed and exchanged before the work is performed. Data has to be managed according the HBM4EU data management plan.</p>
Information sources	<p>Further details on HBM4EU can be found on the project website (www.hbm4eu.eu) and the national project website of the participating studies.</p>